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PATENTS

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The Law of
PATENTS

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For Patricia, Gabriel, Victor, and Elsa

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P R E F A C E

Patent law has rapidly assumed center stage in the global marketplace and information economy, presenting some of the most exciting, important, and complex issues facing not only our legal system, but also the business and technology communities. Indeed, patent law's presence in our legal, economic, and social fabric has increased dramatically in the past 25 years, and particularly, since the beginning of this century. The growing significance of patent law is understandable given the importance of intellectual capital to a firm's economic well being and the fact that for the past decade—and perhaps longer—a majority of firm value has been attributable to intangible assets. As such, legally protecting these assets—oftentimes with patents—is instrumental to a firm's business strategy. Constructing and judiciously managing a patent portfolio can lead to competitive advantages and lucrative revenue streams, through licensing, commercialization, or blocking competitor entry. Patent law's enhanced profile is manifested in the significant increase in patent applications filed in various countries throughout the world over the past several years. In the United States, for instance, 162,708 applications were filed in 1990; in 2006, there were 415,551.

In addition to raw numbers and corporate patent strategies, I am personally reminded of patent law's star power every academic year, not only because I teach and write about this particular area of the law, but also because of the number of law students who have an interest in pursuing careers in patent law. It was not uncommon for patent attorneys of my generation (I received my law degree in 1990) to “fall into” patent law after a few years working as an engineer or a chemist—law school just wasn't on the radar screen for many of us during college. While this remains an indirect route to the patent world, many more students today major in engineering or a physical or biological science fully expecting to go to law school with patent law in their sights. (Or, at least, students majoring in technical fields become aware of patent law soon after entering university.) This student demand prompted a number of law schools (including my own) to create centers and courses devoted to law and technology and intellectual property. Concomitantly, law schools hired people with an interest in teaching and writing in patent law, which has led to an extraordinary amount of patent law scholarship in recent years.

This book was designed with the aforementioned student and academic in mind. The book begins with a discussion of the history and economics of patent law, as well as an exploration of what a patent is and how one is obtained. With this foundation in place, chapter two introduces patent law's important disclosure and claiming requirements. These requirements are explored first

because they introduce the student to the entire patent document and capture patent law's "big picture," namely the bargain between the inventor and society. Chapter three discusses eligible subject matter and the utility requirement. Chapters four through six explore, respectively, the patentability requirements of novelty (chapter four), statutory bars (chapter five), and non-obviousness (chapter six). Among these requirements, non-obviousness has the most practical significance and can be a particularly robust policy tool. This requirement demands that the inventor provide society with an invention that is more than simply new, what the Europeans call an "inventive step." Chapter seven is devoted to patent enforcement, and includes some of patent law's most controversial and important issues and doctrines such as claim interpretation and the doctrine of equivalents. Defenses to patent infringement are explored in chapter eight, including the role of antitrust and issues at the intersection of contract and patent law. And lastly, chapter nine is about remedies, namely money damages and equitable relief.

Four additional features of the book are worth mentioning. First, most of the chapters have *Comparative Perspectives* or *Policy Perspectives*. The former is designed to explore a particular issue through a comparative lens, with an emphasis on Europe and, less so, Japan. Patent law is a global affair, and having insight into how other jurisdictions approach a given issue can inform and enrich one's understanding of American patent law. The policy perspectives seek to provide a richer and more in depth discussion of a given issue, and introduce secondary, academic literature for further reading and exploration. Second, each case or set of cases is preceded by reference to applicable statutory section numbers, tailored to the specific issues raised in the cases. And the relevant *statutory provisions* are reproduced and integrated into the text (near the end of the book), thus eliminating the need for students to buy a separate statutory supplement. Third, each case or set of cases is preceded with a description of the issues to be discussed in the case and followed by *Comments* that explore the case and issues raised therein in greater detail. And fourth, I tried to include technologically accessible principal cases.

It is a wonderfully propitious time to engage the rich world of patent law, and if you decide to continue reading *The Law of Patents*, I encourage you to contact me with your questions, comments, and suggestions at craig.nard@case.edu.

Craig Allen Nard

Shaker Heights, Ohio
March 2008

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Composing an acknowledgements section for a patent law book is particularly appropriate because I am reminded of the inventive enterprise and the fact that we are all standing on the shoulders of those who came and created before us. For the past 15 years or so, scholars from the legal and economics communities provided us with a more sophisticated and deeper understanding of the inner workings of patent law and its relationship to innovation. I have benefitted a great deal from this rich literature. I also have the good fortune of having generous friends and colleagues who read and commented on drafts of *The Law of Patents*. Indeed, the following people made *The Law of Patents* a better book: Christopher Cotropia, Steve Errick, Troy Froebe, Mark Lemley, Clarisa Long, Joseph Miller, Andy Morriss, Patricia Motta, Janice Mueller, Josh Sarnoff, Sean Seymore, and Andrew Torrance.

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CHAPTER

1

History and Architecture of the Patent System

INTRODUCTION

The term “patent” is short for “letters patent,” derived from the Latin *litterae patentes*, meaning open letters.¹ Generally, letters patent were letters addressed by the sovereign “to all whom these presents shall come,” reciting a grant of some dignity, office, franchise, or other privilege that has been given by the sovereign to the patentee.² The modern American patent is a government issued grant, which confers upon the patent owner the right to exclude others from “making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a period of 20 years ending from the filing date of the patent application.³ A patent gives its owner the *right to exclude*; a patent does not provide a positive right to make, use, or sell the invention.⁴ As Chief Justice Taney, in the mid-19th

1. It should be noted that a patent for invention was just one form of “letters patent.” In England, the Crown would conduct much of its state business by means of charters and letters patent, including the grant of privileges to inventors to practice their inventions. As William Blackstone writes in his *Commentaries*:

The King’s grants are also matter[s] of public record. . . . These grants, whether of lands, honors, liberties, franchises, or aught besides, are contained in charters, or letters patent, that is, open letters, *litterae patentes*: so called, because they are not sealed up, but exposed to open view, with the great seal pendant at the bottom; and are usually directed or addressed by the King to all his subjects at large.

WILLIAM BLACKSTONE, 2 COMMENTARIES ON THE LAWS OF ENGLAND 316-17 (1768). The opposite of letters patent is letters close or *litterae clausae*, which are sealed so that only the addressee can read the contents of the letter.

2. ENCYCLOPEDIA BRITANNICA 969-70 (1942).

3. 35 U.S.C. § 154 (2006). Prior to June 8, 1995 (the effective date of the GATT-TRIPS legislation), the term for a United States patent was 17 years from the date the patent *issued*. In April 1994, the United States and several other countries participated in the Uruguay Round Agreements. The Uruguay Round included an “Agreement on Trade-Related Aspects of Intellectual Property” (TRIPS). The TRIPS patent section precipitated the change of the U.S. patent term from 17 years from date of issuance to 20 years from the filing date. As a result, the present patent term for applications filed before June 8, 1995, is (1) 17 years from date of issuance; or (2) 20 years measured from the filing date of the earliest referenced application, whichever is greater. For applications filed on or after June 8, 1995, the patent term is 20 years measured from the earliest claimed application filing date.

4. For a very good early 20th century discussion on the confusion that persisted in the lower courts as to what a patent granted to the inventor *see* FRANK Y. GLADNEY, RESTRAINTS OF TRADE IN PATENTED ARTICLES 1-17 (1910).

century, stated in *Bloomer v. McQuewan*, “[t]he franchise which the patent grants consists altogether in the right to exclude everyone from making, using or vending the thing patented without the permission of the patentee. This is all that he obtains by the patent.”⁵

Our patent laws operate as part of an interdependent mix of incentives and restraints that bestow benefits and impose costs on society and individuals alike. Patent law can be viewed as offering a potential financial reward as an inducement to invent, to disclose technical information, to invest capital in the innovation process, and to facilitate efficient use and manufacturing of invention through licensing. The patent system does not, however, guide inventors as to where they should channel their inventive energies; rather, it is the marketplace that signals to inventors where the financial rewards reside, and the costs and benefits of a given research project.⁶ Thus, the patent system and the marketplace work hand-in-hand to foster innovation in a decentralized setting.⁷

In this decentralized setting, some industries respond to the incentives of the patent system differently than others. For instance, the pharmaceutical and medical equipment industries rely heavily on patents, whereas the chemical process and communications equipment industries prefer trade secrecy and

5. 14 How. 539, 549 (1852). The right to exclude, without the right to use, is somewhat peculiar to patent law (as well as the law of copyright and negative easements). In contrast, the property right in real property (e.g., land) or personal property (e.g., a car or a computer) is a right to use that carries with it a logically subordinate right to exclude. That right to exclude exists to ensure the owner’s full enjoyment of the right to use. This issue is explored further in Section B. Economics of Patent Law.

6. See B. ZORINA KHAN, *THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790-1920* 66 (2005) (stating that in the United States, patent “statutes from the earliest years ensured that the ‘progress of science and useful arts’ was to be achieved through a complementary relationship between law and the market in the form of a patent system”); JOEL MOKYR, *THE GIFTS OF ATHENA: HISTORICAL ORIGINS OF THE KNOWLEDGE ECONOMY* 76 (2002) (stating “which of all the problems that might be solved will an ingenious and creative individual apply his or her efforts to? The answer must be based in part on the signals that the market or another device sends to the potential inventor about the private and social benefits”); STEVEN W. USSELMAN, *REGULATING RAILROAD INNOVATION: BUSINESS, TECHNOLOGY, AND POLITICS IN AMERICA, 1840-1920* 97-98 (2002) (stating “a patent in and of itself conveyed no rewards or special privileges. Inventors did not receive a bounty based on the perceived utility of their handiwork. Rather, a patent merely extended to creative individuals a legal claim upon those who wished to use their novelties. The market would determine the number of takers and the amount they were willing to pay”); NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS* 1-9 (2nd ed. 2005) (discussing relationship between patent system and marketplace). Reflecting this sentiment, Henry Ellsworth, the superintendent of the patent office from 1835-45, in his report to the Secretary of State about the need for patent reform, wrote “for no sooner are the wants of the public known than men of ingenuity attempt to supply them.” *REPORT FROM THE HON. HENRY L. ELLSWORTH TO THE SECRETARY OF STATE AND TRANSMITTED TO THE SELECT COMMITTEE ON THE PATENT LAWS* 175, 177 (1836).

7. See Peter Menell & Suzanne Scotchmer, *Intellectual Property Law*, in *HANDBOOK OF LAW & ECONOMICS* 1477 (A. Mitchell Polinsky & Steven Shavell eds., 2007) (referring to decentralization in intellectual property systems as a “virtue” and stating “[p]robably the most important obstacle to effective public procurement is in finding ideas for invention that are widely distributed among firms and inventors. The lure of intellectual property protection does that automatically”). See generally MOKYR, *GIFTS OF ATHENA*, *supra* note 6, at 239 (noting overall welfare is enhanced in decentralized systems because they tend “to be more efficient than centralized ones in engendering technological progress because they do not depend on the personal judgment and survival of single-minded and strong-willed individuals”). Indeed, the decentralized nature of the American patent system is evident in the design of the patent and copyright clause of the Constitution. See notes 75-79 for a discussion of this point.

lead time into the market, respectively, relying less on patents.⁸ And some industries seek patent protection with an eye towards commercialization and generating revenue, while others obtain patents to block competitors from developing competing products or to enhance their bargaining position during cross-licensing negotiations, particularly when a “complex” technology (*i.e.*, a product or process that comprises several patented components) is involved.⁹ Indeed, patent law is not a one-size-fits-all regime, and demands a nuanced approach of its costs and benefits. As two commentators note:

In some areas, patent rights certainly are economically and socially productive in generating invention, spreading technological knowledge, inducing innovation and commercialization, and providing some degree of order in the development of broad technological prospects. However, in many areas of technology this is not the case. In a number of these, strong broad patent rights entail major economic costs while generating insufficient additional social benefits. And in some strong broad patents are simply counterproductive. One needs to be discriminating and cautious on this front.¹⁰

Over the past 20 years, scholars have increasingly acquired a greater understanding of the patent system as reflected in the increasing amount of empirical and social science scholarship. Much of the scholarship that forms the empirical current has examined the relationship between patent law and innovation practices of firms in various industries, including investment in research and development (and related decisionmaking) and the extent to which divergent industries rely on the patent system or other appropriability mechanisms;¹¹ the role of juries in patent cases;¹² Federal Circuit voting patterns;¹³ patent filing;¹⁴ litigation trends;¹⁵ and patent law’s effect on

8. See Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* (2004) (NBER Working Paper 7552) (finding different industries rely on different appropriability mechanisms to varying degrees. For instance, a majority of the industries surveyed noted that they rely on more than one “appropriability mechanism” as part of their “appropriability strategy” (*e.g.*, a combination of lead time and trade secrets or patents and lead time)); WILLIAM M. LANDE & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 312 (2003) (“Many highly progressive, research-intensive industries, notably including the computer software industry, do not rely heavily on patents as a method of preventing free riding on inventive activity”); Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson, & S.G. Winter, *Appropriating the Returns from Industrial Research and Development* (1987) (Brookings Papers on Economic Activity), 783–831.

9. See Cohen et al., *Protecting Their Intellectual Assets*, *supra* note 8.

10. Robert Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RESEARCH POLICY 273, 281 (1998).

11. See, *e.g.*, Cohen, *Protecting Their Intellectual Assets*, *supra* note 8; Levin, *Appropriating the Returns*, *supra* note 8.

12. See, *e.g.*, Kimberly A. Moore, *Judges, Juries, and Patent Cases: An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365 (2000) (illustrating patent holders success rates in jury and bench trials).

13. See, *e.g.*, John R. Allison & Mark A. Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLA. ST. U. L. REV. 745 (2000) (chronicling patent validity decisions).

14. See, *e.g.*, John R. Allison & Mark A. Lemley, *The Growing Complexity of the Patent System*, 82 B.U. L. REV. 77 (2002).

15. See, *e.g.*, Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237 (2006) (analyzing patent litigation and settlement trends); Jean O. Lanjouw & Mark Schankerman, *Protecting Intellectual Property Rights: Are Small Firms Handicapped*, 47 J.L. & ECON. 45 (2004) (studying patent litigation and settlements and concluding firms with small patent portfolios are at higher litigation risk); Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & ECON. 463 (1995) (analyzing patenting patterns of firms with differing litigation costs).

innovation in specific technologies.¹⁶ A good deal of the social science work is law- and economics-oriented, focusing on the important normative issues of proprietary claim scope and patentability standards in the context of innovation policy;¹⁷ patent law's relationship to R & D;¹⁸ and innovation.¹⁹

With this introduction in hand, this chapter is designed to introduce the history and economics of patent law, as well as the process by which patents are obtained. The goal is to provide you with a historical, doctrinal, and theoretical foundation to build upon as you proceed through the subsequent chapters.

A. A HISTORY OF PATENT LAW

1. The Classical Period

Dating back to ancient Greece, one can discern at least the idea of an incentive-based mechanism wherein a potential inventor is encouraged to disclose something new and useful to society. The incentive could take the form of a prize reward or exclusive right in the inventor's contribution. One of the earliest expressions of an incentive-based system can be found in Sybaris, a Greek colony in southern Italy that existed from 720 to 510 B.C. Known for their luxurious and decadent lifestyle, the Sybarites were said to have enacted a law that gave exclusive rights to those who created certain culinary delights. Quoting from the historian, Phylarcus, the Greek writer, Athenaeus, states:

The Sybarites, having given loose to their luxury, made a law that . . . if any confectioner or cook invented any peculiar and excellent dish, no other artist was allowed to make this for a year; but he alone who invented it was entitled to all the profits to be derived from the manufacture of it for that time; in order that others might be induced to labour at excelling in such pursuits. . . .²⁰

16. See, e.g., John P. Walsh, Ashish Arora & Wesley Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285-340 (National Academies Press 2003); Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1 (2001).

17. See, e.g., Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990) (concluding that law should favor a competitive environment for improvements rather than one dominated by the pioneer firm); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (1991) (investigating the use of patent protection and cooperative agreements to protect incentives for cumulative research); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

18. See, e.g., Ashish Arora, Marco Ceccagnoli & Wesley M. Cohen, *R & D and the Patent Premium* (National Bureau of Econ. Research Working Paper No. 9431, 2003).

19. For a nice overview of the empirical literature, see Bronwyn H. Hall, *Business Method Patents, Innovation, and Policy* (Competition Policy Center, Univ. of California, Berkeley, May 4, 2003) (Working Paper No. CPC03-39).

20. Giles S. Rich, *The "Exclusive Right" Since Aristotle*, 2 (1990) (manuscript on file with the authors). According to the intellectual property historian, F.D. Prager, it was said "that the more excellent cooks received golden crowns and other prizes usual in Greek cities." F.D. Prager, *The Early Growth and Influence of Intellectual Property*, 34 J. PAT. OFF. SOC'Y 106, 114 n.17 (1952). Even before the classical period, "primitive people assert[ed] personal ownership claims . . . to what we would consider intellectual property, namely songs, legends, designs, and

Although the Sybaritic “law” is arguably “apocryphal,”²¹ it should give us pause that the very idea of an incentive-based system expressed, remarkably, over two thousand years ago, anticipates some of the very concepts that embody our modern patent code and demonstrates how closely tied patent law is to human nature.

A few centuries after the destruction of Sybaris, Aristotle addressed the notion of an exclusive right for those individuals who discovered something “good” for the state. Specifically, Aristotle addressed Hippodamus of Miletus, a noted city builder and contemporary of Pericles, who proposed that a law be enacted “to the effect that all who made discoveries advantageous to their country should receive honours.”²² Although prize rewards, primarily for aesthetic contributions, were common in classical Greece, Aristotle reacted negatively to Hippodamus’s assertion, arguing that it would “lead to alterations to the constitution.”²³ While Aristotle’s concern was with new political and social ideas and not technological discoveries, he would probably have the same suspicion of the latter because technological change can no doubt alter the political landscape; but perhaps more importantly, Aristotle viewed the “banausic” or useful arts with disdain,²⁴ writing that they “degrade the mind” and are unworthy of the free and thinking man.²⁵ Thus, although classical Greece is well known for its prominent scientists and mathematicians and certain inventions have their origins in Greece, the scientific culture placed emphasis on knowledge rather than the application or use of knowledge.

In Greece, exclusive rights were debated and rejected. In classical Rome, monopolies were outlawed. The Emperor Zeno (c. 480 A.D.) proclaimed that

magic incantations.” RICHARD PIPES, *PROPERTY AND FREEDOM* 80 (Vintage 2000). *See also* RICHARD H. LOWIE, *PRIMITIVE SOCIETY* 235-36 (New York 1920) (characterizing some primitive society practices as corresponding to modern notions of patent and copyright laws).

21. In his history of American patent and copyright law, Bruce Bugbee writes that the Sybaritic law was “[w]ell-known—but apocryphal.” *See* BRUCE BUGBEE, *GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW* 166, n.5 (1967). According to F.D. Prager, the Sybaritic law is a story that “was current in classic times but it was merely a joke. Even if the story was true, it was not taken seriously in the Greek cities or Hellenistic empires.” Argues Prager, “[i]t seems that all this was merely in the spirit of revelry and carousing and that no ‘law’ was involved.” Prager, *Early Growth*, *supra* note 20, at 114.

22. ARISTOTLE, *POLITICS II* (1268a6) (Penguin Classics 1981).

23. *Id.* at 1268b22. In short, Aristotle preferred political stability, and proposals of the sort made by Hippodamus were suspect.

24. Although it should be noted that Aristotle is credited for producing *Mechanics*, the world’s first engineering text. *See* FRANCIS & JOSEPH GIES, *CATHEDRAL, FORGE, AND WATERWHEEL* 21 (1994).

25. *Id.* Although for different reasons, Plato too considered the “banausic” as contemptible. F.D. Prager writes:

[Plato] took no serious interest in any promotion of what is now called the useful arts. He was expressly opposed to most of the fine arts. In his ideal state there was no room for political or industrial development; only scientific research, and that only for few. He held that every craftsman should exercise only one craft, or even part of one craft only. . . . His reason for this strange view was metaphysical; he thought that in this manner the artisan might come closer to an eternal “idea” of the goods that he produced.

Prager, Early Growth, supra note 20, at 113. According to Bugbee, “Plato, who regarded the useful arts as ‘base and mechanical’ and the expression of ‘base and mechanical handicraft’ as one of reproach, assigned craftsmen and artisans to the lowest stratum of his ideal State.” *See* BUGBEE, *GENESIS, supra* note 21, at 166 n.6.

[n]o one shall exercise a monopoly over any . . . material, whether by his own authority or under that of an imperial rescript heretofore or hereafter promulgated.²⁶

Indeed, during the Roman period, with the exception of glassmaking, there was very little technological advancement.²⁷ This may be due in part to the lack of a government-sponsored, incentive-based system, which may have been derived from the anti-technological philosophy inherited from Aristotle and Plato.²⁸

Although the ancient Greeks and Romans contributed a great deal to scientific knowledge and left a legacy of impressive structures and design,²⁹ they did not officially recognize a property interest in intangible goods.³⁰ There existed no incentive-based legal regime whereby novel and significant contributions to society were encouraged.

2. European Origins

a. The Italian Renaissance

The Middle Ages are widely considered to be a period of technological stagnation and intellectual darkness, or as Edward Gibbon wrote in his *Decline and Fall of the Roman Empire*, a society that witnessed “the triumph of

26. See CORPUS JURIS CIVILIS v.XIII, Title LIX, p. 120 (S.P. Scott trans., 1932) (“We order that no one shall be so bold as to monopolize the sale of clothing of any kind, or of fish, combs, copper utensils, or anything else having reference to the nourishment or the common use of mankind, no matter of what material it may be composed, whether he does so by his own authority, or under that of a Rescript already promulgated, or which may hereafter be promulgated . . .”). See also 4 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND ch. 9 (1768) (expressly mentioning Zeno’s law prohibiting monopolies).

27. See GIES, CATHEDRAL, *supra* note 24, at 17 (“Nearly everything that sixth-century Europe knew about technology came to it from Rome. Rome, however, invented few of the tools and processes it bequeathed to the Middle Ages. Roman civilization achieved a high level of culture and sophistication and left many monuments, but most of its technology was inherited from the Stone, Bronze, and early Iron Ages.”); see also BUGBEE, GENESIS, *supra* note 21, at 13.

28. See BUGBEE, GENESIS, *supra* note 21, at 13 (quoting a 20th century scholar’s explanation of Rome’s poor technological advancement: “The central government did nothing to protect Italian industry. There was no legislation in the Imperial period comparable to modern legislation concerning patents. Everybody was free to imitate, and even to counterfeit, the products of a rival.”). See also, GIES, CATHEDRAL, *supra* note 24, at 36-37 (“[F]or the most part theoretical science was underemployed by the Romans in dealing with technical problems. One explanation that had been offered blames the rhetoric-based Roman education system, which in emphasizing composition, grammar, and logical expression rather than knowledge of nature, reflected what Lynn White called ‘the anti-technological attitudes of the ruling class.’ Yet another problem ‘was in the realm of economics. . . . The economy, in short, was weak in the dynamics that make for the creation and diffusion of technological innovation.’”)

29. For an account of technology and engineering during the classical period, see DONALD HILL, A HISTORY OF ENGINEERING IN CLASSICAL AND MEDIEVAL TIMES (1984).

30. See Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part I)*, 76 J. PAT. & TRAD. OFF. SOC’Y 697, 702 (1994) (“Despite occasional argument to the contrary, ancient law failed completely to recognize the concept of intellectual property. While accusations of theft and plagiarism were common in both the Greek and Roman worlds, they were almost always tied to concerns about honor, credit or fame.”). See also P.O. Long, *Inventions, Authorship, “Intellectual Property,” and the Origin of Patents: Notes Toward Conceptual History*, 32 TECHNOLOGY AND CULTURE 846, 854 (1991) (stating “[n]either Greek nor Roman laws included any notion of intellectual property”).

barbarism and religion.”³¹ But scholars have since cast this characterization into doubt, arguing that, although the Aristotelian attitude toward the useful arts remained for the most part, technology was beginning to be viewed more favorably,³² and indeed, several noteworthy technological advancements were made during the Middle Ages.³³ In an attempt to promote technological innovation within the confines of the state or to import such from abroad, several privileges, monopolies, and importation franchises were granted to local guilds or to artisans from afar in an attempt to lure them away from their home state.³⁴ Nevertheless, any notion of patent-like rights in inventive contributions was lacking.

It was not until the Renaissance, specifically Renaissance Italy, that the first true patent was issued; and the first true patent statute was enacted. The former occurred when the Republic of Florence, in 1421, issued a patent to the eminent architect and inventor, Filippo Brunelleschi, for his ship, which transported famed Carraran marble for his famous dome of the Duomo of Florence.³⁵ But Brunelleschi’s ship sank in the Arno River and with it the Florentine patent system.³⁶ The Italian textile guilds, reflecting the growth of commercial activity, filled the void, enacting private rules granting exclusive rights to those members of the guild who invented “certain . . . designs and patterns” of silk or wool.³⁷ Indeed, in the Renaissance city-states of Italy and most of Europe at that time, commerce and the arts were “dominated by

31. EDWARD GIBBON, *II DECLINE AND FALL OF THE ROMAN EMPIRE* 1443 (Modern Library edition).

32. See JOEL MOKYR, *THE LEVER OF RICHES* 30-56 (1990) (detailing technological advances during middle ages); NORMAN F. CANTOR, *THE CIVILIZATION OF THE MIDDLE AGES* 228-29 (1993) (noting technological innovations in horsepower, waterpower, and wind power); GIES, *CATHEDRAL*, *supra* note 24, at 13 (Middle Age thinkers were beginning to accept “technology as a part of human life, inferior to intellectual and spiritual elements but necessary and natural. Technology made life easier, freeing the mind from material concerns and supplementing man’s innate powers”).

33. GIES, *CATHEDRAL*, *supra* note 24, at 2 (“Today . . . the innovative technology of the Middle Ages appears as the silent contribution of many hands and minds working together. The most momentous changes are now understood not as single, explicit inventions but as gradual, imperceptible revolutions—in agriculture, in water and wind power, in building construction, in textile manufacture, in communications, in metallurgy, in weaponry—taking place through incremental improvements, large or small, in tools, techniques, and the organization of work. This new view is part of a broader change in historical theory that has come to perceive technological innovation in all ages as primarily a social process rather than a disconnected series of individual initiatives.”).

34. See Walterscheid, *Early Evolution*, *supra* note 30, at 707; Prager, *Early Growth*, *supra* note 20, at 117-26; BUGBEE, *GENESIS*, *supra* note 21, at 12-17.

35. See F.D. PRAGER & GUSTINA SCAGLIA, *BRUNELLESCHI: STUDIES OF HIS TECHNOLOGY AND INVENTIONS* 111 (2004); BUGBEE, *GENESIS*, *supra* note 21, at 17-18; M. Frumkin, *The Origin of Patents*, 27 J. PAT. OFF. SOC’Y 143, 144 (1943). See also GIES, *CATHEDRAL*, *supra* note 24, at 254 (stating that Brunelleschi “pioneered patent protection for inventors”). But see Walterscheid, *Early Evolution*, *supra* note 30, at 707 (“While it is generally agreed that the custom of granting patents of monopoly, *i.e.*, exclusive right to practice a particular art, in return for its introduction into the state, originated in Italy, there is some question as to whether it began in Venice or in Florence.”). For more on Brunelleschi’s ship and his patent, see ROSS KING, *BRUNELLESCHI’S DOME* 112-13 (2000).

36. See Craig Allen Nard & Andrew P. Morriss, *Constitutionalizing Patents: From Venice to Philadelphia*, 2 REV. L. & ECON. 223, 250-56 (2006) (discussing reasons why patent system did not take hold in Florence). Cf. BUGBEE, *GENESIS*, *supra* note 21, at 19.

37. See Long, *Inventions*, *supra* note 30, at 870 (“In promoting attitudes of ownership toward intangible property—craft knowledge and processes as distinct from material products—the guilds developed the concept of ‘intellectual property’ without ever calling it that.”)

guilds,”³⁸ and these private guild rules led eventually to the first known patent statute, enacted on March 19, 1474, by the Venetian Republic, which had sought to “benefit” the “commonwealth” by encouraging technological innovation through the issuance of private grants and importation licenses. The statute read:

WE HAVE among us men of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our city, more such men come to us every day from diverse parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor’s honor away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our commonwealth. Therefore:

Be it enacted that, by the authority of this Council, every person who shall build any *new and ingenious device* in this City, *not previously made in our Commonwealth*, shall give *notice* of it to the office of our General Welfare Board when it has been *reduced to perfection so that it can be used and operated*. It being forbidden to every other person in any of our territories and towns to make any further device conforming with and *similar* to said one, *without the consent and license of the author, for the term of 10 years*. And if anybody builds it in violation hereof, the aforesaid author and inventor shall be entitled to have him summoned before any magistrate of this City, by which magistrate the said infringer shall be constrained to *pay him hundred ducats; and the device shall be destroyed at once*. It being, however, within the power and discretion of the Government, in its activities, to take and use any such device and instrument, with this condition however that no one but the author shall operate it.³⁹

The Venetian statute is notable for two reasons. First, it was written in Venetian—which was then a dialect of Italian—rather than Latin, suggesting the audience was the artisan and inventor, not the learned professional class. Second, and more importantly, every feature modern patent policymakers regard as fundamental can be found in the Venetian statute. For instance, the *quid pro quo*—the right to exclude is bestowed upon one who discloses a useful invention to society—is at the heart of the Venetian statute. Moreover, the invention must have possessed utility and novelty, implying an examination system.⁴⁰ The novelty requirement was also geographically limited to the

38. See Walterscheid, *Early Evolution*, *supra* note 30, at 704 (“The example of glassmakers of Venice is particularly instructive. At the time of the Renaissance, Venetian glasswork was recognized as the finest in Europe. . . . There were detailed guild regulations covering a variety of matters, including legal workdays, election of guild officials, judicial procedures, apprenticeships, and relations between masters and patrons. Selling stolen, defective, or non-Venetian glass products was forbidden.”).

39. The statute is reproduced in Giulio Mandich, *Venetian Patents (1450-1550)*, 30 J. PAT. OFF. SOC’Y 166, 176-77 (1948) (emphasis added).

40. Mario Biagioli writes about the nature of the Venetian examination system:

The Venetian patent system involved some kind of examination, but not one that primarily centered on the performance of the invention or the soundness of its principles. . . . Technical examinations were common when inventors requested funds to develop inventions of particular public relevance, or pensions and rewards in exchange for communicating new military technologies to the state (Galileo’s demonstration of his telescope to the Venetian Senate in 1609 is an example of this practice). Such tests, however, were rarely performed when inventors applied for privileges without the additional request of state funds. . . . Having effectively farmed out the technical tests to highly motivated patentees, the officials focused on the economic and bureaucratic aspects of the privilege. They assessed the local utility and novelty of the invention, its impact on local labor,

Commonwealth. (The American novelty provision—§ 102(a)—limits prior knowledge and use to the United States.) And it has been plausibly argued that the phrase “ingenious device” was the precursor to the nonobviousness requirement.⁴¹ Third parties were prohibited from making the same or “similar” device, suggesting the grant of rights was not limited to the specific embodiment of the inventor. Furthermore, the statute required the invention be operable and to have been reduced to practice. There was also a temporal dimension to the exclusive right (*i.e.*, 10 years), and a remedy was provided to the inventor for an infringing act, whereby the inventor could obtain damages from the infringer and have the latter’s infringing device “destroyed at once.” Indeed, the Venetian statute of 1474 established a foundation for the world’s first patent system and prompted one historian to proclaim that “the international patent experience of nearly 500 years has merely brought amendments or improvements upon the solid core established in Renaissance Venice.”⁴² Or, to paraphrase the American philosopher, Alfred North Whitehead, all modern patent regimes consist of a series of footnotes to the Venetian patent statute of 1474.

Begun in Italy, the European patent custom spread rapidly throughout Europe, due largely to the migration of Venetian artisans and craftsman.⁴³ As a result, “a patent system almost identical with that of Venice grew up everywhere, before 1600,”⁴⁴ including, France,⁴⁵

commerce, and prices, and did preliminary checks to see whether someone else had already received a privilege for it.

Mario Biagioli, *Patent Republic: Representing Inventions, Constructing Rights and Authors*, SOCIAL RESEARCH, v. 73, pp. 1129-72 (Winter 2006), p. 1133.

41. Mandich, *Venetian Patents*, *supra* note 39 at 177 (arguing that “[t]here is reference to an ‘inventive device’ (*nuovo et ingegnoso artificio*); in outline, a requirement of inventive merit seems to emerge, according to which the invention must not be a trifling, all too obvious application of known technology”).

42. BUGBEE, *GENESIS*, *supra* note 21, at 24. For a detailed discussion of the creation of the Venetian patent statute from a public choice perspective, see Nard & Morriss, *Constitutionalizing Patents*, *supra* note 36, at 233-58.

43. See Mandich, *Venetian Patents*, *supra* note 39, at 205 (noting Italian immigrants are among the first to seek monopoly patents); C.H. Greenstreet, *History of Patent Systems* 4 in MAINLY ON PATENTS (F. Liebesny ed. 1972) (“Familiar with the Venetian law and fearful of local competition, the glassmakers asked for and received patent protection wherever they settled abroad.”); CHRISTINE MACLEOD, *INVENTING THE INDUSTRIAL REVOLUTION: THE ENGLISH PATENT SYSTEM, 1660-1800*, 11 (Cambridge 1988) (“Emigrant Italian craftsmen, seeking protection against local competition and guild restrictions as a condition of imparting their skills disseminated knowledge of their patent systems around Europe.”).

44. Prager, *Early Growth*, *supra* note 20, at 139. See also MOKYR, *LEVER OF RICHES*, *supra* note 32, at 79 (noting the Venetian “example was followed widely and by the middle of the sixteenth century the idea had penetrated much of Europe”). It is not surprising that many of the initial patents issued by other European countries were to Italian artisans. See Walterscheid, *Early Evolution*, *supra* note 30, at 710.

45. See F.D. Prager, *A History of Intellectual Property from 1545 to 1787*, 26 J. PAT. OFF. SOC’Y 711, 723 (1944). It has been asserted that the first French patent was granted in 1551 to an Italian inventor for glassmaking, but Bugbee argues that the grant was more of an importation franchise than a patent, and the first French patent was “probably” given to Abel Foullon in 1551 for a “rangefinder.” BUGBEE, *GENESIS*, *supra* note 21, at 25. Of some significance is the examination procedure adopted by France in 1699 to determine the novelty of an invention. This procedure was known by America’s founding fathers and not surprisingly found its way into the 1790 Patent Act. France subjected inventions to the scrutinizing eye of trained examiners under the auspices of the Royal Academy of Sciences and required inventors who received a patent to deposit a model with the Academy. The 1699 French Act stated that:

Germany,⁴⁶ the Netherlands,⁴⁷ and England, to which we now turn.

b. English Patent Policy and the Statute of Monopolies

England was not unlike its European neighbors in its attempt to attract foreign know-how to its shores and to cultivate domestic industry. During the 15th and 16th centuries, the English crown was fairly active in granting importation franchises and monopolistic privileges, particularly under Elizabeth I. With England still largely agricultural and lagging behind much of the rest of Europe in the industrial arts,⁴⁸ the Queen made aggressive use of patents of monopoly to encourage the growth of manufacturing and to lure skilled foreigners.⁴⁹ More than fifty patents of monopoly were granted from 1561 to 1590, for example.⁵⁰ In addition to expanding the number of patents, Elizabeth anglicized them as well. Over the course of her reign there was a gradual shift from the award of patents to foreigners to their award to locals.⁵¹ There were thus more new ideas with potentially patentable consequences.

The Academy shall, on order of the King, examine all machines for which privileges are solicited from his majesty. It shall certify whether they are new and useful. The inventors of those which are approved shall leave a model thereof.

According to Prager, however, the “basic defect” of the examination procedure was “that it was not obligatory” and “[w]hile it was usual for the king’s council and also for the Parliament to consult the academy, no such consultation was strictly necessary for either.” Prager, *Intellectual Property from 1545 to 1787*, *supra*, at 725. Furthermore, even though “the academy scrutinized novelty and ‘utility’ of the invention, the Parliament was most interested in the competitive chances and prospective tax value of the proposed enterprise” and the technical merits were not examined exclusively. *Id.* at 726.

46. See Walterscheid, *Early Evolution*, *supra* note 30, at 711; BUGBEE, GENESIS, *supra* note 21, at 26 (asserting that an “advanced patent institution flourished in the German states during most of the sixteenth century and the first three decades of the seventeenth before the destructive Thirty Years War brought its decline”). See also, Hansjoerg Pohlmann, *The Inventor’s Right in Early German Law*, 43 J. PAT. OFF. SOC’Y 121, 122-23 (1961).

47. It is arguable that the patent system of the Netherlands was the most advanced and sophisticated during the 16th and 17th century. See generally GERARD DOORMAN, PATENTS FOR INVENTION IN THE NETHERLANDS DURING THE 16TH, 17TH, AND 18TH CENTURIES (The Hague 1942). As one commentator writes:

From the very beginning of the patent custom in the [Netherlands], the States General required the applicant to clearly delineate the subject matter to be covered by the patent grant. Typically, this was done before a committee appointed for the purpose. Initially, at least, a drawing or a specification had to be submitted. The purpose of the specification, drawing, or model was not to educate the public as to the nature of the invention, but rather solely to provide evidence as to the nature of the invention for purposes of granting the patent or to indicate the nature of the patented matter in the event of later litigation.

Walterscheid, *Early Evolution*, *supra* note 30, at 714.

48. See JOHN E. NEALE, THE ELIZABETHAN HOUSE OF COMMONS 19 (1949) (“Elizabethan England was primarily an agricultural community. Its chief wealth was in land and its ruling class was the landed gentry — the middling and big businessmen of a rural society.”); MARK KISHLANSKY, A MONARCHY TRANSFORMED: BRITAIN 1603-1714, at 6 (1997) (“At the beginning of the seventeenth century most British people were farmers.”); J.P. KENYON, STUART ENGLAND (1978) at 15 (England “was a small, poor country with a single crop economy; her dependence on the exports of unfinished woollens put her on a par with the modern African cocoa state . . . her industries made a minuscule contribution toward the gross national product.”)

49. See H.G. FOX, MONOPOLIES: A STUDY OF THE HISTORY AND FUTURE OF THE PATENT MONOPOLY 61 (Toronto 1947).

50. See Greenstreet, *History of Patent Systems*, *supra* note 43, at 6.

51. See FOX, MONOPOLIES, *supra* note 49, at 61.

Not only did scientific knowledge grow, but so did legal knowledge, caused by the “invasion of the universities and the Inns of Court by the gentry.”⁵²

After an initial tendency to reward innovation, “exhaustion of the Crown’s reserves of patronage” forced her to increasingly bestow unwarranted and abusive privileges upon favorite courtiers such as Sir Walter Raleigh.⁵³ In fact, three of the most notorious patents (for vinegar, starch, and playing cards) were created late in Elizabeth’s reign.⁵⁴ As Christine MacLeod has written, “without a committed, firm hand guiding the system to well-defined ends, malpractices began to creep in that were to bring it into disrepute and ultimately endanger its existence.”⁵⁵ Some of the late-period patents granted rights to established techniques or items and so constituted attacks on established industries, spurring opposition to the most egregious.⁵⁶ Elizabeth’s court had become “the Mecca of patronage, a place and incomparable profit to be had through the favour of the great ones of the land,”⁵⁷ making the abuse of patents no surprise.

Thus, it would not be long before a public outcry ensued leading to several celebrated cases by the Queen’s Bench holding that monopolies were against the common law.⁵⁸ As a result, the abuses temporarily subsided, but it would not be long before the Crown, namely James I, who neither possessed the political savvy nor popularity of his predecessor, resumed granting “odious monopolies.”⁵⁹ This led to yet another public

52. NEALE, *supra* note 48, at 291. The education many received gave heavy emphasis to the classics and the Bible. “All this material trained members to see issues of high principle in the details of proposals which came before them, probably made their speeches longer, and made it far more improbable that they would meekly submit to proposals put before them.” CONRAD RUSSELL, *THE CRISIS OF PARLIAMENTS* 181 (1971).

53. D.L. FARMER, *BRITAIN AND THE STUARTS* 3 (1967); ALAN G.R. SMITH, *THE EMERGENCE OF A NATION STATE: THE COMMONWEALTH OF ENGLAND 1529-1660* (2nd ed. 1984) at 240 (“One way she could reward [her courtiers and officials] without direct cost to the Crown was by granting them patents of monopoly” at a time when “the Queen was saving every penny she could for the war and had even less money than usual to bestow on her courtiers and officials.”).

54. See E. Wyndham Hulme, *The History of the Patent System Under the Prerogative and at Common Law*, 16 L.Q. REV. 44, 53 (1896). See also WILLIAM HYDE PRICE, *THE ENGLISH PATENTS OF MONOPOLY* 8 (1906) (“In the course of the third decade (1581-90), more obvious abuses crept in.”).

55. MACLEOD, *INDUSTRIAL REVOLUTION*, *supra* note 43, at 14. Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550-1800*, 52 HASTINGS L.J. 1255, 1266 (“During Queen Elizabeth’s reign, the Privy Council’s records are replete with patent monopolies issuing regardless of whether an industry was new to the realm or not, which was the original purpose and justification for the issuance of such letters patent); Michael Les Benedict, *Laissez-Faire and Liberty: A Re-Evaluation of the Meaning and Origins of Laissez-Faire Constitutionalism*, 3 LAW & HIST. REV. 293, 314 (1985) (noting that during the 17th century, the Crown “could bestow a monopoly in the privilege of selling salt as easily as he could bestow an escheated manor”);

56. See PRICE, *ENGLISH PATENTS*, *supra* note 54, at 9.

57. NEALE, *supra* note 48, at 213.

58. See *Davenant v. Hurd* (1599) and *Darcy v. Allin* (1602) (This case is also known as “The Case of Monopolies”). But while *Darcy* was the “first complete judicial pronouncement upon the common law principles concerning monopolies,” FOX, *MONOPOLIES*, *supra* note 49, at 87, as Adam Mossoff suggests, the key to understanding *Darcy* was that “no one . . . was out to repudiate the Queen’s royal prerogative *in toto*, but rather the judges simply enunciated the first common-law rule for adjudicating the legitimacy of a grant of monopoly privileges.” Mossoff, *Rethinking the Development of Patent Law*, *supra* note 55, at 1269 (emphasis in original).

59. W.S. Holdsworth captures nicely the abusive mind-set of James I:

James I was always hard up; and for a consideration he was prepared to grant many privileges both of the governmental and of the industrial varieties. . . . Of the second of these varieties of grants the following are a few examples: grant of an exclusive right to

outcry,⁶⁰ which ultimately culminated in parliamentary action. In 1624, Parliament enacted the Statute of Monopolies. Section I of the statute declared all monopolies and grants as void and contrary to law; however, Section VI provided a noteworthy exception:

Provided also, and be it declared and enacted, that any declaration before mentioned shall not extend to any Letters Patents and grants of privilege for the term of 14 years or under hereafter to be made of the sole working or making of any manner of *new* manufacture within this Realm to the true and first inventor and inventors of such manufactures which others at the time of making such letters Patents and Grants shall not use so as also they be not contrary to law nor mischievous to the State.⁶¹

Most importantly, Section II “declared and enacted . . . that all monopolies . . . shall be forever hereafter examined, heard, tried, and determined by and according to the common laws.” The statute decisively settled the question of the monarch’s authority to issue patents of monopoly, sharply restricting the permissible grants.⁶² The common law’s limitation to grants that furthered the national interest would henceforth be enforced by the common law courts, not the Privy Council or the Star Chamber. By relocating the decision making authority over the validity of particular patents, Parliament created a binding constraint on the issuance of monopoly patents, limiting them to cases of invention. But it is important to note that the common law did not enjoy prominence immediately after enactment.⁶³ Nor did the Statute of

export calfskins; grant of an exclusive right to import cod and ling; grant of an exclusive right to make farthing tokens of copper.

W.S. Holdsworth, *The Common Debates 1621*, 52 L.Q. REV., 481, 487 (1936). In the wake of *Davenant and Darcy (The Case of Monopolies)*, James I, although eventually resuming his proclivity for granting undeserved monopolies, did make certain concessions. For example, he suspended all monopolies with the exception of “awards to corporations and companies of arts and for promoting commerce.” BUGBEE, GENESIS, *supra* note 21 at 38. He also issued a declaration called the *Book of Bounty* (1610), which affirmed monopolies were against the common law, but reserved the right to grant monopolies for new contributions. The common law also made its mark in 1615 when the Queen’s Bench, in *The Cloth Workers of Ipswich Case*, held that royal grants of a limited duration for *new* manufactures were *not* against the common law.

60. See FOX, PATENT MONOPOLY, *supra* note 49, 104.

61. Sir William Jarrett, *English Patent System*, 26 J. PAT. OFF. SOC’Y 761, 761 (1944) (emphasis added). According to Edward C. Walterscheid, Lord Coke explained that a patent for invention is valid under Section 6 if seven conditions are met:

(1) the term of the patent may not exceed fourteen years, (2) the patent “must be granted to the first and true inventor,” (3) “it must be of such manufactures, which any other at the making of such Letters Patents did not use,” (4) it “must not be contrary to law,” (5) it must not be “mischievous to the State by raising of prices of commodities at home,” (6) it must not “hurt trade,” and (7) it must not be “generally inconvenient.”

Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part II)*, 76 J. PAT. & TRAD. OFF. SOC’Y 849, 876-80 (1994).

62. See MACLEOD, INDUSTRIAL REVOLUTION, *supra* note 43, at 17 (noting that in addition to invention patents, the Statute of Monopolies allowed “grants made or confirmed by Act of Parliament, warrants under the privy seal to justices of the courts of law and of the peace, patents for printing, making ordnance, gunpowder and alum, and the manufacturing patents granted to four named individuals; also exempted were charters to towns, corporations and companies”).

63. See Mossoff, *Rethinking the Development of Patent Law*, *supra* note 55, at 1277 (noting the “Privy Council’s obstinate refusal to concede jurisdiction” allowed it to continue to quash common law actions against patents in some cases); MACLEOD, INDUSTRIAL REVOLUTION, *supra* note 43, at 15 (stating “there were loopholes in the Act which the crown, desperate for new sources of patronage and revenue in the 1630s, was able to exploit”).

Monopolies end the abuses of the royal prerogative.⁶⁴ Patent law was only one of the many arenas in which the larger struggle for supremacy between Parliament and the monarchy was fought. Parliament's victory in the Statute of Monopolies, as important as it was, was still only a single battle in a multi-century campaign. The point is that common law lawyers and members of Parliament shared a mutual interest in challenging the crown's abusive practices regarding monopolistic grants and acted pursuant to that interest to establish the principle of a neutral decision maker to evaluate the legitimacy of monopoly patents. Whether due to "pilot error" or "mechanical error," James's reign produced a fundamental shift in England's approach to patent law, introducing an institution capable of an independent evaluation of the legitimacy of particular patents.⁶⁵

The Statute of Monopolies governed English patent law for more than 200 years, and it was not until the 1852 Patent Law Amendment Act that England witnessed significant patent law legislation.⁶⁶ But prior to the 1852 Act an important development occurred in English patent law: the *specification*, or "a full description of the invention and its operation which would show the scope of the patent."⁶⁷ Indeed, if we were inclined to isolate a noteworthy English contribution to patent law, it would have to be the development of the patent specification. Although the specification was part of the Continental patent systems, particularly in The Netherlands, it was England in the early 18th century that adopted it as part of patent practice and required a much fuller disclosure.⁶⁸ This practice culminated in the well-known case of *Liardet v. Johnson*, decided in 1778, wherein Lord Mansfield held that the "consideration" for a patent grant was the specification rather than the introduction of a new

64. See PRICE, ENGLISH PATENTS, *supra* note 54, at 35 (noting that crown used invention monopolies as a means to reduce existing industries to monopolies "under cover of technical improvements"). Fox notes that attacks on monopolies in Parliament continued into the "Long Parliament" that began in 1640. FOX, MONOPOLIES, *supra* note 49, at 7 ("The attacks upon it [patents of monopoly] were virulent and widespread. At the time of the Long Parliament it had few friends except those who personally profited by holding monopolies.").

65. See Nard & Morriss, *Constitutionalizing Patents*, *supra* note 36, for a discussion of the Statute of Monopolies from a public choice perspective. See also Thomas Nachbar, *Monopoly, Mercantilism, and Intellectual Property*, 91 VA. L. REV. 1313 (2005).

66. For an excellent discussion of the role of the patent system in the Industrial Revolution, see H. DUTTON, THE PATENT SYSTEM AND INVENTIVE ACTIVITY DURING THE INDUSTRIAL REVOLUTION, 1750-1852 (1984) (asserting The patent system had a powerful incentive effect in the rate of invention). See also R.J. Sullivan, *England's "Age of Invention": The Acceleration of Patents and Patentable Invention during the Industrial Revolution* 26 EXPLORATIONS IN ECONOMIC HISTORY, 424-52 (1989).

67. BUGBEE, GENESIS, *supra* note 21, at 41-42 (asserting that a specification "became a standard feature of [English] patents issued after 1734"); see also DOORMAN, PATENTS FOR INVENTIONS IN THE NETHERLANDS, *supra* note 47, at 22-23.

68. The role of the specification in the 18th century can be contrasted that of the 16th century. According to Mario Biagioli, the "primary function" of the description of the invention in the 16th century

was the determination of the patent's subject matter — either to avoid overlaps with pre-existing patents or to archive evidence to be used to adjudicate possible future infringement disputes. Figuratively speaking, the officials used drawings and descriptions of inventions to assemble a bureaucratic cadaster of patents, not a body of publicly available knowledge from which inventions could be produced after their patents had expired.

Biagioli, *Patent Republic*, *supra* note 40, at 1134.

industry.⁶⁹ No longer was the law only concerned with the introduction of an actual inventive device or product; rather, the inventor's contribution in the form of *information* was gradually assuming center stage. The role of the specification was, and still is, the dissemination of knowledge. This focus on information and its dissemination continues to play an important role in modern patent systems.

3. The American Experience

The influence of the English patent custom on American patent practice is undeniable. There were several American colonies that granted patents;⁷⁰ and Colonial patent practice, while limited, due largely to a predominantly agrarian society, influenced the subsequently developed patent custom of the states, as well as the federal patent system. The distractions of the American Revolution discouraged notions of "inventive property" at first, but as the Revolution continued, victory became less uncertain, and the Confederation witnessed a resumption of issued patents, especially during the 1780s.⁷¹ Indeed, the demands of the Revolution coupled with colonial boycotts of British goods and notions of self-sufficiency stimulated industrial development, leading to the creation of various societies whose purpose was to encourage industry and manufacture.⁷² As domestic technology developed and national markets formed, the number of state-issued patents gradually increased, resulting in conflicting private legislative grants among states.⁷³ As the Constitutional Convention drew near, the problems with state patent custom

69. See Jarrett, *English Patent System*, *supra* note 61, at 762. See also Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 3)*, 77 J. PAT. & TRAD. OFF. SOC'Y 771 (1995).

70. See BUGBEE, GENESIS, *supra* note 21, at 57-83; V. CLARK, I HISTORY OF MANUFACTURES IN THE UNITED STATES: 1607-1860 (1916). America's first colonial patent was issued in Massachusetts in 1641 to Samuel Winslow pertaining to the production of salt for the colony's fishing industry. The most active colonies in issuing patents were Massachusetts, Connecticut, and South Carolina. BUGBEE, GENESIS, *supra* note 21, at 75-83. It appears that Delaware, New Hampshire, New Jersey, and North Carolina did not issue patents. It is questionable whether Pennsylvania issued any patents during the Colonial period, whereas New York, Maryland, Rhode Island, and Virginia issued a combined total of ten. Edward C. Walterscheid, *The Early Evolution of United States Patent Law: Antecedents (5 Part I)*, 78 J. PAT. & TRAD. OFF. SOC'Y 615, 630-31 (1996). Colonial patents were issued through private bills or special enactments, not general or public statutory schemes. *Id.* at 624-25.

71. In 1784, for example, South Carolina enacted the first American general patent provision, which essentially was a clause in the state's "Act for the Encouragement of Arts and Sciences." The clause read: "The Inventors of useful machines shall have a like exclusive privilege of making or vending their machines for the like term of 14 years, under the same privileges and restrictions hereby granted to, and imposed on, authors of books." BUGBEE, GENESIS, *supra* note 21, at 92-93.

72. See INLOW, THE PATENT GRANT 45 (1950); BUGBEE, GENESIS, *supra* note 21, at 85; Walterscheid, *Early Evolution*, *supra* note 70, at 632 n.80.

73. Take the famed Rumsey-Fitch steamboat dispute as an example. Both James Rumsey and John Fitch lobbied several state legislatures, each having distinct patent customs, for a monopoly for their respective steamboats. But interestingly, beyond the Fitch-Rumsey dispute, patents did not play a significant role in the development of the steamboat technology. As Louis Hunter wrote, "[t]hrough the men who developed the machinery of the western steamboat possessed much ingenuity and inventive skill, the record shows that they had little awareness of or use for the patent system. . . . [N]o significant part of the engine, propelling mechanism, or boilers during the period of the steamboat's development to maturity was claimed and patented as a distinctive and original development." LOUIS HUNTER, STEAMBOATS ON THE WESTERN RIVERS 175-76 (1949).

became increasingly more apparent, thus giving rise to the desirability of a uniform system of patents.⁷⁴

Therefore, in response to the driving forces of James Madison and Charles Pinckney, it was proposed, on Wednesday, September 5, 1787,⁷⁵ during the closing days of the Constitutional Convention, that Congress shall have the power

[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.⁷⁶

74. See Nard & Morriss, *Constitutionalizing Patents*, *supra* note 36, at 290-304 (noting principal reason for federalizing patent system was desire for a nationally uniform patent policy). Prior to the ratification of the Constitution, there was no federal patent system. The states retained the power to issue patents because under Article II of the Articles of Confederation each state retained “every power, jurisdiction and right, which is not by the confederation expressly delegated to the United States, in Congress assembled.” Edward C. Walterscheid, *To Promote the Progress of Useful Arts: American Patent Law and Administration, 1787-1836 (Part I)*, 79 J. PAT. & TRAD. OFF. SOC’Y 61, 65 (1997). Furthermore, as Bugbee noted:

In 1777, when the Articles of Confederation were drafted, patent granting was temporarily in abeyance, and the framers of the Articles made no attempt to transfer the protection of inventive property to the national scene. Had this colonial prerogative been actively exercised at the time by the newly independent states, the Articles would probably have left it to them nevertheless. By 1787, however, the granting of state patents was at a peak, and the need for a centralized system was strongly indicated by the multiple applications of competing inventors. With the emergence of a small but significant class of manufacturers and promoters stimulated by the war, the economic stakes were now considerably greater than had been the case in colonial times. The merits and shortcomings of the state patent practice were therefore clearly visible to those state legislators who were about to transmit this experience to the national scene.

BUGBEE, GENESIS, *supra* note 21, at 103.

75. The delegates convened in Philadelphia on May 14, 1787. A draft Constitution was reported on August 6 without a patent and copyright clause. However, twelve days later, on August 18, Charles Pinckney of South Carolina, who was serving in the South Carolina legislature when it enacted America’s first general patent and copyright provision in 1784, proposed that Congress have the power to enact patent legislation. Also, on August 18, James Madison submitted a similar proposal. David Brearley of New Jersey, a member of the Committee of Eleven, reported to the Convention what is essentially the patent and copyright clause embodied in Article I, Section 8, Clause 8 of the Constitution. See BUGBEE, GENESIS, *supra* note 21, at 125-31. See also Karl Fenning, *The Origin of the Patent and Copyright Clause of the Constitution*, 17 GEO. L.J. 114 (1929). Unfortunately, the historical record of the clause is sparse. Indeed, there is recorded debate on this provision. As one judge, writing in late 19th century, said when faced with interpreting the patent and copyright clause, “[w]hat immediate reasons operated upon the framers of the Constitution seem to be unknown.” *McKeever v. United States*, 14 Ct. Cl. 396, 420 (1878).

76. The framers, employing colonial syntax as one would expect, were respectively referring to works of authors and inventors when they used the terms “Science” and “useful Arts.” In the 18th century, the term “Science,” from the Latin, *scire*, “to know,” meant learning or knowledge in general and had no particular connection to the physical or biological sciences like it does today. Thus, the operational relationships are between “authors,” “science,” and “writings” for copyright on the one hand and “inventors,” “useful Arts,” and “discoveries” for patents on the other. See Giles S. Rich, *Principles of Patentability*, in NONOBVIOUSNESS, THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980); Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, 18 GEO. WASH. L. REV. 50 (1949); John F. Kasson, *Republican Values as a Dynamic Factor*, in THE INDUSTRIAL REVOLUTION IN AMERICA 6 (1998) (noting that the term *technology* “did not acquire its current meaning until the nineteenth century.” In eighteenth century usage, “technology” denoted “a treatise on an art or the scientific study of the practical or industrial arts” or “useful knowledge”). See generally Kenneth J. Burchfield, *Revisiting the “Original” Patent Clause: Pseudohistory in Constitutional Construction*, 2 HARV. J.L. & TECH. 155 (1989).

This provision, embodied in Article I, Section 8, Clause 8 of the Constitution, passed unanimously without debate and provides the foundation for American patent and copyright law. Indeed, Madison, in Federalist #43, wrote that

[t]he utility of [Article I, Section 8, Clause 8] will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals.⁷⁷

Of particular importance is the structure of the patent and copyright clause. The clause sets forth the specific means of exercising the enumerated power by permitting Congress to promote the progress of the useful arts (*i.e.*, the enumerated power) only by granting *exclusive rights* for *limited times* to *inventors* for their *discoveries*. The delegates most likely had knowledge of the Statute of Monopolies and, therefore, these limitations were arguably influenced by the antimonopoly tradition in England.⁷⁸ The decentralized nature of the patent and copyright clause also reflects an aversion to special Congressional legislation and a desire to check Congressional overreaching.⁷⁹

77. THE FEDERALIST, A COMMENTARY ON THE CONSTITUTION OF THE UNITED STATES 278-279 (Modern Library 1937). The Supreme Court, in *Graham v. John Deere Co.*, 383 U.S. 1, 5-6 (1966), distinguished Article I, Section 8, Clause 8 from English patent custom by stressing that the Constitutional clause was both a grant of and a limitation on Congress's power to make patent policy:

The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the "useful arts. It was written against this backdrop of the practices—eventually curtailed by the Statute of Monopolies—of the Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. . . . The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose.

But see Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 953, 981-83 (2007) (asserting Madison was arguing in Federalist #43 that the policy justification for patents was grounded in natural rights theory).

78. This is not to suggest that the Founders were aware of the common law cases interpreting the Statute of Monopolies, as those cases were largely decided in the second half of the 18th century. Nor is there direct evidence of the influence of the English experience on the structure of Article I, Section 8, Clause 8. See Thomas B. Nachbar, *Intellectual Property and Constitutional Norms*, 104 COLUM. L. REV. 272, 330-31 (2004). Nonetheless, a plausible inference can be made that the Founders were aware of the Statute of Monopolies and were at least sensitive to the English tradition. For instance, Blackstone, whose "Commentaries was the most widely read English law treatise in late-eighteenth-century America," John F. Manning, *Textualism and the Equity of the Statute*, 101 COLUM. L. REV. 1, 35 (2001), specifically mentioned the Statute of Monopolies in his Commentaries. See 4 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND § 9 (stating that royal abuse in granting monopolies was "in a great measure remedied by" the Statute of Monopolies, "which declares such monopolies to be contrary to law and void (except as to patents, not exceeding the grant of fourteen years, to the authors of new inventions)"). See also *Graham v. John Deere Co.*, 383 U.S. 1, 5-6 (1966) ("The [IP] clause is both a grant of power and a limitation. . . . It was written against this backdrop of the practices—eventually curtailed by the Statute of Monopolies—of the [English] Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. . . ."); Robert Patrick Merges & Glenn Harlan Reynolds, *The Proper Scope of the Patent and Copyright Power*, 37 HARV. J. LEG. 45, 52-53 (2000) (asserting that "the constitutional footing for intellectual property protection was constructed with inherent limitations" that "originated in British analogues that were expressly designed to eliminate rent-seeking abuses").

79. Ahkil Amar cites the patent and copyright clause as evidence that one method the delegates employed to deter "pretextual use of congressional power . . . was to specify the purpose of a particular power." AKHIL REED AMAR, AMERICA'S CONSTITUTION 112 (2005). As Alexander Hamilton recalled, a principal argument for limiting government involvement and their ability to direct the path of industry is that state intervention would "sacrifice the interest of

Madison's fellow Virginian, Thomas Jefferson, while no stranger to the inventive process, was skeptical of monopolies and, initially, anything but a devotee of the patent system.⁸⁰ Nevertheless, he came to realize the importance of patents and played a prominent role in the early development of American patent law,⁸¹ assuming primary administrative authority of the Patent Act of 1790, America's first patent statute signed into law on April 10, 1790 by President George Washington.⁸² The 1790 Act authorized the issuance of patents for "any useful art, manufacture, engine, machine, or device, or any

the community to those of particular classes." *Annals of Congress*, 2d Cong., 1st Sess., 972-73). The decentralized nature of the clause and the intent to limit Congressional power are also manifested by the proposals rejected by the delegates during the convention. Dotan Oliar notes, in addition to the language that eventually found its way into Article I, Section 8, Madison and Pinckney also proposed that Congress have the power to encourage the arts, sciences, and useful knowledge by offering rewards, chartering corporations, and establishing seminaries, public institutions, and universities. See Dotan Oliar, *Making Sense of the Intellectual Property Clause: Promotion of Progress as a Limitation on Congress's Intellectual Property Power*, 94 GEO. L.J. 1771, 1791-1805 (2005). These rejected proposals would have allowed for a great deal more Congressional intervention into market dynamics, rendering legislators more susceptible to interest-group pressures and the like.

80. See MERRILL D. PETERSON, *THOMAS JEFFERSON AND THE NEW NATION* 450 (1970) ("The first superintendent of patents did not fully subscribe to the principle of the system. He questioned that ingenuity is 'spurred on by the hopes of monopoly,' and thought 'the benefit even of limited monopolies . . . too doubtful to be opposed to that of their general suppression.'"). This sentiment was expressed by Jefferson in response to a draft of the Constitution sent to him by Madison. Jefferson wrote:

I sincerely rejoice at the acceptance of our new constitution by nine states. It is a good canvas, on which some strokes only want retouching. What are these, I think are sufficiently manifested by the general voice from north to south, which calls for a bill of rights. It seems pretty generally understood that this should go to . . . Monopolies . . . The saying there shall be no monopolies lessens the incitements to ingenuity, which spurred on by the hope of a monopoly for a limited time, as of 14 years; but the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression.

V WRITINGS OF THOMAS JEFFERSON 45, 47 (Ford ed., 1895).

81. In fact, shortly after the 1790 Act was passed, Jefferson, in a letter to Benjamin Vaughn, wrote:

I sincerely rejoice at the acceptance of our new constitution by nine states. It is a good canvas, on which some strokes only want retouching. What are these, I think are sufficiently manifested by the general voice from north to south, which calls for a bill of rights. It seems pretty generally understood that this should go to . . . Monopolies. . . . The saying there shall be no monopolies lessens the incitements to ingenuity, which spurred on by the hope of a monopoly for a limited time, as of 14 years; but the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression.

An act of Congress authorizing the issue of patents for new discoveries has given a spring to invention beyond my conception. Being an instrument in granting the patents, I am acquainted with the discoveries. Many of them indeed are trifling, but there are some of great consequence, which have been proved of practice, and others which, if they stand the same proof, will produce greater effect.

Tom Arnold, *The Historical Perspective for the Occasion of the Bicentennial of U.S. Patent Law*, in *THE BICENTENNIAL OF THE AMERICAN PATENT SYSTEM* 309, 317 (1990). A great deal has been written about Jefferson's role in the creation and support the American patent system. See, e.g., Kendall J. Dodd, *Patent Models and the Patent Law: 1790-1880 (Part I)*, 65 J. PAT. & TRAD. OFF. SOC'Y 187, 196 (1983); Levi N. Fouts, *Jefferson the Inventor, and His Relation to the Patent System*, 4 J. PAT. OFF. SOC'Y 316, 322 (1922). Cf. Edward C. Walterscheid, *Patents and the Jeffersonian Mythology*, 29 JOHN MARSHALL L. REV. 269, 276-79 (1995) (questioning the historical scholarship on Jefferson); Mossoff, *Who Cares What Thomas Jefferson Thought About Patents?* *supra* note 77, at 955 (noting that "Jefferson's hegemony over the history of American patent law is as indisputable as it is wrong").

82. Act of Apr. 10, 1790, ch. 7, 1 Stat. 109. A total of 55 patents were issued under the 1790 Act. The Patent Act of 1790 was passed on April 5, 1790, by the Congress of twelve states. Rhode Island did not join the Union as the thirteenth state until May 29, 1790, 49 days after President Washington signed the bill. See KENNETH W. DOBYNS, *THE PATENT OFFICE PONY—A HISTORY OF THE EARLY PATENT OFFICE* 22 (1994).

improvement therein not before known or used.”⁸³ The Act did not create a patent office, but instead designated a patent board that would *examine* patent applications, comprising a specification and drawings, to determine if “the invention or discovery [was] sufficiently useful and important” so as to merit a patent. The board, self dubbed the “Commissioners for the Promotion of the Useful Arts,” comprised the Secretary of State (Thomas Jefferson), Secretary of War (Henry Knox), and the Attorney General (Edmund Randolph).⁸⁴ The first patent under the 1790 Act issued to Samuel Hopkins for a method of “making Potash and Pearl ash by a new apparatus and Process.”⁸⁵

83. One issue that occupied the debate over the 1790 Act was whether to adopt a geographic specific novelty requirement. That is, should the statutory language read “not known or used in the United States” or simply “not known or used,” as was ultimately adopted. The former would have allowed for patents of importation, which was for technology unknown in the United States, but already invented or in use outside of the U.S. American government officials and others in the United States knew that several European countries, most notably Great Britain, were successful in attracting foreign-developed technology through patents of importation. The most prominent government official favorably disposed to the introduction of technology from abroad was George Washington, who could not “forbear intimating to” Congress, in his State of the Union Address of January 8, 1790, of “the expediency of giving effectual encouragement . . . to the introduction of new and useful inventions from abroad.” III Documentary History of the First Federal Congress of the United States of America, *House of Representatives Journal* (1977:253). Another significant proponent was Alexander Hamilton, who in his *Report on Manufactures*, strongly urged a government initiative aimed at encouraging the importation of technology and skilled artisans from abroad. See Alexander Hamilton, *Report on Manufactures*, 308 in ALEXANDER HAMILTON: A PROFILE, 1964 (J.E. Cooke ed.). There were voices who were adamantly opposed to patents of importation. The nascent American manufacturing class would be harmed if patents of importation were allowed since they would have to license foreign innovations, now available for free, from the first person to patent them domestically. Doron Ben-Atar speculates that the 1790 Act and its official rejection of patents of importation (or “technology piracy”) was a façade for an unofficial policy designed to facilitate technology piracy. See DORON BEN-ATAR, *TRADE SECRETS: INTELLECTUAL PROPERTY AND THE ORIGINS OF AMERICAN INDUSTRIAL POWER* 168 (2004).

84. It was said of Jefferson that he “scrupulously guarded the privilege and investigated every claim to satisfy the statutory test of originality.” PETERSON, THOMAS JEFFERSON, *supra* note 80, at 450. The United States was one of the first countries to enact a statute requiring patent applications to be subjected to an examination so as to ascertain the invention’s usefulness and sufficiency. Other countries, most notably England, employed a registration system that was simply ministerial in nature. That is, no examination of the invention’s validity or sufficiency is conducted.

85. The original patent document is part of the collections of the Chicago Historical Society. There is presently some dispute as to the origins of Mr. Samuel Hopkins, the first patentee. For years it was thought that Hopkins was from Pittsford, Vermont, but a recent article convincingly argues that he was actually from Philadelphia. See David W. Maxey, *Samuel Hopkins, The Holder of the First U.S. Patent: A Study of Failure*, THE PENNSYLVANIA MAGAZINE OF HISTORY AND BIOGRAPHY 3-37 (January/April 1998). Eighteenth century potash was a form of potassium carbonate that had several industrial applications. As David Maxey writes:

Timber felled in the clearing of land that was not used for lumber or fuel was burned in huge bonfires; the ashes were segregated and saturated with water in a trough, and the resulting mixture was subjected to intense heat in containers that Hopkins and his contemporaries more often than not referred to as pots or kettles, but which actually amounted to cauldrons because of their size. The residue in the pot was potash, a black substance that with refluxing and the application of further heat to eliminate impurities evolved into pearlash.

One authority would put potash in a class by itself as “America’s first industrial chemical.” From the vast forests that covered New England and portions of New York and Pennsylvania came the raw material which, through a primitive process accessible to the enterprising farmer or the frontier storekeeper, yielded an ingredient of value in the manufacture of soap, in glassmaking, in dyeing fabrics, and in the production of saltpeter for gunpowder. . . .

Id. at 10-11.

The examination system under the 1790 Act proved to be too burdensome for the three-member patent board, and in 1793 a new patent act was on the books. Although the 1793 Act contained several fundamental patent law concepts that are extant today,⁸⁶ the Act did away with the patent board and the examination proceedings and implemented a registration system, clerical in nature.⁸⁷ Needless to say, the lack of an examination requirement attracted several fraudulent or duplicative patents.⁸⁸ The 1793 Act lasted for 43 years, but during this time it came to be widely recognized that its provisions led to “unrestrained and promiscuous grants of patent privileges”;⁸⁹ or, more generously, patents issued that “would not be capable of sustaining a just claim for the exclusive privileges acquired.”⁹⁰ The result was a 19th century version of a patent thicket, with conflicting and overlapping rights.

The shortcomings of the 1793 Act produced regular calls for reform and, eventually, the 1836 Act. In the interim, the patent bar had produced innovations such as the patent claim,⁹¹ which was codified in the 1836 statute.⁹² The 1836 Act introduced (and in some cases reintroduced) important features to patent law, including the creation of a Patent Office⁹³ as a distinct bureau of

86. For example, Section 6 of the 1793 Act provided an accused patent infringer with certain defenses, namely that the invention was not novel, or was not sufficiently disclosed in the patent specification. Other examples are the all too important “public use” or “on-sale” defenses. Lastly, the 1793 Act gave us the four statutory subject matter categories that we use today (*i.e.*, process, machine, manufacture, or composition of matter). The 1793 Act used the term “art,” which meant process. The 1952 Act changed “art” to “process,” and states that the term process “means process, art, or method.” See 35 U.S.C. § 101.

87. See DOBYNS, *THE PATENT OFFICE PONY*, *supra* note 82, at 35 (“The Act of 1793 went from the extreme of rigid examination to the opposite extreme of no examination at all. The Patent Board was abolished. The State Department was to register patents, and the courts were to determine whether the patents were valid.”).

88. See EDWARD WALTERSCHEID, *TO PROMOTE THE PROGRESS OF THE USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION* 325 (stating “[t]hroughout the era of registration, a substantial number of useless or invalid patents would issue”). See also Senate Report accompanying Senate Bill 239, 14th Cong., 1st Sess. (April 1836), which led to the 1836 patent act (Senator Ruggles, the bill’s sponsor, noted the 1793 Act was thought to lead to “the unrestrained and promiscuous grants of patent privileges”).

89. Ruggles, Senate Report accompanying Senate Bill 239, 14th Congress, 1st Sess. (April 28, 1836), at 4.

90. See JOHN REDMAN COXE, *OF PATENTS, EMPORIUM ARTS & SCIENCES* 76 (1812); T. COOPER, *EMPORIUM ARTS & SCIENCES* 435 (1812) (asserting that “patents, frivolous, absurd, and fraudulent, threaten to become taxes on the community”); WALTERSCHEID, *AMERICAN PATENT LAW AND ADMINISTRATION*, *supra* note 88, at 325 (“Throughout the era of registration, a substantial number of useless or invalid patents would issue”).

91. See John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 308 (noting the claim “arose not from any administrative, judicial, or legislative requirement. Instead, it was an innovation of patent attorneys, and it was formulated to protect and to expand the rights of patentees”); *Hilton Davis v. Warner-Jenkinson*, 62 F.3d 1512, 1530 (Fed. Cir. 1995) (en banc) (Newman, J., concurring) (noting the “development of claim style was guided by growing cadres of professional patent examiners and registered patent attorneys, along with the growth of prior art and competing technologies”).

92. N.J. Brumbaugh, *History and Purpose of Claims in United States Patent Law*, 14 J. PAT. OFF. SOC’y 273, 276 (1932) (referring to the patent claim, and stating the 1836 Act “merely endorsed and positively required what inventors had been doing voluntarily for years”).

93. Mark Twain wrote, “the very first official thing I did, in my administration — and it was on the very first day of it too — was to start a patent office; for I knew that a country without a patent office and good patent laws was just a crab and couldn’t travel any way but sideways or backways.” *A CONNECTICUT YANKEE IN KING ARTHUR’S COURT*, Chapter 9 (Bantam Classics edition 1983). In 1810, Congress passed a law authorizing “a building suitable for the accommodation of the general post office, and of the office of the keeper of the patents, in such situation, and finished in such manner, as the interest of the United States and the safety and convenience of those

the Department of State, and vested it with greater responsibilities;⁹⁴ created the position of Commissioner of Patents;⁹⁵ the present-day patent numbering system;⁹⁶ and an appellate structure for patent applicants seeking to appeal an examiner's refusal to issue a patent. Finally, and most importantly, the 1836 Act codified the claiming requirement⁹⁷ and re-instituted the patent examination proceeding that charged the Commissioner of the newly created Patent Office with performing "an examination of the alleged new invention or discovery."⁹⁸

The 1836 Act, considered the first modern patent statute, laid the foundation for the modern patent system.⁹⁹ This Act reflected the changes in the American industrial landscape between 1793 and 1836. During this time, the new nation began to develop domestic manufacturing, national markets formed and certainly in one's property rights became increasingly more important.¹⁰⁰ As one commentator put it, the 1793 Act "may have been good enough for the agricultural country that founded it, but it was not sufficient for

offices respectively, and the arrangement of the models in the patent office shall, in his opinion, require." 11th Cong., Section 2, Chapter 34 (April 28, 1810). The Blodgett Hotel, home of the patent office from 1810-1836, was designed by James Hoban, the architect of the White House.

94. It is difficult to say when exactly the United States Patent Office was created. It was not a part of the Acts of 1790 and 1793. In 1802, Secretary of State James Madison, who was instrumental in the development of patent and copyright law during the early years of the Republic, made the Patent Office a distinct division of the Department of State by appointing the highly regarded Dr. William Thornton, the designer of the U.S. Capitol, at a salary of \$1,400 a year to the full-time position of supervising the issuance of patents. Thus, one can argue that it was with this full time appointment of Dr. Thornton in 1802 that the Patent Office was created. It was the 1836 Act, however, that gave the Patent Office legitimacy in the eyes of the law. Furthermore, the 1836 Act provided for the construction of a new building to house the Patent Office. That Patent Office was completely destroyed by fire on December 15, 1836.

95. Henry Leavitt Ellsworth (1791-1858), one of the twin sons of Justice Oliver Ellsworth, was appointed as the first Commissioner of Patents in 1836.

96. Patent Number 1 was issued to Senator John Ruggles of Maine, who was primarily responsible for the passage of the 1836 Act. Prior to 1836, patents were identified by the date they were issued. Unfortunately, the 10,000 pre-1836 patents were destroyed in a patent office fire in 1836. But through careful restoration of patent records and private files many of the pre-1836 patents have been reconstructed and models have been reproduced. (Those patents that could not be recovered were cancelled.) The restored pre-1836 patents were subsequently numbered chronologically and an "X" suffix was added to distinguish them from the new numbered patents. Thus, the first U.S. patent ever issued is number 1X issued to Samuel Hopkins. These older patents are now collectively referred to as the "X-patents."

97. See notes 91-92, *supra*.

98. Applicants, as under the 1790 and 1793 Acts, were required to submit a specification, drawings, and models with their application. The 1836 Act required the Commissioner of Patents to publicly display the models. See F.D. Prager, *Examination of Inventions from the Middle Ages to 1836*, 46 J. PAT. OFF. SOC'Y 268, 289-91 (1964). For many years, patent models were a major tourist attraction in Washington until 1880 when models were no longer required to be submitted with a patent application. Several of these models are now housed in the Smithsonian Institution where they can presently be seen. Also, Judge Giles S. Rich of the United States Court of Appeals for the Federal Circuit has assembled a handsome collection of patent models, which are on display at the Federal Circuit court house.

99. See BUGBEE, GENESIS, *supra* note 21, at 152 ("With the act of 1836, the United States patent system came of age.").

100. For a discussion of the relationship among inventive activity, patenting, and market demand, see B. Zorina Khan & Kenneth L. Sokoloff, "Schemes of Practical Utility": *Entrepreneurship and Innovation Among "Great Inventors" in the United States, 1790-1865*, 53 J. ECON. HISTORY 289 (1993); Kenneth L. Sokoloff & B. Zorina Khan, *The Democratization of Invention During Early Industrialization: Evidence from the United States, 1790-1846*, 50 J. ECON. HISTORY 363 (1990).

the manufacturing nation which had arisen through American ingenuity and intellect.”¹⁰¹

The next noteworthy Congressional intervention came in 1870. Although the 1870 Patent Act was largely a re-codification of the 1836 Act, there was one significant exception: the 1870 Act placed more emphasis on the importance of the patent claim, and therefore the public notice function of patents. Whereas the 1836 Act required an inventor to “particularly specify or point out” what he regards as his invention, the 1870 Act required that inventors “particularly point out and *distinctly claim*” their inventions.¹⁰² In the post-bellum era, the patent claim would become increasingly more important.¹⁰³ As the author of the leading 19th century patent law treatise wrote, the “claim is thus the life of the patent so far as the rights of the inventor are concerned, and by it the letters-patent, as a grant of an exclusive privilege, must stand or fall.”¹⁰⁴

101. DOBYNS, *THE PATENT OFFICE PONY*, *supra* note 82, at 100. During the post-bellum era, several patent wars were being waged. For example, Elias Howe, Jr. and Isaac Merritt Singer battled over the sewing machine; Alexander Graham Bell and his telephone went up against Elisha Gray, Thomas Edison, and Emile Berliner and the phonograph; and the reaper saw Cyrus McCormick involved in a patent dispute with Obed Hussey and John H. Manny. See DANIEL J. BOORSTIN, *THE AMERICANS: THE DEMOCRATIC EXPERIENCE* 57 (1973) (“There was hardly a major invention in the century after the Civil War which did not become a legal battlefield.”). Of some interest is that Abraham Lincoln was “involved” in the McCormick case tried in Cincinnati, Ohio. But in his biography of Lincoln, David Herbert Donald explains that although Lincoln was retained by McCormick’s eastern lawyers, they rebuffed him and treated him very rudely. According to Donald, McCormick’s “lawyers made it clear to Lincoln that he could not participate in the trial. ‘We were all at the same hotel,’ [George] Harding recalled; but neither he nor [Edwin McMasters] Stanton ‘ever conferred with him, ever had him at our table or sat with him, or asked him to our room, or walked to or from the court with him, or, in fact, had any intercourse with him.’” DAVID HERBERT DONALD, *LINCOLN* 186 (1995). Interestingly, Stanton would later become Lincoln’s Secretary of War, a position he fulfilled admirably. Stanton grew fond of Lincoln and would later write, “No men were ever so deceived as we at Cincinnati.” And upon Lincoln’s death, Stanton was reported to say, “Now he belongs to the ages.” See DORIS KEARNS GOODWIN, *TEAM OF RIVALS: THE POLITICAL GENIUS OF ABRAHAM LINCOLN* (2005)). One last notable point about Lincoln: he was the only American president to obtain a patent. See U.S. Patent No. 6,469, issued in 1849, entitled “Manner of Buoying Vessels.”

102. Patent Act of 1870, ch. 230, § 26, 116 Stat. 198, 201 (1871) (emphasis added). This new requirement, which came to be known as “peripheral claiming,” highlighted the notice function of the claim and provided the applicant with more autonomy in setting forth the outer boundaries (periphery) of his invention. The public, it was thought, could now have more confidence on where the patentee’s proprietary boundaries reside because peripheral claiming reduced the need for the DOE. Central claiming was officially dead, and the patent claim from 1870 to the present day has held center stage. See e.g., *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) (asserting that the claim is of “primary importance” in ascertaining exactly what is patented).

103. See RISDALE ELLIS, *PATENT CLAIMS* 3 (1949) (claims under the 1836 Act “served merely to call attention to what the inventor considered the salient features of his invention. The drawing and description were the main thing, the claims were a mere adjunct thereto. . . . The idea that the claim is just as important if not more important than the description and drawings did not develop until the Act of 1870 or thereabouts”). This is not to suggest the claim was an unimportant feature of the patent document. Recall, the claim was a pre-1836 creation of the patent bar, and as Woodward reminds us, applicants expended a “great deal of effort . . . in formulating claims, and the practice grew of presenting a profusion of claims of varying form and scope.” William Redin Woodward, *Definiteness and Particularity in Patent Claims*, 46 MICH. L. REV. 755, 764 (1948). Our point is only that for much of the 19th century, the claim was not regarded as the central, institutionalized feature of the patent document.

104. WILLIAM C. ROBINSON, 2 *THE LAW OF PATENTS* § 505 (1890).

After the 1870 Act, it would 82 years before the Patent Code was meaningfully revised. But before discussing the important 1952 Patent Act, a brief discussion of the Supreme Court's attitude towards patents prior to the 1952 Act will shed light on the Act itself, as well as the driving forces behind the Act. From 1890 to 1930, patents were viewed favorably by the Court. But from about 1930 to 1950, the Court approached patents with a great deal of suspicion, emphasizing the monopolistic and social-cost aspects of patents. For example, the Court expanded the patent misuse doctrine (*Mercoid*),¹⁰⁵ did away with the common practice of drafting claims in functional terms (*Halliburton*),¹⁰⁶ and, most significantly, enhanced the so-called "requirement for invention" by invoking the "flash of genius" test (*Cuno*),¹⁰⁷ and cast doubt on the patentability of "combination" patents (*i.e.*, combination of old elements) by requiring a display of synergism (*Great Atlantic*);¹⁰⁸ that is, the combination, to be patentable, had to equal more than the sum of its parts. Indeed, this anti-patent fervor, led by Justices Douglas and Black, prompted Justice Jackson, in a dissenting opinion, to write that "the only patent that is valid is one which this Court has not been able to get its hands on."¹⁰⁹

It was inevitable that members of the patent bar would take action. The 1952 Act, drafted primarily by Giles S. Rich, P.J. Federico, Paul Rose, and Henry Ashton, was largely a response to what was perceived to be the Supreme Court's anti-patent attitude. What did the 1952 Act, codified in Title 35 of the United States Code, accomplish? First, section 112 overturned *Halliburton's* invalidation of functional claiming.¹¹⁰ Second, sections 271(b), (c) and (d) overturned *Mercoid's* broad reading of the misuse doctrine with respect to contributory infringement.¹¹¹ Third, section 103 replaced the polysemous "invention" requirement with a less subjective standard of nonobviousness.¹¹² *Cuno's* "flash of genius" test was no more. All of these issues are explored in the subsequent chapters.

The 1952 Act did a great deal to strengthen the patent system, but concerns, mainly procedural in nature, remained. The Evarts Act of 1891 created geographically situated regional circuit courts of appeal. Prior to 1982, regional circuits heard patent infringement appeals from their respective district courts, as they do presently, for example, with most criminal or civil (*e.g.*, trademark and copyright infringement) cases. But there were disparities among the regional circuits in the treatment patents received with some

105. *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944). See also *Carbice Corp. v. American Patents Development Corp.*, 283 U.S. 27 (1931). See Chapter 9 for a discussion of patent misuse.

106. *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946).

107. *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941).

108. *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950).

109. *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949).

110. See Chapter 7 for a discussion of means-plus-function claims.

111. See Chapters 8 and 9 for a discussion of contributory infringement and misuse, respectively.

112. See Chapter 6 for a discussion of the non-obviousness doctrine. For a history of section 103 of the 1952 Act, see generally NONOBVIOUSNESS, THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980).

circuits viewing patents very favorably, upholding their validity a vast majority of the time, and other circuits displaying a distinct anti-patent bias. This divergent treatment of patents, it was argued, led to forum shopping and a greatly weakened patent system. In response, Congress, in 1982, created the United States Court of Appeals for the Federal Circuit as a unified forum for patent appeals, with the intent of strengthening the American patent system.

4. The U.S. Court of Appeals for the Federal Circuit

The United States Court of Appeals for the Federal Circuit (pictured) was created by Congress in 1982 as the nation's thirteenth federal court of appeals.¹¹³ The creation of the Federal Circuit, which is located in Washington, D.C., has been called “perhaps the single most significant institutional innovation in the field of intellectual property in the last quarter-century.”¹¹⁴



Indeed, the court represents the first significant consolidation of a particular area of law in American history.¹¹⁵ The Federal Circuit has exclusive subject matter jurisdiction over patent cases,¹¹⁶ as well as numerous other areas of law.¹¹⁷ (The court's jurisdiction is discussed in greater detail in Chapter 7, Section D.)

113. Federal Courts Improvement Act of 1982, P.L. 97-164, 96 Stat. 25 (April 2, 1982). This Act merged the Court of Claims, which had seven judges, and the Court of Customs and Patent Appeals, which had five judges. The Federal Circuit came into existence on October 1, 1982. *See THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT: A HISTORY* (1991). For a discussion of some of the contested issues surrounding the creation of this new nationwide court, *see* Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1 (1989) and sources cited therein.

114. LANDES & POSNER, *ECONOMIC STRUCTURE*, *supra* note 8, at 7.

115. It should be noted that efforts to create a national court for patent appeals began more than 100 years before the creation of the Federal Circuit. *See* Subcomm. on Patents, Trademarks & Copyrights, Senate Comm. on Judiciary, 85th Cong., 2d Sess., Study No. 20 (1959). For instance, in 1900 the American Bar Association's Section of Patent, Trademark and Copyright Law recommended the creation of a “Court of Patent Appeals” with national jurisdiction. *See* Report of the Committee of the Section of Patent, Trademark and Copyright Law, 23 ABA Rep. 543, 543 (1900). For an excellent discussion of the history of the Federal Circuit's creation and previous efforts to create a national court for patent appeals, *see* Paul M. Janicke, *To Be or Not to Be: The Long Gestation of the U.S. Court of Appeals for the Federal Circuit (1887-1992)*, 69 ANTITRUST L.J. 645 (2002).

116. The court's patent-related cases are appealed from either a U.S. District Court (in a litigation context) or the USPTO (prosecution context). On occasion, other circuit courts will have jurisdiction to hear patent-related disputes. Jurisdictional issues are explored in Chapter 7, § D.

117. *See* 28 U.S.C. § 1295. The court's docket includes appeals from, for example, the Court of International Trade, International Trade Commission, Merit Systems Protection Board, Court of Veterans Appeals, and Court of Federal Claims. It was the intent of Congress to provide

Some of the oft-cited reasons for the creation of the Federal Circuit are that—during the 1970s—there existed rampant forum shopping by patent litigants,¹¹⁸ disparate circuit court treatment of patents, and accompanying disuniformity in patent law.¹¹⁹ In the first decade of its existence, the Federal Circuit earned praise for achieving a desirable degree of uniformity in place of regional circuit precedents perceived to be disjointed and conflicting.¹²⁰ And the court has had a significant impact on the patent landscape. Recent studies, for example, have shown the Federal Circuit has strengthened patent rights with respect to validity challenges, with the court affirming district court “decisions of invalidity significantly less often,” resulting in patentees appealing “decisions of invalidity significantly more often, and district courts” holding “patents to be invalid significantly less often.”¹²¹

But the Federal Circuit is not without critics.¹²² For example, the court has been accused of producing precedents that “increase the cost of patent

the court with a diverse jurisdiction. See H.R. Rep. No. 312, *supra* note 110, at 19 (“The proposed new court is not a ‘specialized court.’ Its jurisdiction is not limited to one type of case, or even to two or three types of cases. Rather, it has a varied docket spanning a broad range of legal issues and types of cases.”); S. Rep. No. 275, *supra* note 110, at 6 (“[The Federal Circuit’s] rich docket assures that the work of the . . . court will be a broad variety of legal problems. Moreover, the subject matter of the new court will be sufficiently mixed to prevent any special interest from dominating it.”). For FY 2006, 33% of merit panel adjudications were patent law related. See <http://www.fedcir.gov/pdf/ChartAdjudications06.pdf>.

118. See H.R. Rep. No. 312, 97th Cong., 1st Sess. 20-22 (1981) (“Patent litigation long has been identified as a problem area, characterized by undue forum-shopping and unsettling inconsistency in adjudications.”). But some commentators have questioned this scenario. See Scott Atkinson, Alan C. Marco & John L. Turner, *The Economics of a Centralized Judiciary: Uniformity, Forum Shopping, and the Federal Circuit*, <http://ssrn.com/abstract=961035> (econometric study finding “strong evidence that forum shopping on the basis of validity rates ceased several years prior to the” Federal Circuit’s creation); Testimony of James W. Geriak, Hearings before the Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice on H.R. 2405 (April 1981), 709 (stating that claims of forum shopping are “seriously exaggerated”); Cecil D. Quillen, *Innovation and the U.S. Patent System*, 1 VA. L. & BUS. REV. 207, 228 (2006) (asserting forum shopping and outcome variability were not problematic during the 1970s).

119. *Id.* (“[S]ome circuit courts are regarded as ‘pro-patent’ and others ‘anti-patent,’ and much time and money is expended in ‘shopping’ for a favorable venue.” Furthermore, “the validity of a patent is too dependent upon geography (*i.e.*, the accident of judicial venue) to make effective business planning possible. . . . A single court of appeals for patent cases will promote certainty where it is lacking to a significant degree and will reduce, if not eliminate, the forum-shopping that now occurs.”). See also S. Rep. No. 275, 97 Cong., 1st Sess. 5 (1981) (“The creation of the Court of Appeals for the Federal Circuit will produce desirable uniformity in this area of . . . [patent] law. Such uniformity will reduce the forum-shopping that is common to patent litigation.”).

120. See, e.g., Rochelle Cooper Dreyfuss, *Federal Circuit*, *supra* note 113, at 74 (concluding that “[o]n the whole, the CAFC experiment has worked well for patent law, which is now more uniform, easier to apply, and more responsive to national interests”). Some have suggested the court “has had a significant positive effect on both the number of patent applications and the number of patent grants.” LANDES & POSNER, *ECONOMIC STRUCTURE*, *supra* note 8, at 340. Indeed, patent applications have increased from 109,625 utility patent applications filed in 1982 (with 57,888 issuing) to 356,943 applications (with 164,293 issuing) in 2004. See www.uspto.gov.

121. See Matthew D. Henry and John L. Turner, *The Court of Appeals for the Federal Circuit’s Impact on Patent Litigation*, 35 J. LEG. STUD. 85, 112 (2006).

122. Indeed, it is worth noting that there was not uniform support for the creation of the Federal Circuit. For instance, an ABA Report and Recommendation disapproving of the creation of the Federal Circuit was adopted by the ABA House of Delegates in 1980. See Testimony of Benjamin L. Zelenko, Hearings before the Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice on H.R. 2405 (April 1981), 423 (quoting the ABA recommendation). There was also Congressional testimony against the creation of the court. See Testimony of James W. Geriak, Hearings before Committee, H.R. 2405, *supra*, 69

acquisition, augment the burdens of patent administration, and encourage free riders — trends that make both the patent system, and the process of innovation, less attractive alternatives.”¹²³ And the court and its doctrine are said to “have brought less certainty and predictability to patent enforcement.”¹²⁴ Even commentators who are positive about the Federal Circuit experiment have acknowledged the “continuing problems perceived in the court’s administration” of patent law.¹²⁵ These criticisms, some commentators argue, are largely due to the Federal Circuit’s structural constraints in that the court does not enjoy the benefit of sister-circuit competition and a diversity of view points.¹²⁶ Accordingly, it has been argued that “patent law’s complex mixture of fact and law scenarios coupled with the fluid nature of innovation practices requires a competitive and diverse appellate enforcement model,” one where diversity, competition, and incremental innovation are equally, if not more, important than uniformity.¹²⁷

COMPARATIVE PERSPECTIVE *The European Patent Convention*

The European Patent Convention (“EPC”) — officially known as the “Convention on the Grant of European Patents” — took place on October 5, 1973 in Munich, Germany (sometimes the EPC is referred to as the “Munich Convention”). The EPC, which is not European Union legislation or an EU body, entered into force on October 7, 1977. The EPC was last amended in November 2002. These amendments, known as “EPC 2000,” entered into force on December 13, 2007. The EPC created a centralized, unitary process for obtaining “European patents” through the newly created European Patent Office (“EPO”) located in Munich, Germany with branches in Berlin and The Hague. The EPC is comprised of 178 Articles establishing various institutions, procedural rules, and substantive laws. See <http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN>. For more on the European patent system and the EPC, see Friedrich-Karl Beier, *The European Patent System*, 14 VAND. J. TRANSNAT’L L. 1 (1981).

Under the EPC, a member state defers to the EPO examination process; the member state’s patent office does not need to conduct a separate or independent examination. But it is important to understand that the EPC only relates to obtaining patent rights; enforcement of patents remains with the EPC member states, of which there are

(stating “that would be a very, very substantial error for the subcommittee to conclude that all patent lawyers are agreed upon the desirability of the . . . Federal Circuit legislation”).

123. John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 773 (2003)

124. Glynn S. Lunney, *Patent Law, the Federal Circuit, and the Supreme Court: A Quite Revolution*, 11 SUP. CT. ECON. REV. 1, 76 (2004). See also Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 40-41 (2005) (discussing “[k]ey areas of expanding uncertainty” in Federal Circuit doctrine, including areas such as claim construction methodology, the doctrine of equivalents, and the written description requirement).

125. Dreyfuss, *Federal Circuit*, *supra* note 113, at 773-86.

126. See Craig Allen Nard and John F. Duffy, *Rethinking Patent Law’s Uniformity Principle*, 101 NW. U. L. REV. 1619 (2007). Cf. S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law’s Uniformity Principle: A Response to Nard and Duffy*, 101 NW. U. L. REV. 1735 (2007)

127. Nard and Duffy, *Rethinking Uniformity*, *supra* note 126, at 1623.

currently 31. Thus, the term “European patent” is a misnomer because upon issuance, the patent loses its European character and becomes a national patent in those member countries that the applicant designates, and the patent is subsequently translated into the language of the designated state. In short, there is no community-wide patent.

Because of its distinct cost and efficiency advantages, a community patent has been part of the European patent agenda since the mid-1970s. *See* Community Patent Convention (1975) and the Luxembourg Agreement (1989). But implementation has been blocked because of issues relating to translation of patents into the various national languages. As Laurent Manderieux explains, there is no effective EU consensus on the community patent because:

Several countries want their language to be an official one for patents, and at the same time, if too many translations are compulsory, operators would find no cost advantage over the present system, and thus they would show no interest in the new system. Also several states have reservations on how to establish an EU-wide jurisdiction which could decide on questions regarding an EU-wide patent right.

Laurent Manderieux, *Europe’s IP Architecture*, in *THE HANDBOOK OF EUROPEAN INTELLECTUAL PROPERTY MANAGEMENT* 3-10 (Jolly & Philpott eds., 2007). To address this concern, the EPC member states have proposed the London Agreement of 2000, which would require EPC states to waive their requirement for translation into the state’s language. (The London Agreement will likely be implemented, which will facilitate the introduction of a community patent.) Moreover, patent enforcement remains with the member states, which means that because there is no community patent, litigation over national patent rights can lead to disparate holdings and disuniformity. For a discussion of the procedure for enforcing patent rights in Europe and proposals to address concerns relating to enforcement, *see Comparative Perspective: Enforcing Patents in Europe* in Chapter 7.

Although it is common for a member state to enact domestic patent legislation that largely mirrors the EPC, some member states enjoy a greater percentage of designations from applicants. In 2005, the top designation countries for patent protection were Germany (98.33%), France (93.53%), and the U.K. (92.96%). Only these three countries had a designation rate of over 90%. Other than these countries and Italy (76.28%), Spain (62.95%), and the Netherlands (61.57%), the remaining EPC contracting states had a designation rate of below 60%. *See* EPO ANNUAL REPORT (2006).

B. ECONOMICS OF PATENT LAW

To fully appreciate the economic theories of patent law, it would first be helpful to have an understanding of the distinctive quality of information. The use, diffusion, and production of information are at the core of patent law. But information—unlike tangible property (*e.g.*, a pen or olive oil)—is

what economists call a public good, meaning that it is both non-rivalrous and non-excludable.¹²⁸ For example, many people can benefit from information without interfering in the pleasure others get from the same information—it is non-rivalrous. One person’s use of the creative ideas embodied in a word processing program or chemical formula does not interfere with another’s use of those ideas. As Thomas Jefferson wrote, “He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me.”¹²⁹

At the same time, once disclosed, it is extremely difficult to exclude others from using the information—it is non-excludable.¹³⁰ You cannot build a fence around your idea as you can your backyard or ranch. And therein lies the catch-22 for inventors. Inventors often need to disclose their ideas to facilitate licensing negotiations, secure venture capital, arrange for manufacturing capabilities, or otherwise efficiently utilize their invention. And even if the inventor obtains a contractual obligation from the person whom he disclosed his idea, the inventor will likely remain fearful that his idea will be exploited by persons subject to the contractual arrangement or even persons not in a fiduciary relationship with the inventor; in other words, transaction costs are prohibitively high. Absent a property right, the inventor will likely be reticent to disclose information for fear of inducing competition. Thus, there is an inherent conflict between the desire to disclose information and the need to limit access and use to those whom the inventor has authorized. This problem is commonly referred to as “Arrow’s Information Paradox,” named after the economist, Kenneth Arrow.¹³¹

The two distinctive features of information goods (non-rivalrous and non-excludable) can lead to a free-rider problem—that is, consumers who exploit the information without sufficiently contributing to its creation.¹³² As such, information will tend to be underproduced, or not produced at all, due to the

128. See THE MIT DICTIONARY OF MODERN ECONOMICS 352 (David W. Pearce ed., 4th ed. 1992). See also Paul A. Samuelson, *The Pure Theory of Public Expenditure*, 36(4) REV. ECON. & STAT. 387-89 (Nov. 1954) (referring to “collective consumption goods” as that “which all enjoy in common in the sense that each individual’s consumption of such a good leads to no subtractions from any other individual’s consumption of that good”); ROBERT COOTER & THOMAS ULEN, LAW AND ECONOMICS 46 (4th ed. 2004) (noting that public goods have the characteristics of “nonrivalous consumption” and “nonexcludability”).

129. Letter to Isaac McPherson (Aug. 13, 1813), reprinted in JEFFERSON WRITINGS 1291-92 (M. Peterson ed., 1984). Elsewhere in Jefferson’s letter, he wrote:

If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it.

Id.

130. See FRANÇOIS LÉVÊQUE & YANN MÉNIÈRE, THE ECONOMICS OF PATENTS AND COPYRIGHT 4-7 (Berkeley Economic Press 2004) (stating “information is a non-excludable good. This means that it is impossible to exclude an individual from using the good even if he does not”).

131. See Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in RATE AND DIRECTION OF INVENTIVE ACTIVITY 609 (NBER ed. 1962).

132. See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, FINDING A BALANCE: COMPUTER SOFTWARE, INTELLECTUAL PROPERTY AND THE CHALLENGE OF TECHNOLOGICAL CHANGE 185 (1992) (stating “individuals have an incentive not to pay for the good, or to undervalue it, in hopes of getting access as ‘free riders’”); COOTER & ULEN, LAW AND ECONOMICS, *supra* note 128, at 46 (referring to public goods as a “source of market failure” and noting that “there is a strong

riskiness associated with disclosing information or others discovering the information.¹³³ A common response to this problem is government intervention, which can—for example—take the form of research grants (subsidies), or using the taxing power to fund production or create incentives.¹³⁴ (National defense—a classic public good—is provided for through tax revenue.) Another form of government intervention is to create a private property right to induce the production of information goods, which has been a government response in the form of patent legislation since 1790.

A patent system, however, is not a costless enterprise. With exclusivity comes the risk of reduced output, excessively high prices, and therefore less access to the patented product, because some consumers who value the good at a competitive price will not buy it at a supracompetitive price. This is referred to by economists as deadweight loss.¹³⁵ But to the extent these costs are cause for concern, they are thought to be offset by the benefits engendered by a patent system, which leads us to the economic theories for the existence of a patent system.

The historically predominant theory is the *incentive to invent*, which focuses on efficiency gains and the internalization of externalities.¹³⁶ (An externality

inducement for consumers of the privately provided public good to try to be *free riders*: they hope to benefit at no cost to themselves from the payment of others”) (emphasis in original).

133. See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 132, at 185 (“The inability to exclude free riders distorts market signals and is thought to result in inefficient allocation of resources to nonexclusive goods and underproduction of them, relative to socially optimal quantities.”). Adam Jaffe and Josh Lerner describe the difference between tangible and intangible assets as follows:

Investment in new technology is . . . handicapped by riskiness, when compared to other forms of spending. . . . [W]hen a business builds a new factory or buys some equipment, it does not normally worry that its competitors will simply come and steal the equipment. When a business invests in R&D, it is “building” an asset that it hopes to profit from, just as it does when it builds a factory. But the asset you build with research is intangible. Being intangible, it is much easier for other firms to steal.

ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT? 43 (2004).

134. See MIT DICTIONARY OF MODERN ECONOMICS, *supra* note 128, at 163-64 (stating “[i]f the free rider phenomenon is a strong one, public goods will be systematically under-provided and there is a *prima facie* case for the good to be provided through government action”).

135. See Mark A. Lemley, *Property, Intellectual Property and Free Riding*, 83 TEX. L. REV. 1031, 1059 (2005) (discussing “classic deadweight loss associated with deviations from competitive norm”); COOTER & ULEN, LAW AND ECONOMICS, *supra* note 128, at 122 (stating “monopolies impose social costs in that too little of the monopolized good is produced and the price is too high”). While very few patents confer market power (an economic monopoly), patents do generally allow a patentee to price the patented product above marginal cost—otherwise, the incentive to invent would be greatly undercut.

Price discrimination—selling the patented product at different prices based on what various consumers are willing to pay—may reduce deadweight loss and allow the seller/producer to capture some of the market’s consumer surplus. Thus, perfect price discrimination leads to market efficiency gains, but transfers wealth to the seller/producer. (In a competitive market, it is the consumer who captures most of this surplus.) But information deficiencies make perfect price discrimination highly unlikely because it is very difficult for sellers to know exactly each consumer’s demand curve. And even if perfect price discrimination were possible, some economists remain doubtful of its effect on deadweight loss. See, e.g., V. Bhaskar & Ted To, *Is Perfect Price Discrimination Really Efficient? An Analysis of Free Entry*, 35 RAND J. OF ECON. 762, 775 (2004).

136. See Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 348, 359 (1967) (asserting the “primary function of property rights is that of guiding incentives to achieve a greater internalization of externalities,” and further noting “if a new idea is freely appropriable by all, if there exist communal rights to new ideas, incentives for developing such ideas will be lacking. The benefits derivable from these ideas will not be concentrated on their originators. If

is a cost or benefit that affects parties external to the given transaction.)¹³⁷ This theory seeks to address the effects of Arrow's paradox, and holds that—due to the public goods nature of information—without the prospect of a property right, inventors would be unable to recoup (internalize) their research and development costs because third parties could simply copy the invention and compete with the inventor unencumbered by the need to recover fixed costs. In an increasingly competitive market, prices will be driven down, resulting in an under-investment in invention.¹³⁸

The second economic theory is the *incentive to disclose*. This theory, which is informed in part by the availability of trade secret protection, posits that the prospect of a property right will induce inventors to seek patent protection, and thereby disclose their inventions in accordance with patent law's disclosure requirements.¹³⁹ As explored in Chapter 2, the disclosure rules of § 112

we extend some degree of private rights to the originators, these ideas will come forth at a more rapid pace"); WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMICS STRUCTURE OF INTELLECTUAL PROPERTY LAW* 294 (2003) (stating the "standard rationale of patent law is that it is an efficient method of enabling the benefits of research and development to be internalized, thus promoting innovation and technological progress"); DOUGLASS C. NORTH & ROBERT PAUL THOMAS, *THE RISE OF THE WESTERN WORLD: A NEW ECONOMIC HISTORY* 144-55 (1973) (discussing the significance of patents as a means of internalizing positive externalities). The same rationale exists for copyright law. See Neil Weinstock Netanel, *Copyright and a Democratic Civil Society*, 102 YALE L.J. 283, 312 n.117 (1996) (stating according to Demsetz, "[i]ntellectual property . . . exists in order to internalize the positive externalities of creating intellectual works. By according property rights in such works, copyright and patent concentrates the social benefits of original expression and invention in authors and inventors, giving them a greater incentive to engage in creative activity"). Cf. Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 276 (2007) (stating "that there is no reason to think that complete internalization of externalities is necessary to optimize investment incentives; at some point, there are decreasing returns (in terms of improved incentives) to allowing property owners to capture more of the value from their inventions. Spillovers do not always interfere with incentives to invest; in some cases, spillovers actually drive further innovation").

137. See Demsetz, *Property Rights*, *supra* note 136, at 348 (stating "[w]hat converts a harmful or beneficial effect into an externality is that the cost of bringing the effect to bear on the decisions of one or more of the interacting persons is too high to make it worthwhile"); John F. Duffy, *Intellectual Property Isolationism and the Average Cost Thesis*, 83 TEX. L. REV. 1077, 1081 (2005) (stating externality "is defined as arising where 'some activity of party A imposes a cost or benefit on party B for which party A is not charged or compensated by the price system of a market economy'") (citing DAVID K. WHITCOMB, *EXTERNALITIES AND WELFARE* 6 (1972)).

138. See F.M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 444 (2d ed. 1980) (stating "[i]f pure and perfect competition in the strictest sense prevailed continuously," then "incentives for invention and innovation would be fatally defective without a patent system or some equivalent substitute"); JAFFE & LERNER, *INNOVATION AND ITS DISCONTENTS*, *supra* note 133, at 8 (stating "[p]otential inventors realize that without adequate protection rivals will rapidly copy their discoveries, and that therefore innovation is at best an uncertain route to future profit. As a result, companies would be unlikely to spend significant amounts of money on the Research and Development"); Kenneth Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL. STUD. 247, 247 (1994) (stating it is "important to recognize the primary problem that the patent system solves. This problem—often called the 'appropriability problem'—is that, if a firm could not recover the costs of invention because the resulting information were available to all, then we could expect a much lower and indeed suboptimal level of innovation"). Cf. Frischmann & Lemley, *Spillovers*, *supra* note 136, at 276 (asserting that "inventors do not need to capture the full social value of their inventions in order to have sufficient incentive to create").

139. See *Universal Oil Products v. Globe Oil and Refining Co.*, 322 U.S. 471, 484 (1944) ("As a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret."); Rebecca Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1028 (1989) (stating "[t]he incentive to disclose argument . . . rests on the premise that in the absence of patent protection inventors would keep their inventions secret in order to prevent competitors from exploiting them. Secrecy prevents the public from gaining the full benefit of new knowledge and leads to wasteful duplicative research"); Margo A. Bagley, *Academic*

require that the inventor—in return for a patent right—sufficiently disclose his invention to enable a person of ordinary skill in the art to make and use the invention. Without the availability of patent protection, this theory holds that inventors are more likely to opt for trade secret protection, thus depriving competitors (and the public generally) of a technical disclosure—that is, information that can be used by competitors to improve the patented technology or design around it.¹⁴⁰ Moreover, the importance of access to and dissemination of information to the pace of technological innovation and economic growth is well documented.¹⁴¹

The third economic theory is commonly referred to as the *incentive to innovate* (or incentive to commercialize).¹⁴² An innovation is considered different from an invention,¹⁴³ and relates to a finished and commercialized product that actualizes an invention. As two commentators wrote, “invention is a subset of innovation,” which entails “[t]he entire process of research, development, and turning an idea into a finished product.”¹⁴⁴ Thus, the incentive to innovate focuses on the role of patents in inducing the transformation of inventions into downstream, commercialized products by serving as a signal to relevant parties, namely investors (*e.g.*, venture capitalists), potential licensees, and downstream players (*e.g.*, entities with marketing, distribution, advertising, and manufacturing capabilities). In this sense, a patent is seen as reducing transaction costs and facilitating coordination efforts, resulting in the patent efficiently ending up in the hands of the party who is best suited to bring the technology to market.¹⁴⁵

Discourse and Proprietary Rights: Putting Patents in Their Proper Place, 47 B.C. L. REV. 217, 238 n.985 (2006) (stating “[p]roviding an incentive to disclose an invention is a well-established function of patent law”).

140. See LANDES & POSNER, *ECONOMIC STRUCTURE*, *supra* note 8, at 328 (stating “[i]n the absence of a patent option, inventors would invest many more resources in maintaining trade secrets (and competitors in unmasking them) and inventive activity would be inefficiently biased toward inventions that can be kept secret”).

141. See WILLIAM J. BAUMOL, *THE FREE-MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM* 75 (2002) (stating “innovation and quick dissemination are two of the critical stimuli to economic growth”); MOKYR, *GIFTS OF ATHENA*, *supra* note 6, at 34 (asserting “[r]egardless of how one thinks of science, it seems incontrovertible that the rate of technological progress depends on the way human useful knowledge is generated, processed, and disseminated”).

142. This theory is commonly associated with the work of Joseph Schumpeter. See JOSEPH SCHUMPETER, *CAPITALISM, SOCIALISM, AND DEMOCRACY* 81-110 (1950) and JOSEPH SCHUMPETER, 1 *BUSINESS CYCLES* 84-192 (1939).

143. Schumpeter is credited with making a distinction between invention and innovation. See RICHARD R. NELSON & SIDNEY G. WINTER, *AN EVOLUTIONARY THEORY OF ECONOMIC CHANGE* 263 (1982). See also Eisenberg, *Patents and the Progress of Science*, *supra* note 139, at 1038 (asserting Schumpeter “emphatically distinguishes innovation from invention, noting that invention itself produces ‘no economically relevant effect at all’”); THE NATIONAL INTEREST 126 (Nov/Dec 2007) (“Schumpeter’s description of the entrepreneurial process found its first expression in *The Theory of Economic Development*. . . . Among its many conceptual contributions is the first clear expression of the vital distinction between invention and innovation—the latter being, to Schumpeter, far more important than the former. Schumpeter stressed that an invention is of no economic significance until it is brought into use.”).

144. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1661 (2003).

145. See Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276 (1977) (asserting a patentee with a broad property right will “coordinate the search for technological and market enhancement of the patent’s value”). Kitch—who referred to this arrangement as the “prospect theory” because he analogized the United States patent system to a mineral claims system—viewed patent rights, at least in part, as solving Arrow’s Information Paradox. See Dan L. Burk & Brent H. McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 U. ILL. L. REV. 575, 585 (asserting “[b]y publicly disclosing technical information, while protecting it by exclusivity, patents circumvent the Arrow paradox. Patent licensing is no longer a bargain for disclosure, as that has already been

There are weaknesses to these incentive-based rationales, which predominate patent law's justificatory framework. For instance, the incentive to invent theory assumes the inventive act is driven by the prospect of a patent, rather than reputational gains, monetary prizes or rewards.¹⁴⁶ And to the extent a patent is the driving force behind creation, wasteful patent races (because the winner takes all), duplicative research,¹⁴⁷ and excessive rent seeking¹⁴⁸ may ensue. With respect to the incentive to disclose theory, an "enabling" disclosure seldom suffices for potential licensees to practice the claimed invention. This results in licensees asking the licensor/patentee to provide them with an "enabling package," which includes technical know-how and other forms of tacit knowledge not required to be disclosed under § 112.¹⁴⁹ Moreover, this theory does not fully take into account that—because of reverse engineering concerns or other issues associated with confidentiality—trade secrecy is sometimes not a viable option. The incentive to innovate theory loses some of its force when one considers that oftentimes patentees neither commercialize, nor license their patented technology.¹⁵⁰ In other words, the development and realization of downstream products may not be consistent with the preferences of the patentee.

In addition, recent scholarship relating to patent law's relationship to innovation reveals that, "[t]aken as a whole, the empirical literature is inconclusive on the question of whether stronger patents increase or decrease innovation."¹⁵¹ And while patents play an extremely important role in some industries (e.g., pharmaceutical), their valued less in others, particularly

accomplished by the publication of the patent. Licensees need only look at the patent to determine whether the information will be valuable to them. Neither need the patentee worry about unauthorized use of the disclosed invention, as it has been secured by a property right that covers the invention regardless of contractual protection"). Kitch's prospect theory is also relevant to the issue of claim scope and incentives to improve extant technology. This important issue is discussed in Chapter 2, following the *O'Reilly v. Morse* and *Incandescent Lamp* cases.

146. For a discussion of using non-IP related rewards as an incentive to create, see Brian Wright, *The Economics of Invention Incentives: Patents, Prizes and Research Contracts*, 73 AM. ECON. REV. 691 (1983); Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003); Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525 (2001).

147. But see LANDES & POSNER, *ECONOMIC STRUCTURE*, *supra* note 8, at 301 (stating "research expenditures of the losers of the race may not be wasted" because they "will generate information that the losers may be able to use in other projects"); John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439 (2004) (asserting patent races bring about innovations quicker).

148. Rent-seeking has been defined as "behavior in institutional settings where individual efforts to maximize value generate social waste rather than social surplus." James M. Buchanan, *Rent Seeking and Profit Seeking*, in *TOWARD A THEORY OF THE RENT-SEEKING SOCIETY* (Buchanan et al. eds., 1980). Dennis Mueller elaborates, tying the term to the traditional evaluation of losses imposed by monopolies: "The government can, for example, help create, increase, or protect a group's monopoly position. In so doing, the government increases the monopoly rents of the favored groups, at the expense of the buyers of the group's products or services. The monopoly rents that the government can help provide are a prize worth pursuing, and the pursuit of these rents has been given the name of rent seeking." DENNIS C. MUELLER, *PUBLIC CHOICE* II 229 (1989).

149. See MOKYR, *GIFTS OF ATHENA*, *supra* note 6, at 15 (stating "it would be too expensive to write a complete set of instructions for every technique. Judgment, dexterity, experience, and other forms of tacit knowledge inevitably come into play when a technique is executed").

150. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1507 (2001) (approximating no more than 3.5% of patents are licensed without filing a lawsuit); John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 GEO. L. J. 435 (2004) (asserting "[m]any patents are not worth enforcing—either because the inventions they cover turn out to be worthless, or because even if the invention has economic value the patent does not").

151. Robert W. Hahn, *The Economics of Patent Protection: Policy Implications from the Literature* 2 (AEI-Brookings Joint Center for Regulatory Studies 2003) (emphasis in original).

compared to trade secret protection and lead time into the market.¹⁵² Moreover, patent law's relationship to R&D is uncertain,¹⁵³ and although there is good evidence that the private value of patents has increased,¹⁵⁴ and that technological innovation coupled with increases in human capital are agents of economic growth,¹⁵⁵ our understanding of patent law's affect on social welfare remains incomplete.¹⁵⁶ This latter point is important because, American patent law is a utilitarian-based regime, designed to promote social welfare by encouraging technological innovation.¹⁵⁷ In other words, the idea of a natural right in one's invention never firmly took hold in American patent law jurisprudence, despite early signs of a natural rights approach.¹⁵⁸ It is not

152. See Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* (2004) (NBER Working Paper 7552) (finding different industries rely on different appropriability mechanisms to varying degrees. For instance, a majority of the industries surveyed noted that they rely on more than one "appropriability mechanism" as part of their "appropriability strategy" (e.g., a combination of lead time and trade secrets or patents and lead time)); F.M. SCHERER & DAVID ROSS, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 628-30 (1980) (noting that for many industries, incentives to innovate other than patent rights are important, if not more important).

153. Hahn, *Economics of Patent Protection*, *supra* note 151, at 2. (stating "[s]ome studies report that strengthening patents leads to more R&D, and thus more innovation. Others conclude patent protection and the pace of research are, at best, tenuously related"); Zvi Griliches, Ariel Pakes & Bronwyn H. Hall, *The Value of Patents as Indicators of Inventive Activity*, in *ECONOMIC POLICY AND TECHNICAL PERFORMANCE* 97, 120 (1987) (stating "while the aggregate value of patent rights appears to be quite high, it is estimated to be only on the order of 10 to 15 percent of total national expenditures on R&D"). Cf. Ashish Arora, Marco Ceccagnoli & Wesley Cohen, *R&D and the Patent Premium* (NBER Working Paper No. 9431) ("Although patent protection is found to provide a positive premium on average in only a few industries, our results also imply that it stimulates R&D across almost all manufactures industries, with the magnitude of that effect varying substantially.").

154. See Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 *BERKELEY TECH. L.J.* 577, 603 (1999) (noting the "increase in the private value of patents since the early 1980s"). See also Allison et. al, *Valuable Patents*, *supra* note (exploring what makes a patent have private value and how to identify those valuable patents).

155. See R.M. Solow, *Technical Change and the Aggregate Production Function*, 39 *REV. ECON. STAT.* 312 (1957); F.M. SCHERER & D. ROSS, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* (1990).

156. See LANDES & POSNER, *ECONOMIC STRUCTURE*, *supra* note 8, at 310 ("Although there are powerful economic reasons in favor of creating property rights in inventions, there are also considerable social costs and whether the benefits exceed the costs is impossible to answer with confidence on the basis of present knowledge"); Richard Brunell, *Appropriability in Antitrust: How Much Is Enough*, 69 *ANTITRUST L.J.* 1, 4 (2001) ("[I]f the vast economics literature on intellectual property conveys one message, it is that the relationship between intellectual property protection and economic welfare is unclear"); Adam Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process* (NBER Working Paper No. 7280) (stating "despite the significance of policy changes and the wide availability of detailed data relating to patenting, robust conclusions regarding the empirical consequences for technological innovation of changes in patent policy are few").

157. In support of this view, commentators point to the preamble of the Article I, § 8, cl. 8 of the Constitution, which has come to be known as the IP clause. The preamble reads, Congress shall have the power "to promote the Progress of the useful Arts." In discussing the IP clause, the Supreme Court wrote in *Mazer v. Stein*, the "economic policy behind the clause empowering Congress to grant patents and copyrights is the conviction that it is the best way to advance public welfare." See Section A.3 for a discussion of the IP clause.

158. For instance, Justice Story, the leading patent law jurist of the 19th century, wrote, "[t]he inventor has . . . a property in his inventions; a property which is often of very great value, and of which the law intended to give him the absolute enjoyment and possession." *Ex parte Wood*, 22 U.S. 603, 608 (1824). And Circuit Justice Marshall, in *Evans v. Jordan*, stated that "the constitution and law, taken together, give to the inventor, from the moment of invention, an inchoate property therein, which is completed by suing out a patent." 8 F. Cas. 872, 873 (C.C. Va. 1813). In *Lowell v. Lewis*, the court wrote that "let the damages be estimated as high, as they can be,

surprising, therefore, that given some of the perceived weaknesses of the incentive-based theories, some commentators have proposed non-incentive based theories to complement the traditional incentive rationale.¹⁵⁹

The aforementioned discussion suggests that while scholars continue to unmask the benefits and shortcomings of the patent system, much remains to be discovered. In 1958, economist Fritz Machlup conducted a study of the patent system and famously concluded that “[i]f we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible on the basis of our present knowledge, to recommend abolishing it.”¹⁶⁰ Our understanding of the patent system has increased tremendously since 1958, but Machlup’s conclusion still resonates. And, to the extent answers remain unclear, Machlup encouraged us to continue “to muddle through.”¹⁶¹

C. THE PATENT DOCUMENT AND PROCESS OF OBTAINING PATENT RIGHTS

There are three types of patents: utility, design, and plant. Approximately 90 percent of issued patents are utility, and therefore, this and the remaining chapters pertain exclusively to utility patents.¹⁶² Unlike trademark law, there is no such thing as common law patent rights. Nor do patent rights subsist upon fixation in a tangible medium of expression as provided for by copyright law. Rather, a United States patent can only be acquired by filing a patent

consistently with the rule of law on this subject, if the plaintiff’s patent has been violated; wrongdoers may not reap the fruits of the labor and genius of other men.” 15 F. Cas. 1018, 1019 (C.C. Mass. 1817). Favorable judicial disposition was matched by patent administrators such as William Thornton, the Superintendent of Patents from 1802 to 1828, who were of the view that the patent system was designed to serve and reward inventors. See EDWARD C. WALTERSCHEID, TO PROMOTE THE PROGRESS OF THE USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1798-1836 244 (noting that Thornton, “like many of his contemporaries, . . . viewed the patent system not so much as being embued [sic] with a public interest, but rather as a mechanism for rewarding legitimate inventors and protecting their rights”). For a discussion of William Thornton’s tenure as Superintendent of Patents, see Daniel Preston, *The Administration and Reform of the U.S. Patent Office, 1790-1836*, 5 J. EARLY REPUBLIC 331 (1985); KENNETH W. DOBYNS, THE PATENT OFFICE PONY: A HISTORY OF THE EARLY PATENT OFFICE 42-57 (1994). For a good discussion of the influence of natural rights theory in early American patent law, see Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550-1800*, 52 HASTINGS L.J. 1255, 1266 (2001) (asserting natural rights theory played prominent role in IP development); Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents: Reconsidering the Patent “Privilege” in Historical Context*, 92 CORNELL L. REV. 953 (2007) (forthcoming) (same).

159. See, e.g., Clarisa Long, *Patent Signals*, U. CHI. L. REV. 625 (2002) (arguing patents act as a signal for firms, thus reducing information costs regarding firm’s financial and technologic strength); Paul J. Heald, *A Transactions Costs Theory of Patent Law*, 66 OHIO ST. L.J. 473 (2005) (asserting patent law serves to lower transaction costs).

160. ECONOMIC REVIEW OF THE PATENT SYSTEM: STUDY OF THE SUBCOMM. ON PATENTS, TRADEMARKS, & COPYRIGHTS OF THE COMM. ON THE JUDICIARY, 85th Cong. 80 (1958). For a copy of this study, see the casebook website at <http://law.case.edu/lawofpatents/>.

161. *Id.*

162. Thus, unless expressly noted otherwise, utility patent is implied when the word “patent” is used in this book. The only exception is in Chapter 3, which devotes a small section to the discussion of design and plant patents,

application with the United States Patent and Trademark Office (“USPTO”). The USPTO is a federal agency that is under the Department of Commerce,¹⁶³ and is located in Alexandria, Virginia, just across the Potomac River from Washington, D.C. The agency does not have jurisdiction over issues relating to infringement or enforcement. Rather, according to its 2006 Performance and Accountability Report:

The USPTO’s mission is to foster innovation and competitiveness by providing high quality and timely examination of patent and trademark applications, guiding domestic and international intellectual property policy, and delivering intellectual property information and education worldwide. Intellectual property includes inventions or creations embodied in the form of a patent, trademark, trade secret, or copyright.¹⁶⁴

The agency is led by the Under Secretary of Commerce for Intellectual Property, who is also Director of the USPTO.¹⁶⁵ The Patent Code states the “Director shall be responsible for providing policy direction and management supervision for the Office and for the issuance of patents and the registration of trademarks.”¹⁶⁶ Several officials comprise the Director’s staff, including the Deputy Under Secretary of Commerce and Deputy Director of the USPTO, the Commissioner for Patents, and the Commissioner for Trademarks. The examination of patent applications is divided among eight technology centers, which are under the general supervision of the Deputy Commissioner for Patent Operations. Each center is led by a group director and subdivided into art units staffed by patent examiners.¹⁶⁷ In 2006, the USPTO employed approximately 4,800 patent examiners. The organization of the agency is reflected in the chart below.¹⁶⁸

Filing an application does not guarantee that a patent will issue; in fact, in 2006, fewer than half (39 percent) of filed applications resulted in issued patents.¹⁶⁹ The total average pendency for patent applications in 2006 was 31.1 months; in 2003, it was 26.7 months.¹⁷⁰ The number of patent applications has increasingly grown over time and, naturally, a corresponding increase in issuances in terms of raw numbers.¹⁷¹ For instance, in 2006 the USPTO received 415,551 applications (up 55 percent from 1996) and issued

163. See 35 U.S.C. § 1. For more on the history of USPTO, see *supra* notes 93-4. See also KENNETH W. DOBYNS, *THE PATENT OFFICE PONY: A HISTORY OF THE EARLY PATENT OFFICE* (1994).

164. See USPTO PERFORMANCE AND ACCOUNTABILITY REPORT (2006) at http://www.uspto.gov/web/offices/com/annual/2006/30100_mission_org.html.

165. See 35 U.S.C. § 3 (2000).

166. See 35 U.S.C. § 3(a)(2) (2000).

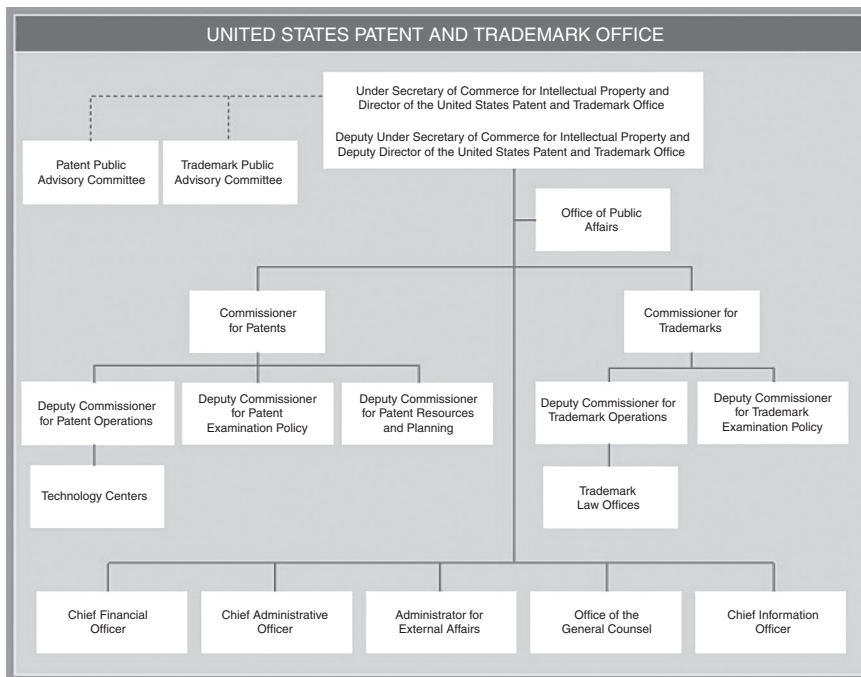
167. For example, technology center 1600 is entitled “Organic Chemistry and Biotechnology.” This center includes several art units such as Art Unit 1630, which handles patent applications related to “Molecular Biology, Bioinformatics, Nucleic Acids, Recombinant DNA and RNA, Gene Regulation, Nucleic Acid Amplification, Animals and Recombinant Plants, Combinatorial/Computational Chemistry.” Technology Center 2100 is entitled “Computer Architecture, Software and Information Security.” One of its many art units is “Database and File Management,” art unit 2160. See <http://www.uspto.gov/web/info/pat-tech.htm>.

168. See PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* note 164.

169. *Id.* The percentage of issued patents has steadily decreased over the past four years. For example, in 2005 (40%); 2004 (48% issued); 2003 (52%).

170. *Id.*

171. Although it should be noted that the period from 1870-1920 witnessed a considerable number of patents issued on a per capita basis in the United States. In fact, based on this metric, two commentators have referred to these five decades as the “most technologically fertile period in American history.” Naomi R. Lamoreaux & Kenneth L. Sokoloff, *Intermediaries in the U.S.*



162,509 (up 35 percent from 1996) (see the graph below).¹⁷² In comparison, the European Patent Office (EPO) received 208,502 applications in 2006 (up 58 percent from 1996), and issued 62,780 patents (up 36 percent from 1996).¹⁷³ The Japanese Patent Office (JPO) received 408,674 applications in 2006 (up 8.5 percent from 1996), and issued 141,399 (a 34 percent decrease from 1996).¹⁷⁴ In addition to raw filing numbers, ownership of patent rights is highly concentrated, with patent applicants from the United States, Japan, and Germany comprising 23%, 23%, and 11%, respectively, of all applications filed in other countries.¹⁷⁵ The number of “busy” patent offices is also highly concentrated. In 2005, the patent offices, in descending order, in Japan, the United States, China, the Republic of Korea, and Europe (*i.e.*, the EPO) were the largest recipient offices, accounting for 77% of patent filings worldwide.¹⁷⁶ Indeed, patent filings worldwide have increased from 884,400 in 1995 to 1,660,000 in 2005.¹⁷⁷ China has experienced the largest percentage increase (nearly 600 percent) during this time, followed by India (365 percent).¹⁷⁸

Market for Technology, 1870-1920 in FINANCE, INTERMEDIARIES, AND ECONOMIC DEVELOPMENT 211 (Cambridge University Press 2003).

172. See USPTO PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* at 164.

173. See EPO Annual Report (1995, 2006). According to the World Intellectual Property Organization there were nearly 1.6 million patent applications filed worldwide in 2004 compared to 884,000 in 1985. See WIPO Patent Report at http://www.wipo.int/ipstats/en/statistics/patents/patent_report_2006.html#P93_7755.

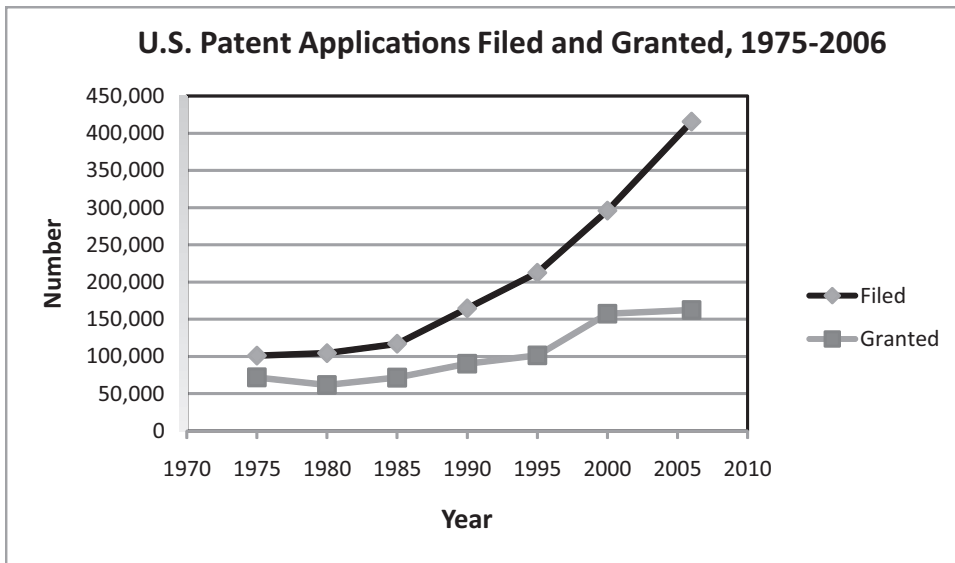
174. See Japanese Patent Office Statistics at http://www.jpo.go.jp/shiryou_e/index.htm.

175. See World Intellectual Property Organization Patent Report: Statistics on Worldwide Patent Activity (2007).

176. *Id.*

177. *Id.*

178. *Id.*



What explains this steep increase in the number of patent filings? Commentators have offered a number of explanations. First, it can be quite difficult to gauge commercial potential during the application phase;¹⁷⁹ indeed, commercial potential may not manifest itself — if at all — until several years after issuance, and therefore, applicants err on the side of filing. Second, the creation of the United States Court of Appeals for the Federal Circuit, from its beginning in 1982, altered the legal landscape of patents, resulting in a significant strengthening of the patent grant.¹⁸⁰ Third, Congress has enacted patent and other forms of legislation that have incentivized certain technologic and industrial segments of society (*e.g.*, research universities) to pursue patent protection on their innovations, particularly in the fields of biotechnology and genomics.¹⁸¹ Fourth, a patent is an increasingly important tool to attract venture capital and financing.¹⁸² Fifth, a patent can be used to reduce information costs by acting as a vehicle to publicize information, in addition to being used for privatizing information.¹⁸³ Sixth, there has been an increase in research productivity.¹⁸⁴ And lastly, patentees may simply

179. See F.M. Scherer, *The Innovation Lottery*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 3-21 (Dreyfuss et al. eds., 2001).

180. See LANDES & POSER, ECONOMIC STRUCTURE, *supra* note 8, at 337-44 (suggesting the Federal Circuit “has had a significant positive effect on both the number of patent applications and the number of patent grants”); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 241 (1998) (noting increase in patent validity rate after creation of Federal Circuit). Cf. Samuel Kortum & Josh Lerner, *Stronger Protection or Technological Revolution: What Is Behind the Recent Surge in Patenting?*, Carnegie-Rochester Series on Public Policy 48:247-304 (rejecting the “friendly court” hypothesis).

181. See, *e.g.*, 35 U.S.C. §§ 200-212 (2000) (“Bayh-Dole Act”).

182. See Bronwyn H. Hall, Adam B. Jaffe & Manuel Trajtenberg, *Market Value and Patent Citations*, 36 RAND J. ECON. 1 (2005); PAUL A. GOMPERS & JOSH LERNER, *THE MONEY OF INVENTION: HOW VENTURE CAPITAL CREATES NEW WEALTH* (2001); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137 (2000).

183. See Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002).

184. See Kortum & Lerner, *Stronger Protection or Technological Revolution*, *supra* note 180 (finding the reason for the increase in patent filings resides outside the patent system such as increase in research productivity).

want to block competitors from patenting similar technology,¹⁸⁵ enhance their bargaining position during licensing negotiations,¹⁸⁶ or deter law suits.¹⁸⁷

In addition to more filings, the cost of obtaining patent rights has increased. A recent survey of patent attorneys shows that the median costs for preparing and filing a patent application in the biotech/chemical arts is \$12,393, for electrical/computer arts \$10,993, and for mechanical, \$9,412.¹⁸⁸ As these are median costs, some applications, depending on the complexity of the technology and geographic location of the law firm, can be considerably more. And there are, typically, after-filing costs that have a median range \$2,000-4,000.¹⁸⁹

The process of applying for a patent is called *patent prosecution*, and the record of the prosecution proceedings before the PTO is called the *prosecution history* (sometimes referred to as file history).¹⁹⁰ Prosecution is governed by three sets of rules and regulations: (1) the patent code set forth in Title 35; (2) Title 37 of the Code of Federal Regulations, which embodies the USPTO's rulemaking; and (3) the Manual of Patent Examining Procedure (commonly referred to as the "MPEP"), which provides important guidance to applicants and examiners, but does not have the force and effect of law.¹⁹¹ The proceeding is *ex parte*, meaning that the prosecution is only between the applicant and the examiner. Although there are opportunities for third parties to submit information to the examiner regarding the patentability of the application in question, these opportunities are not constructed to optimize a legitimate challenge. Opposition proceedings have been implemented in numerous other jurisdictions, however.¹⁹²

It is common for an inventor and his attorney, before filing a patent application, to conduct a prior art search to get a better understanding of the patentability of the invention.¹⁹³ Prior art has been defined as "knowledge

185. See Cohen et al., *Appropriability Conditions*, *supra* note 8, at 24.

186. *Id.*

187. See Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1 (2005).

188. See AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, REPORT OF THE ECONOMIC SURVEY I-72-73 (2006). These numbers reflect attorney fees, not the PTO filing fees, which are relatively modest in comparison.

189. *Id.* at I-73-74.

190. To prosecute a patent or otherwise represent clients before the PTO, one must be licensed to practice before the agency, which means one must have passed the patent bar exam. One does not have to be an attorney to sit for the patent bar and represent clients before the PTO. Non-attorneys who practice before the PTO are called patent agents. The exception to this rule is pro se applicants; that is, an applicant representing himself. See <http://www.uspto.gov/web/offices/dcom/gcounsel/oed.htm> for more information about the patent bar and its eligibility requirements.

191. All three sources can be found on the USPTO's website—www.uspto.gov.

192. For an empirical study of opposition proceedings, see Stuart J.H. Graham & Dietmar Harhoff, *Can Post-Grant Reviews Improve Patent System Design? A Twin Study of U.S. and European Patents*, at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=921826. See also Bronwyn Hall, Stuart J.H. Graham, Dietmar Harhoff & David Mowery, *Prospects for Improving U.S. Patent Quality via Post-Grant Opposition*, at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=410657.

193. There are several databases for searching patents. See, e.g., <http://www.uspto.gov/patents/> and <http://www.google.com/patents/>. There is no duty to conduct a prior art search, but it is usually advisable because novelty-defeating prior art may be discovered and save the inventor thousands of dollars. Moreover, if the invention has commercial significance, the inventor may want to conduct a thorough (and costly) prior art search to enhance the patent's strength and render it less susceptible to invalidity challenges. A court is more deferential to the PTO if all the defendant has by way of an invalidity defense is the same prior art the PTO considered during prosecution. See *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359

that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in an art.”¹⁹⁴ Once filed, the application is examined by a patent examiner who is trained in the technology to which the claimed invention pertains. The examiner usually conducts a search of the prior art to determine if the claimed invention satisfies the novel and non-obvious requirements, explored in Chapters 4 and 6, respectively. The examiner will also determine whether the application satisfies the disclosure requirements, discussed in Chapter 2, and meets the utility and subject matter eligibility requirements, both of which are explored in Chapter 3. The examiner will then issue an initial *office action*, most likely rejecting some or all of the claims, and setting forth the reasons for the rejection. Upon receipt of the office action, the inventor and his attorney can either abandon the application or, more commonly, reply to the office action by submitting an *amendment*. The amendment may modify the claims, usually in a manner that narrows them, and put forward arguments aimed at persuading the examiner to allow the application in its amended form. (The inventor and his attorney, as discussed in Chapter 7, have to be very careful how they amend the application lest the amendment come back to haunt them during litigation.) At this stage in the prosecution, the examiner can either allow the application or reject it yet again. If opting for the latter, the rejection is usually final as reflected in a *final office action*, which means that the inventor’s options are more limited than they were after receipt of the initial office action. The inventor’s choices are (1) appeal the decision to the Board of Patent Appeals and Interferences (the “BPAI”), an administrative body within the USPTO;¹⁹⁵ (2) file a continuation application;¹⁹⁶ (3) file a continuation-in-part (C-I-P);¹⁹⁷ (4) request for continued examination (RCE);¹⁹⁸ or (5) abandon the application.

(Fed. Cir. 1984) (stating “[w]hen no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency”). Lastly, having a broad understanding of extant prior art may be beneficial for purposes of claim scope. This issue is explored in detail in Chapter 7.

194. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1453 (Fed. Cir. 1984).

195. See 35 U.S.C. § 6. See also <http://www.uspto.gov/web/offices/dcom/bpai/index.html>.

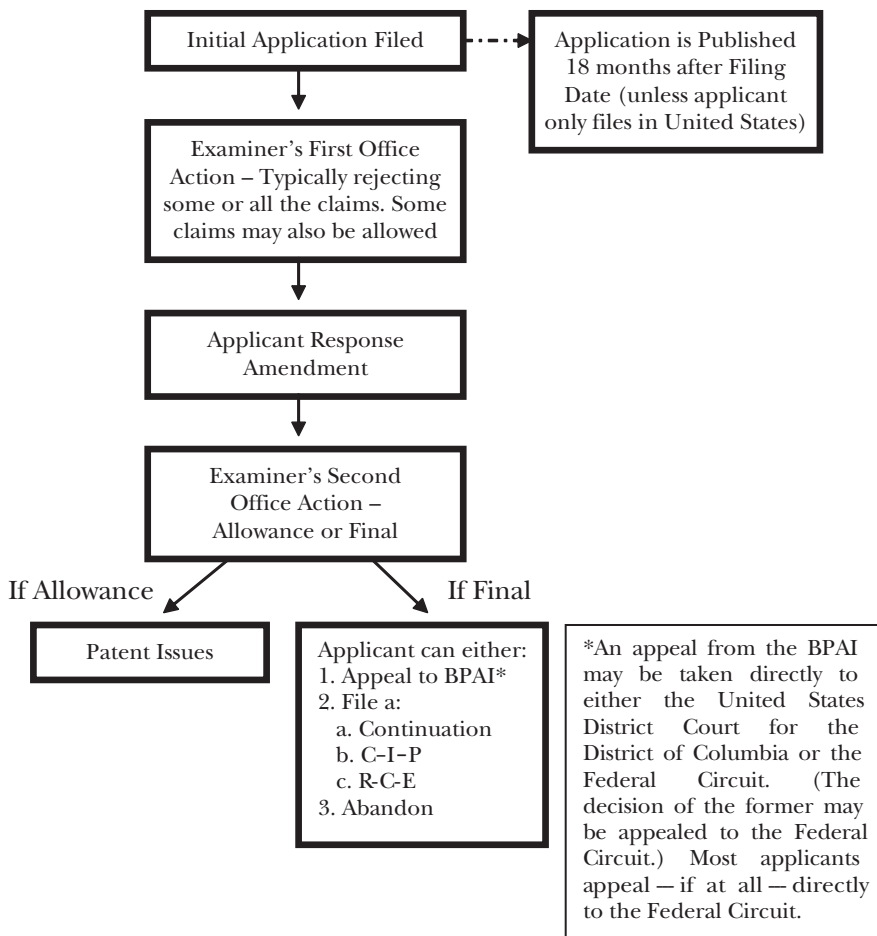
196. A continuation application enjoys the same filing date as the original application. The claims may be modified in the continuation, but the specification must remain the same. See 35 U.S.C. § 120; 37 C.F.R. § 1.53(b).

197. A continuation-in-part is an application filed during the lifetime of an earlier application, disclosing some or all of the earlier application and adding new matter not disclosed in the earlier application. A C-I-P has two filing dates, the filing date of the original application for the repeated information and the actual C-I-P filing date for the new matter. See 35 U.S.C. § 120; 37 C.F.R. § 1.53(b).

198. An RCE can be viewed as a request to keep the current application alive, without requiring the applicant to file a new application such as a continuation. According to § 706.07(h) the Manual of Patent Examination Procedure (MPEP):

35 U.S.C. 132(b) provides for continued examination of an application at the request of the applicant (request for continued examination or RCE) upon payment of a fee, without requiring the applicant to file a continuing application under 37 CFR 1.53(b). To implement the RCE practice, 37 CFR 1.114 provides a procedure under which an applicant may obtain continued examination of an application in which prosecution is closed (*e.g.*, the application is under final rejection or a notice of allowance) by filing a submission and paying a specified fee. Applicants cannot file an RCE to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined as a matter of right (*i.e.*, applicant cannot switch inventions). See 37 CFR 1.145. Any newly submitted claims that are directed to an invention that is independent and distinct from the invention previously claimed will be withdrawn from consideration and not entered. An RCE is not the filing of a new application. Thus, the Office will not

A Flow Chart of the Patent Prosecution Process



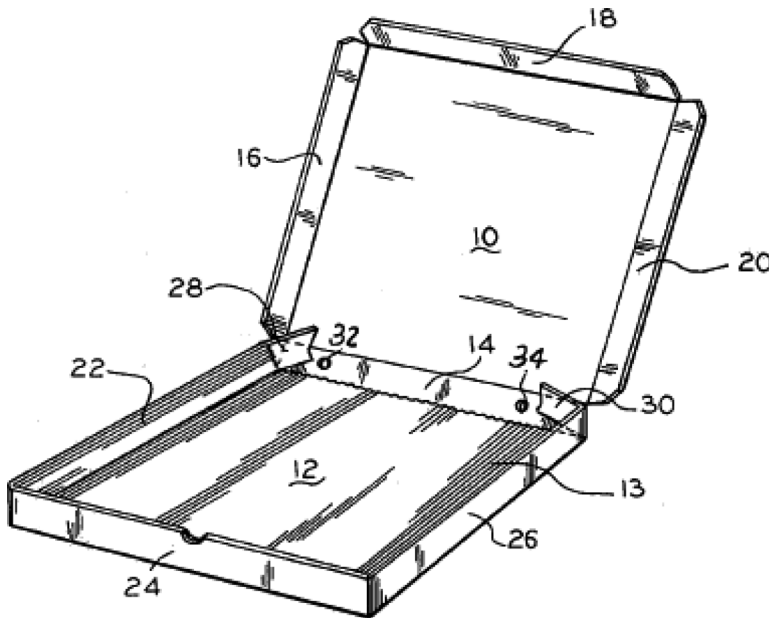
The patent application (and issued patent) is comprised of two parts: (1) the specification (sometimes referred to as the written description); and (2) the claims, both of which are written in highly stylized language. (The claims are technically part of the specification under 35 U.S.C. § 112, but it is common practice for patent professionals and courts to refer to and treat the “claims” and “specification” as distinct components of the patent, and this book will assume the same approach.) The claims are considered to be the most important part of the patent document because the claims delineate the patent owner’s property right. To borrow real property terminology, the claims set forth the metes and bounds of the patentee’s proprietary interest. (Claims are discussed in more detail in Chapters 2 and 7.) The specification, on the other hand, contains an extensive disclosure of the claimed invention and can be

convert an RCE to a new application such as an application filed under 37 CFR 1.53(b) or a continued prosecution application (CPA) under 37 CFR 1.53(d).

viewed as a teaching device, informing its reader of the particulars of the claimed invention. As the Federal Circuit has noted, “Specifications teach. Claims claim.”¹⁹⁹

Patent claim drafting is a difficult endeavor that takes many years of practice to achieve a high level of competency.²⁰⁰ Indeed, poorly drafted claims can be particularly costly if the patent is subject to licensing negotiations or eventually litigated. To illustrate the difficulty of claim drafting, consider the following familiar invention: a pizza box. How would you draft a claim to cover the fundamental features of this invention? Keep in mind you want to draft a claim with an eye towards litigation, meaning that you want a claim that provides the maximum amount of protection, but does not overlap with the prior art.

Figure 1. Pizza Box
U.S. Patent 4,441,626



The following is an excerpt from the specification of the patent:

As shown in FIG. 1, a pizza box constructed in accordance with the teachings of this invention comprises upper and lower members having a top panel 10, a bottom panel 12 and a central panel 14. The top panel 10 and the bottom panel 12 include side panels 16, 18, 20, 22, 24, 26 and various side flaps 28, 30, to complete the folding and assembly of the box.

According to the invention, means are provided for venting the box at holes 32 and 34. Research has found that proper ventilation should be attained

199. *SRI Int'l. v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1984).

200. There are several excellent books on claim drafting; the most well known of these is ROBERT C. FABER, *LANDIS ON THE MECHANICS OF PATENT CLAIM DRAFTING* (2005).

inside the box to keep the pizza hot and still retain good crust quality, when approximately one square inch of ventilation is provided for each cubic foot of volume, to acquire a proper balance between heat and steam.

There is a great deal of prior art showing many of the features of FIG. 1 (*e.g.*, upper and lower members with a central plane), but none of the prior art discloses flaps and ventilation holes together in a single pizza box. Think about the features of FIG. 1 you want to protect, while also keeping in mind that you have to draft a claim that avoids the prior art. A sample claim may look like the following:

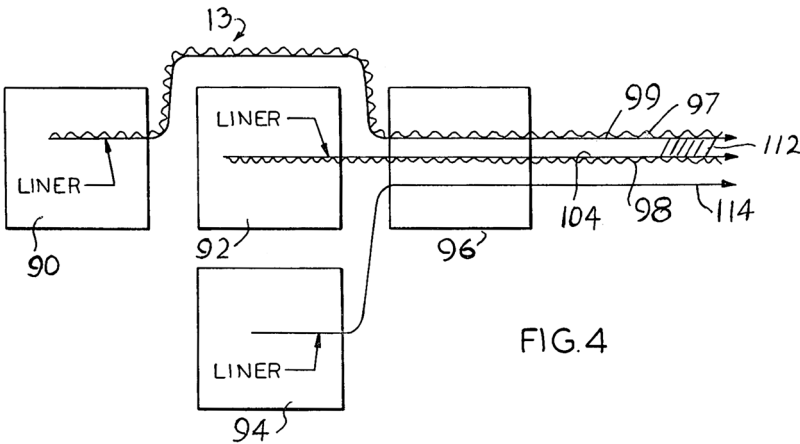
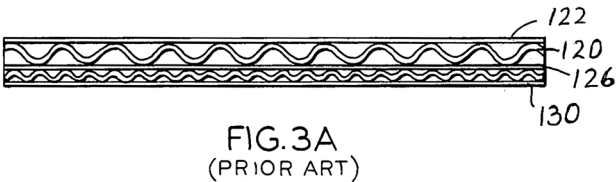
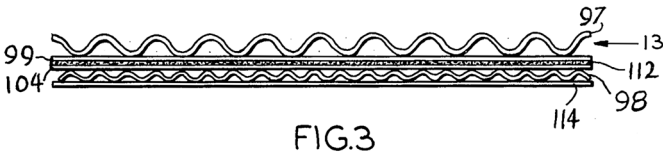
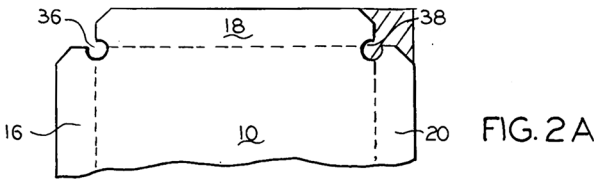
Claim 1: A box comprising upper and lower members that open and close relative to each other, a plurality of side panels, and a central panel having holes for ventilation, said upper and lower members having side flaps.

There are many ways to draft this claim. One could modify “box” with the word “pizza,” but recall you want to claim as broadly as the prior art would allow. Moreover, instead of claiming “holes for ventilation,” one could claim “means for ventilation” and disclose the means (*i.e.*, the holes) in the specification. *See* 35 U.S.C. § 112 (allowing means-plus-function claims, discussed in Chapter 7). Also, instead of claiming the “side flaps” in claim 1, a dependent claim could be added. Dependent claims incorporate all of the limitations in the independent claim on which it depends plus the limitations set for in the dependent claim itself. *See* 35 U.S.C. § 112, ¶¶ 3, 4. *See also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (“[T]he presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim.”). A dependent claim may read:

Claim 2: A box as in claim 1, wherein said upper and lower members have side flaps.

The point here is that no matter how basic or straightforward the invention, claim drafting is a difficult endeavor, yet one that is extremely important because of the legal weight claims assume within the patent system. As you read the actual claims in the 4,441,626 patent below, you will notice the highly structured nature of claim language, each word having significance, including words such as “said,” “substantially,” “intermediate,” and “comprising.”

Below is the cover page of issued U.S. Patent No. 4,441,626 entitled “Pizza Box.” Notice that there are several important features on this page, including: [11] patent number and [22] filing date; [75] name of inventor and [73] assignee; [52] technical class that “pizza boxes” are a part of; for instance, U.S. Class 220/443 is for “receptacles coextensively bonded;” [56] references cited or prior art the PTO considered when examining the patent; and [57] abstract. Also, above the abstract is listed the names of the examiner and attorneys who prosecuted the patent application. A full copy of the pizza box patent is reproduced below, and the patent and its prosecution history can also be found on the casebook website at <http://law.case.edu/lawofpatents/>. Please note that the patent claims not only the box, but also the method for making the box.

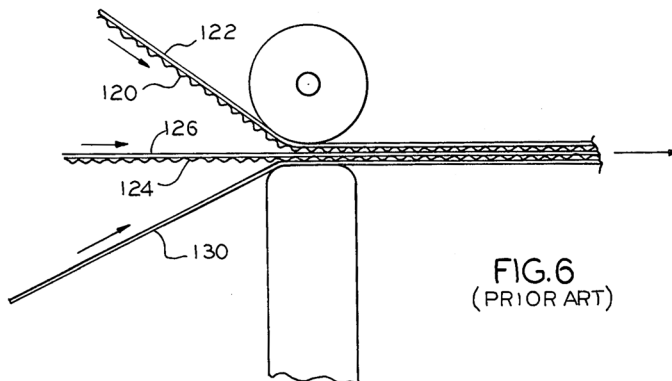
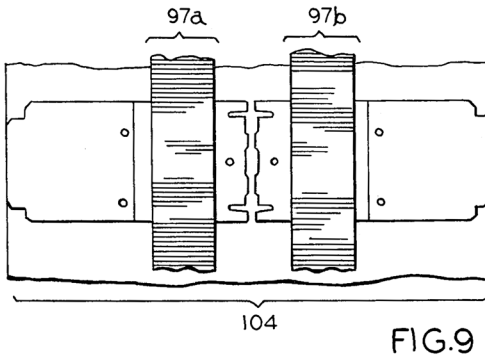
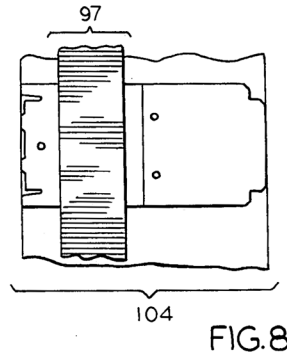
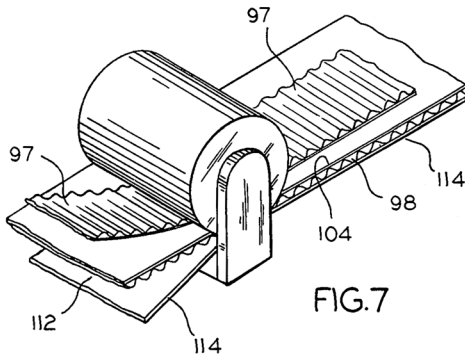


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PIZZA BOX

This invention relates to boxes for packaging foods, and more particularly, to boxes for packaging and maintaining the temperature of foods such as pizza, in an optimal state, as during delivery, for example, and to methods for making the boxes.

Hereinafter, it will be convenient to refer to pizza boxes, by way of example. However, the invention is equally applicable to any of many similar foods, products, or the like, especially when it is desirable to keep the foods or products elevated above any liquid dripping off the foods or products. The box is designed to retain the temperature of either hot or cold food, or the like, over an extended period of time.

Conventional pizza boxes do not enable good air circulation or heat retention. They do not prevent a penetration of grease through the box. As a result, both the boxes and pizzas are often delivered in a soggy condition resulting in either damage to the pizzas or inconvenience to anyone or anything with which the boxes come in contact. Sometimes, the pizzas may be delivered inside large paper bags which can maintain the heat of the pizzas for only a few minutes. Usually, inserts in the form of corrugated cardboard discs must be added to the boxes or the bags. Thus, present day pizza boxes do not provide for delivery of pizzas in the same condition that they have when taken from the oven. These boxes require excessive set-up time for erecting boxes, installing inserts, etc.

Accordingly, an object of the invention is to provide new and improved packaging boxes, and particularly, food packaging boxes. More particularly, an object is to provide boxes which will enable grease or other liquids to drip or wick off pizzas, but not to penetrate through the boxes.

Here, an object is to provide boxes which help enable delivery of pizzas in a crisp, optimal state, without creating a greasy condition which may stain clothes, car seats, or the like.

Another object is to provide easy-to-assemble pizza boxes which set up with minimum effort, require no inserts, and enable a good air circulation and heat retention. Yet another object is to provide a method for assembling such pizza boxes.

In keeping with one aspect of this invention, a box is formed from a unitary, double-sided corrugated cardboard blank having a plurality of scored lines to enable a quick and easy folding of panels to set up the box form. The bottom panel of the box has a single-sided, fluted corrugated cardboard medium glued to the double-sided corrugated cardboard blank. The fluted side of the medium faces upwardly, out of the box. A moisture-resistant glue is used between the smooth faces of the fluted corrugated medium and the confronting liner of the blank to provide an impenetrable barrier which prevents grease from penetrating through the box. The boxes are manufactured on a conventional production line which is modified by, in effect, running one stage in a reverse direction in order to invert the single-sided medium and to apply the glue in a different manner to establish the moisture barrier.

The invention will be best understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, in which:

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FIG. 1 is a perspective view of the erected box, in an open position;

FIG. 2 is a plan view of a blank for the unerected box;

FIG. 2A is a view of the top panel of FIG. 2 which shows an alternative cutting of the box for ventilating the box without requiring holes made from loose parts;

FIG. 3 is a cross-section of the inventive box taken along line 3—3 of FIG. 2;

FIG. 3A is a cross-section of a conventional double-layer corrugated liner;

FIG. 4 is a block diagram of a production line for constructing the inventive box;

FIGS. 5 and 5A together show a diagrammatic view in side elevation of a corrugation cardboard production line for making the inventive box with a liner having upstanding flutes, such as that shown in FIG. 3;

FIG. 6 is a view of a work station in FIG. 5, showing a conventional method of making a double-layer corrugated liner, such as that shown in FIG. 3A;

FIG. 7 is a perspective view of the last work station in the production line of FIG. 5;

FIG. 8 is a plan view of the product of the production line, of FIG. 7, showing how the blank is cut for large boxes; and

FIG. 9 is a similar plan view showing how the blank is cut for smaller boxes.

As shown in FIG. 1, a pizza box constructed in accordance with the teachings of this invention comprises upper and lower members having a top panel 10, a bottom panel 12 and a central panel 14. The top panel 10 and the bottom panel 12 include side panels 16, 18, 20, 22, 24, 26 and various side flaps 28, 30, to complete the folding and assembly of the box.

If the pizza box described thus far is made of conventional corrugated cardboard, it is subject to two faults. First, bottom panel 12 does not prevent grease from penetrating through the box. Thus, a pizza which drips causes stains on clothes, auto seats, or anything else which may come into contact with the box. Second, the flat smooth surface of the bottom panel 12 does not provide for good air circulation and heat retention in the area under the pizza which leads to a soggy crust.

In keeping with one aspect of this invention, means are provided for preventing grease penetration and for enabling air circulation within the pizza box, and especially under the crust. In greater detail, a corrugated cardboard medium 13, with the upstanding flutes is glued to the bottom panel 12 with a moisture-resistant glue which forms an impenetrable layer or moisture barrier. The upstanding flutes are made of a material which wicks grease; thus grease not only drips, but also is positively wicked off the pizza and into the medium. However, that grease cannot penetrate through the layer of moisture resistant glue. The pizza and the box are kept in an optimal state. Air can also circulate around the pizza since it is held up and supported on the tops of the upstanding flutes of the corrugated medium, and out of any pool of grease or other liquid which may form in the bottom of the box.

According to the invention, means are also provided for venting the box either at holes 32, 34 in FIG. 2 or at several selvage enlargements which are cutout at 36, 38 when the blank is formed (FIG. 2A). Research has found that proper ventilation should be attained inside the box to keep the pizza hot and still retain good crust quality, when approximately one square inch of ventilation is provided for each cubic foot of volume, to acquire a proper balance between heat and steam. There-

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fore, the size of the holes or cutouts is selected to enable just enough steam to escape to prevent the pizza from becoming soggy, but not so much that the pizza box will lose heat. Conveniently, the venting area may be controlled by selecting a correct number of holes so that one size punch will serve all box sizes.

FIG. 2 shows the basic, unitary blank for making the folded pizza box. The top panel 10 is defined by a plurality of scored lines 40, 42, 44, 46. The bottom panel 12 is defined by scored lines 48, 50, 52, 54. The bottom panel 12 has a medium 13 of single-faced corrugated cardboard glued to it with the exposed flutes facing upward as viewed in FIGS. 1, 2 and 3. In this embodiment, the top 10 and bottom 12 are joined by a central side panel 14 containing holes 32, 34 for venting steam without an undue loss of heat.

In FIG. 2, dashed lines are used to indicate where scoring forms fold lines and solid lines are used to indicate where blank cutting occurs. A semi-piercing rule die is used to form an alternating cut and score line at 46, non-cutting rule dies form score lines elsewhere as indicated by dashed lines (e.g. line 42), and cutting rule dies cut through the blank as indicated by solid lines, as at 56, for example. The cutouts are formed at points 56-70 to make locking tabs and to reduce binding where the folding cardboard would otherwise form undue bulk, bind, or prevent smooth folds.

These score and cut lines divide the top panel 10 into matched side panels 16, 20 and an end panel 18, and divide the bottom panel 12 into matched side panels 22, 26, and a double end panel 24 divided by a scored line 72 into panels 74, 76. Folding corner tabs or panels 78, 80 are formed on ends of the side panels 22, 26 at the front of the bottom panel 12 of the box. Corner tabs or panels 28, 30 are formed at the opposite ends of the side panels 22, 26 to hinge, fold inside, and support the sides and corners of the box. The corner tabs or panels 28, 30, 78, 80 enable and cause the side and end panels 14, 22, 26, 74, 76 to articulate and lock into a box configuration. A pair of locking tabs 82, 84 fit into cutouts at locations 56, 58 while tabs 78, 80 are captured between end panels 74, 76, for locking the bottom panel 12 of the box into its fully-folded condition.

To fold and assemble the box, the side panels 22, 26 are first folded upwardly and out of the plane of the paper at lines 50, 54, as viewed in FIG. 2. The corner panels 28, 30, 78, 80, are folded inwardly toward the center of the box. Next, the double end panel 24 (divided into panels 74, 76) is folded at line 52 upwardly out of the plane of the paper, and the panel 76 is then folded along two scored lines 72, 73 downwardly, over intumed corner panels 78, 80, and into the box where locking tabs 82, 84 fit into the cutouts 56, 58. Finally, side panels 16, 20 and end panel 18 are folded along lines 42, 44, 40 up out of the plane of the paper as shown in FIG. 2. The entire top panel 10 is then folded, at line 46, upwardly, out of the plane of the paper as shown in FIG. 2. The side panels 16, 20 and end panel 18 tuck neatly into the bottom of the box. The circular hole punched at point 86 folds in half to provide a semi-circular cutout when panel 24 is folded along lines 72, 73 to provide a place where a person can place a thumb nail for an easy opening of the box.

FIG. 2A shows an alternative venting of the box wherein selvage cutouts 36, 38 replace holes 32, 34. A possible problem with punched holes 32, 34 is that a cutout disc is formed which may not lift completely out of the remaining hole. If this should happen, someone

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could eat the disc. Thus, the corner cutouts 36, 38 are desirable because each "disc" forming a hole is integral with a corner member (the selvage is cross-hatched in FIG. 2A) which may be removed as a unit so that there is no clean-out problem requiring a removal of the cut disc portions, such as might be required at 32, 34. Thus, it is seen that, while present day machinery includes a certain amount of risk that the discs forming holes 32, 34 will not be cleaned out properly, the embodiment of FIG. 2A completely removes that risk. Therefore, none of the discs may fall into the box to be swallowed by a person who is eating the pizza.

The inventive production method of gluing the corrugated cardboard medium 13 is shown in the block diagram in FIG. 4. The back of corrugated cardboard medium 13 (with upstanding flutes) is cemented to and becomes integral with the bottom panel 12, and with the fluted side of the cardboard medium 13 facing upwardly. More particularly, at a first work station 90, an upper flute corrugated, single-face board is formed. At another work station 92, a lower flute corrugated, double-face board is prepared. At work station 96 the smooth faces of the liners of the upper fluted single-face board and the lower fluted corrugated double-face boards are glued together with the use of a moisture resistant adhesive. The upper flutes are upstanding and a moisture resistant layer (shown by cross-hatching 112) is formed inside the box. Work station 94 supplies a liner which is also added at work station 96 to complete the bottom of the double-faced corrugated board as shown in FIGS. 3 and 4.

The preferred embodiment (FIG. 3) uses "B" and "E" flutes for the upper and lower flutes 97, 98, respectively. By industry standards, a "B" flute is relatively large, perhaps one-eighth inch in height, while an "E" flute is relatively small, about one-sixteenth inch in height. However, these particular dimensions are not critical and other flute sizes could be used.

A more detailed view of the production line of FIG. 4, for making the inventive box, is shown in FIG. 5 (with FIG. 5A placed to the right of and joining FIG. 5).

At work station 90, a bleached white medium is corrugated into upper (preferably "B" size) flutes 97. The bleached medium 97, which comes into direct contact with the pizza is sanitary, and has a clean, fresh look (as compared to conventional brown Kraft paper). The medium 97 is then glued to a liner 99 pulled from a roll 100 of heavy Kraft paper. The bleached white flutes 97 are preferably adhered to liner 99 by a regular water resistant starch adhesive, altered by the addition of Ketones. The Ketones create an adequate moisture resistance to prevent delamination of the flute tips from the liner when the steam and grease from the pizza come into contact with them.

More particularly, the adhesive is added by glue applicator roll 102. Since, the corn starch adhesive is not moisture-proof, pizza grease is able to both wick through the corrugated medium and drip into the bottom of the flutes. The flutes 97 should be large enough, for any food resting thereon, to be above any pool of grease or juices collected in the bottoms of the flutes.

At work station 92, an unbleached Kraft paper medium is corrugated to form lower (preferably "E" size) flutes 98. The "E"-fluted medium 98 is then glued to a heavy Kraft paper liner 104 from spool 106 with a conventional corn starch glue. The glue is added by glue applicator roll 108. It should be noted that upper flutes

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97 face upwardly while lower flutes 98 face downwardly so that the smooth liners 104, 99 form first and second substantially flat surfaces which come into face to face contact. The upper flutes 97 comprises a plurality of upwardly directed ridges defining therebetween open channels which are upwardly directed to convey heat and steam from under the pizza and toward vents 32, 34 or 36, 38. The flat surface 104 is the upper surface of any suitable support layer, here elements 114, 98, 112, by way of example.

The two, single-faced corrugated cardboards, thus formed at work stations 90, 92, are transported in a more or less spaced parallel relationship to another work station 96 where the smooth faces 99, 104 of the liner are laminated together, with a moisture-resistant glue 112 from gluer 110 which forms the moisture barrier. The glue preferably used to bond the two liners 99, 104 to each other is a P.V.A. type adhesive 112 which creates a grease and moisture barrier. The P.V.A. adhesive conforms with the composition requirements of the FDA Food Additives Regulation 175.105 for food packaging adhesives. A bottom liner 114 pulled from spool 94 is then glued to the lower fluted edge of medium 98 with a conventional corn starch glue, to complete the lower surface of the inventive material.

A station from a conventional production line for a double corrugation board is shown in FIG. 6, and the end product of this conventional production line is seen in FIG. 3A. A corrugated medium 120 is glued to a liner 122, with the flutes facing downwardly. Another corrugated medium 124 is glued to the heavy Kraft center paper liner 126 with its flutes also facing downwardly. Then, the fluted medium 120, with attached liner 122 is glued to the top of center paper liner 126 and a lower liner 130 is glued to the bottom of the double board. The single sheet 126 is not covered with any moisture barrier and there is no space for an insertion of the barrier.

Compare FIGS. 3 and 3A, where the two liners 99, 104 are in a face to face relationship with the inventive moisture barrier 112 formed between them. There is no way of placing the moisture barrier between two face-to-face liners in the layer 126, by the conventional production methods since flutes 120 conventionally point downwardly and there is only one liner in the center. The inventive flutes 97 point upwardly and there are two liners 99, 104 in the middle.

The inventive method achieves this result by, in effect, running work station 90 in a "backward" direction so that the medium 97 and liner 99 are manufactured in an upside down orientation. More particularly, there is no need to physically turn the corrugating machine around in order to run it in a "backward" direction. These corrugation machines may conventionally be given either a "left-hand" or a "right-hand" drive, depending upon the layout of a production line. The "upside down" layer 97, 99 may be made by, in effect, using a "left-handed" drive on a "right-handed" production line, or vice versa. Hence, an advantage of the invention is that a conventional corrugation production line may be re-set in an unconventional manner to produce the inventive box without requiring anything more than set-up time.

FIGS. 7-9 show how the insert layer of upwardly pointing flutes are formed in only the bottom of the box. In greater detail, (as best seen in FIGS. 7 and 8) the E-fluted medium 98 which makes the double-faced corrugated cardboard 104, 114 has a full width, corresponding to the length of the blank of FIG. 2. The insert

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of upwardly pointing flutes 97 has a restricted width, corresponding to the width of the bottom 12.

Thus, the die for cutting the blank of FIG. 2 is positioned across the width of the product, as best seen in FIG. 8. Those portions of the blank which form the top 10 and the double end flap 24 are punched from the conventional double-sided corrugated cardboard 104. The insert material having upwardly pointing flutes 97 are located in only the bottom area 12. Thus, when the blank is cut, as shown in FIG. 8, the insert automatically appears at the desired location, without requiring any extra labor.

The widths of the panel 104 and insert 97 may be made wider or more narrow to accommodate different box sizes. However, the boxes may become so small that it is no longer economically feasible to operate the production line. When this happens, two inserts 97a, 97b are cemented onto the conventional cardboard 104, as best seen in FIG. 9. Thus, two blanks are cut, end to end, or nested in a material saving manner. Likewise, any suitable number of insert stripes and of smaller boxes may be cut across the width of the cardboard, in a similar manner.

The many advantages of this pizza box should now be self-apparent. First, the exposed upstanding upper flutes enable grease to wick and flow off the pizza and into the lower areas of the box. The pizza is held at an elevation above the grease to keep it from becoming soggy. The upstanding corrugation also enables heat retention within the box while maintaining good air circulation around and under the pizza. Second, the moisture-resistant PVA adhesive, used to laminate the upper and lower single faced cardboards together, traps and prevents the pizza grease from penetrating through the box. Third, the size of the holes 32, 34 or cutouts 36, 38 enables controlled amounts of steam to escape, which might otherwise cause the pizza crust to lose crispness, and yet the holes or cutouts are small enough to retain the heat of the pizza. Of course, there are still other advantages which will be apparent to those skilled in the art.

While the principles of the invention have been described above in connection with specific apparatus and applications, it is to be understood that this description is made only by way of example and not as a limitation on the scope of the invention, and the claims are intended to cover all equivalents.

I claim:

1. A box comprising upper and lower members which close or open relative to each other to form a covered box, a bottom of said box being formed by said lower member and comprising three laminated layers, a first and outside one of said three laminated layers forming a supporting layer having a first and substantially flat surface on its interior side, a second and intermediate one of said three laminated layers extending over at least a substantial portion of said first flat interior surface, said second layer comprising barrier layer means resistant to at least moisture and being spread across the said first flat interior surface, a third and inside one of said three layers having a second and substantially flat surface on its lower side with a plurality of spaced parallel flutes upstanding on its upper side, said first and second flat surfaces being bonded together in a face to face relationship with said barrier layer means interposed therebetween, said flutes comprising a plurality of upwardly directed ridges defining therebetween upwardly directed open channels, said ridges forming

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means for supporting an article above the bottoms of said channels, and venting means formed in said box and located in a side wall of said box at the ends of said channels, the dimensions of said box being such that heat from an article resting on said flutes escapes through said ventilation means via said channels.

2. The box of claim 1 wherein said barrier layer means is an adhesive.

3. The box of either of the claims 1 or 2 wherein said flutes are made of a corrugated cardboard medium having a liner cemented to its lower tips and said barrier layer means is a water and grease resistant glue spread between the liner and the bottom of said lower member.

4. The box of claim 3 wherein said box is made from a unitary blank of double sided corrugated cardboard.

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5. The box of either of the claims 1 or 2 wherein said flutes are bleached paper and said barrier layer means is a P.V.A. adhesive.

6. The box of any either the claims 1 or 2 wherein said flutes are made of paper which wicks moisture and grease and said barrier means is a P.V.A. adhesive.

7. The box of claim 1 wherein said venting means is in the order of substantially one square inch for each cubic foot enclosed within said box.

8. The box of claim 1 wherein said venting means is formed by holes in said box.

9. The box of claim 1 wherein said venting means is integrally formed by an enlargement in selvage which is cut from said box during the formation of a blank from which said box is erected.

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CHAPTER

2

Disclosing and Claiming the Invention

INTRODUCTION

The disclosure requirements of § 112 are perhaps the most important of any of the patentability requirements, and are at the heart of patent law's goal of promoting the progress of the useful arts. Thus, it is here that we begin our substantive discussion of patent law. By requiring the patent applicant to claim the invention with clarity and to sufficiently disclose his invention to persons having ordinary skill in the art, patent law seeks to facilitate the dissemination of technical information and follow-on innovation. Moreover, the disclosure requirements oblige the patentee to provide notice to the public of what the patentee regards as the boundaries of his property right.

This chapter explores patent law's four disclosure requirements: (1) Enablement; (2) Written Description; (3) Best Mode; and (4) Definiteness. The first three requirements — set forth in 35 U.S.C. § 112, ¶ 1 — relate to the sufficiency of the disclosure in the patent specification, while the fourth requirement — provided in § 112, ¶ 2 — pertains to the claims. The specification and the claims serve related, yet distinct functions. Patent claims are the touchstone of patent protection, and it is the claims that establish the patentee's property rights, what is often referred to as the “metes and bounds” of the patentee's protected interest. Thus, a crucial and oftentimes determinative aspect of patent litigation is ascertaining what the claim language in question means and determining the proper claim scope. The disclosure requirements, particularly enablement, play an important role in answering these questions.¹ As the Federal Circuit noted, “while the role of the claims is to give public notice of the subject matter that is protected, the role of the specification is to teach, both what the invention is and how to make and use it.”²

1. Who interprets claims and the methodologies employed in claim interpretation are explored in detail in chapter 7.

2. *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922 n.5 (Fed. Cir. 2004).

A. ENABLEMENT

The enablement requirement can be viewed as serving two functions: (1) information dissemination; and (2) constraining claim scope. Technical information disclosed in the patent has potential immediate value to follow-on researchers interested in improving the patented invention or to the public by contributing to the general storehouse of technical knowledge. In this regard, the enablement requirement acts as an information dissemination device.³

The enablement requirement also serves to keep claim scope on a leash by requiring the specification's enablement to be commensurate with the scope of the claims. To satisfy the commensurability requirement, the scope of the claims must bear a reasonable correlation to the scope of enablement, which means that the specification must enable a person having ordinary skill in the art to make and use the claimed invention without "undue experimentation." In short, a patentee cannot claim more than he discloses. What constitutes "undue experimentation" is discussed in *National Recovery Technologies* and *Liebel-Flarsheim*, the principal cases in Section A.2. Subsumed within the commensurability requirement is the very important question of optimal claim scope, that is, the legal and policy determination relating to the breadth of the patentee's property right. Providing a patentee with narrow or broad claim scope can affect patent law's delicate incentive dynamic. The *O'Reilly v. Morse* and the *Incandescent Lamp* cases explore commensurability and claim scope. We will revisit this issue in Chapter 7 in the context of the Doctrine of Equivalents.

3. This view of the specification was embraced by the House of Lords in *Kirin-Amgen, Inc. v. Hoechst Marion Roussel Ltd.*, wherein Lord Hoffmann wrote:

That disclosure is not only to enable other people to perform the invention after the patent has expired. If that were all, the inventor might as well be allowed to keep it secret during the life of the patent. It is also to enable anyone to make immediate use of the information for any purpose which does not infringe the claims. The specifications of valid and subsisting patents are an important source of information for further research, as is abundantly shown by a reading of the sources cited in the specification for the patent in suit.

[2004] UKHL 46, [2004] All ER (D) 286 (Oct. 1, 2004). On the importance of access to and dissemination of information for technological innovation, see JOEL MOKYR, *THE GIFTS OF ATHENA: HISTORICAL ORIGINS OF THE KNOWLEDGE ECONOMY* 28-77 (2002); WILLIAM J. BAUMOL, *THE FREE-MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM* 73-92 (2002). In one of the earliest disclosure cases, *Grant v. Raymond*, 31 U.S. (6 Pet.) 218 (1832), Chief Justice Marshall recognized that a full and enabling disclosure of an invention "is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue the patent."

STATUTE: Specification

35 U.S.C. § 112, ¶ 1

1. Enablement and Claim Scope**O'REILLY v. MORSE**56 U.S. 62 (1854)

Chief Justice TANEY delivered the opinion of the court.

* * *

[In a patent issued to Morse in 1840 and reissued in 1848, Morse described “a new and useful apparatus for, and a system of, transmitting intelligence between distant points by means of electro-magnetism, which puts in motion machinery for producing sounds or signs, and recording said signs upon paper or other suitable material, which invention I denominate the American Electro-Magnetic Telegraph. . . .” The patent described “the instruments and . . . mode of their operation,” including the famed “Code.” The patent continued and set forth the now famous claim eight:]

Eighth. I do not propose to limit myself to the specific machinery, or parts of machinery, described in the foregoing specifications and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances, being a new application of that power, of which I claim to be the first inventor or discovered.

* * *

We perceive no well-founded objection to the description which is given of the whole invention and its separate parts, nor to his right to a patent for the first seven inventions set forth in the specification of his claims. The difficulty arises on the eighth.

* * *

It is impossible to misunderstand the extent of this claim. He claims the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance.

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Nor is this all, while he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light. For he says he does not confine his claim to the machinery or parts of

machinery, which he specifies; but claims for himself a monopoly in its use, however developed, for the purpose of printing at a distance. New discoveries in physical science may enable him to combine it with new agents and new elements, and by that means attain the object in a manner superior to the present process and altogether different from it. And if he can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is. In fine he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of the opinion that the claim is too broad, and not warranted by law.

No one, we suppose will maintain that Fulton could have taken out a patent for his invention of propelling vessels by steam, describing the process and machinery he used, and claimed under it the exclusive right to use the motive power of steam, however developed, for the purpose of propelling vessels. It can hardly be supposed that under such a patent he could have prevented the use of the improved machinery which science has since introduced; although the motive power is steam, and the result is the propulsion of vessels. Neither could the man who first discovered that steam might, by a proper arrangement of machinery, be used as a motive power to grind corn or spin cotton, claim the right to the exclusive use of steam as a motive power for the purpose of producing such effects.

Again, the use of steam as a motive power in printing-presses is comparatively a modern discovery. Was the first inventor of a machine or process of this kind entitled to a patent, giving him the exclusive right to use steam as a motive power, however developed, for the purpose of marking or printing intelligible characters? Could he have prevented the use of any other press subsequently invented where steam was used? Yet so far as patentable rights are concerned both improvements must stand on the same principles. Both use a known motive power to print intelligible marks or letters; and it can make no difference in their legal rights under the patent laws, whether the printing is done near at hand or at a distance. Both depend for success not merely upon the motive power, but upon the machinery with which it is combined. And it has never, we believe, been supposed by any one, that the first inventor of a steam printing-press, was entitled to the exclusive use of steam, as a motive power, however developed, for marking or printing intelligible characters.

Indeed, the acts of the patentee himself are inconsistent with the claim made in his behalf. For in 1846 he took out a patent for his new improvement of local circuits, by means of which intelligence could be printed at intermediate places along the main line of the telegraph; and he obtained a reissued patent for this invention in 1848. Yet in this new invention the electric or galvanic current was the motive power, and writing at a distance the effect. The power was undoubtedly developed, by new machinery and new combinations. But if his eighth claim could be sustained, this improvement would be embraced by his first patent. And if it was so embraced, his patent for the local circuits would be illegal and void. For he could not take out a subsequent

patent for a portion of his first invention, and thereby extend his monopoly beyond the period limited by law.

* * *

. . . Professor Morse has not discovered, that the electric or galvanic current will always print at a distance, no matter what may be the form of the machinery or mechanical contrivances through which it passes. You may use electro-magnetism as a motive power, and yet not produce the described effect, that is, print at a distance intelligible marks or signs. To produce that effect, it must be combined with, and passed through, and operate upon, certain complicated and delicate machinery, adjusted and arranged upon philosophical principles, and prepared by the highest mechanical skill. And it is the high praise of Professor Morse, that he has been able, by a new combination of known powers, of which electro-magnetism is one, to discover a method by which intelligible marks or signs may be printed at a distance. And for the method or process thus discovered, he is entitled to a patent. But he has not discovered that the electro-magnetic current, used as motive power, in any other method, and with any other combination, will do as well.

* * *

It is a well-settled principle of law, that the mere change in the form of the machinery (unless a particular form is specified as the means by which the effect described is produced) or an alteration in some of its unessential parts; or in the use of known equivalent powers, not varying essentially the machine, or its mode of operation or organization, will not make the new machine a new invention. It may be an improvement upon the former; but that will not justify its use without the consent of the first patentee.

* * *

Mr. Justice GRIER.

. . . The . . . point, in which I cannot concur with the opinion of the majority, arises in the construction of the eighth claim of complainant's first patent, as finally amended.

* * *

The great art of printing, which has changed the face of human society and civilization, consisted in nothing but a new application of principles known to the world for thousands of years. No one could say it consisted in the type or the press, or in any other machine or device used in performing some particular function, more than in the hands which picked the types or worked the press. Yet if the inventor of printing had, under this narrow construction of our patent law, claimed his art as something distinct from his machinery, the doctrine now advanced, would have declared it unpatentable to its full extent as an art, and that the inventor could be protected in nothing but his first rough types and ill-contrived press.

* * *

To say that a patentee, who claims the art of writing at a distance by means of electro-magnetism, necessarily claims all future improvements in the art, is to misconstrue it, or draws a consequence from it not fairly to be inferred from its language. An improvement in a known art is as much the subject of a patent as the art itself; so, also, is an improvement on a known machine. Yet, if the

original machine be patented, the patentee of an improvement will not have a right to use the original. This doctrine has not been found to retard the progress of invention in the case of machines; and I can see no reason why a contrary one should be applied to an art.

* * *

The word telegraph is derived from the Greek, and signifies “to write afar off or at a distance.” It has heretofore been applied to various contrivances or devices, to communicate intelligence by means of signals or semaphores, which speak to the eye for a moment. But in its primary and literal signification of writing, printing, or recording at a distance, it never was invented, perfected, or put into practical operation till it was done by Morse. He preceded Steinheil, Cook, Wheatstone, and Davy in the successful application of this mysterious power or element of electro-magnetism to this purpose; and his invention has entirely superseded their inefficient contrivances. It is not only “a new and useful art,” if that term means any thing, but a most wonderful and astonishing invention, requiring tenfold more ingenuity and patient experiment to perfect it, than the art of printing with types and press, as originally invented.

* * *

Now the patent law requires an inventor, as a condition precedent to obtaining a patent, to deliver a written description of his invention or discovery, and to particularly specify what he claims to be his own invention or discovery. If he has truly stated the principle, nature and extent of his art or invention, how can the court say it is too broad, and impugn the validity of his patent for doing what the law requires as a condition for obtaining it? And if it is only in case of a machine that the law requires the inventor to specify what he claims as his own invention and discovery, and to distinguish what is new from what is old, then this eighth claim is superfluous and cannot affect the validity of his patent, provided his art is new and useful, and the machines and devices claimed separately, are of his own invention. If it be in the use of the words “however developed” that the claim is to be adjudged too broad, then it follows that a person using any other process for the purpose of developing the agent or element of electro-magnetism, than the common one now in use, and described in the patent, may pirate the whole art patented.

**CONSOLIDATED ELECTRIC LIGHT CO. v. McKEESPORT
LIGHT CO.
(The Incandescent Lamp Case)**

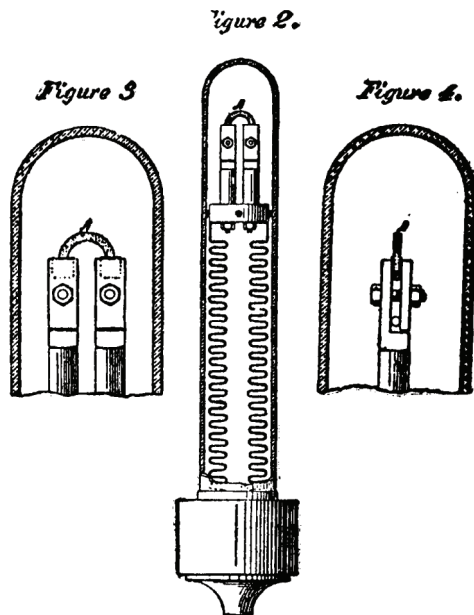
159 U.S. 465 (1895)

This was a bill in equity, filed by the Consolidated Electric Light Company against the McKeesport Light Company, to recover damages for the infringement of letters patent No. 317,076, issued May 12, 1885, to the Electro-Dynamic Light Company, assignee of Sawyer and Man, for an electric light. The defendants justified under certain patents to Thomas A. Edison, particularly No. 223,898, issued January 27, 1880; denied the novelty and utility of the complainant's patent; and averred that the same had been fraudulently and illegally procured. The real defendant was the Edison Electric Light

Company, and the case involved a contest between what are known as the Sawyer and Man and the Edison systems of electric lighting.

In their application, Sawyer and Man stated that their invention related to “that class of electric lamps employing an incandescent conductor enclosed in a transparent, hermetically sealed vessel or chamber, from which oxygen is excluded, and . . . more especially to the incandescing conductor, its substance, its form, and its combination with the other elements composing the lamp. Its object is to secure a cheap and effective apparatus; and our improvement consists, first, of the combination, in a lamp chamber, composed wholly of glass, as described in patent No. 205,144,” upon which this patent was declared to be an improvement, “of an incandescing conductor of carbon made from a vegetable fibrous material, in contradistinction to a similar conductor made from mineral or gas carbon, and also in the form of such conductor so made from such vegetable carbon, and combined in the lighting circuit with the exhausted chamber of the lamp.”

The following drawings exhibit the substance of the invention:



The specification further stated that:

In the practice of our invention, we have made use of carbonized paper, and also wood carbon. We have also used such conductors or burners of various shapes, such as pieces with their lower ends secured to their respective supports, and having their upper ends united so as to form an inverted V-shaped burner. We have also used conductors of varying contours, that is, with rectangular bends instead of curvilinear ones; but we prefer the arch shape.

No especial description of making the illuminating carbon conductors, described in this specification, and making the subject-matter of this improvement, is thought necessary, as any of the ordinary methods of forming the material to be carbonized to the desired shape and size, and carbonizing it while confined in retorts in powdered carbon, substantially according to the methods in practice

before the date of this improvement, may be adopted in the practice thereof by any one skilled in the arts appertaining to the making of carbons for electric lighting or for other use in the arts.

An important practical advantage which is secured by the arch form of incandescing carbon is that it permits the carbon to expand and contract under the varying temperatures to which it is subjected when the electric current is turned on or off without altering the position of its fixed terminals. Thus, the necessity for a special mechanical device to compensate for the expansion and contraction which has heretofore been necessary is entirely dispensed with, and thus the lamp is materially simplified in its construction. . . .

The advantages resulting from the manufacture of the carbon from vegetable fibrous or textile material instead of mineral or gas carbon are many. Among them may be mentioned the convenience afforded for cutting and making the conductor in the desired form and size, the purity and equality of the carbon obtained, its susceptibility to tempering, both as to hardness and resistance, and its toughness and durability. . . .

The claims were as follows:

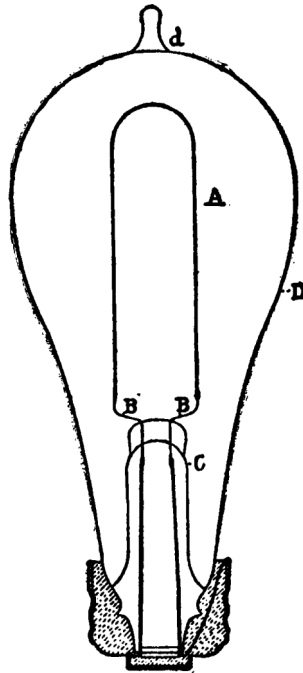
- (1) An incandescing conductor for an electric lamp, of carbonized fibrous or textile material, and of an arch or horseshoe shape, substantially as hereinbefore set forth.
- (2) The combination, substantially as hereinbefore set forth, of an electric circuit and an incandescing conductor of carbonized fibrous material, included in and forming part of said circuit, and a transparent, hermetically sealed chamber, in which the conductor is enclosed.
- (3) The incandescing conductor for an electric lamp, formed of carbonized paper, substantially as described.

The commercial Edison lamp used by the appellee, and which is illustrated below, is composed of a burner, **A**, made of carbonized bamboo of a peculiar quality, discovered by Mr. Edison to be highly useful for the purpose, and having a length of about 6 inches, a diameter of about 5/1000 of an inch, and an electrical resistance of upward of 100 ohms. This filament of carbon is bent into the form of a loop, and its ends are secured by good electrical and mechanical connections to two fine platinum wires, **B**, **B**. These wires pass through a glass stem, **C**, the glass being melted and fused upon the platinum wires. A glass globe, **D**, is fused to the glass stem, **C**. This glass globe has originally attached to it, at the point **d**, a glass tube, by means of which a connection is made with highly organized and refined exhausting apparatus, which produces in the globe a high vacuum, whereupon the glass tube is melted off by a flame, and the globe is closed by the fusion of the glass at the point **d**.

Upon a hearing in the circuit court before Mr. Justice Bradley, upon pleadings and proofs, the court held the patent to be invalid, and dismissed the bill. Thereupon complainant appealed to this court.

Mr. Justice BROWN, after stating the facts in the foregoing language, delivered the opinion of the court.

In order to obtain a complete understanding of the scope of the Sawyer and Man patent, it is desirable to consider briefly the state of the art at the time the application was originally made, which was in January, 1880.



Two general forms of electric illumination had for many years been the subject of experiments more or less successful, one of which was known as the “arc light,” produced by the passage of a current of electricity between the points of two carbon pencils placed end to end, and slightly separated from each other. In its passage from one point to the other through the air, the electric current took the form of an arc, and gave the name to the light. This form of light had been produced by Sir Humphry Davy as early as 1810, and, by successive improvements in the carbon pencils and in their relative adjustment to each other, had come into general use as a means of lighting streets, halls, and other large spaces; but by reason of its intensity, the uncertain and flickering character of the light, and the rapid consumption of the carbon pencils, it was wholly unfitted for domestic use.

The second form of illumination is what is known as the “incandescent system,” and consists generally in the passage of a current of electricity through a continuous strip or piece of refractory material, which is a conductor of electricity, but a poor conductor; in other words, a conductor offering a considerable resistance to the flow of the current through it. It was discovered early in this century that various substances might be heated to a white heat by passing a sufficiently strong current of electricity through them. . . .

For many years prior to 1880, experiments had been made by a large number of persons, in various countries, with a view to the production of an incandescent light which could be made available for domestic purposes, and could compete with gas in the matter of expense. Owing partly to a failure to find a proper material, which should burn but not consume, partly to the difficulty of obtaining a perfect vacuum in the globe in which the light was suspended, and partly to a misapprehension of the true principle of

incandescent lighting, these experiments had not been attended with success; although it had been demonstrated as early as 1845 that, whatever material was used, the conductor must be enclosed in an arc-light bulb, to prevent it from being consumed by the oxygen in the atmosphere. The chief difficulty was that the carbon burners were subject to a rapid disintegration or evaporation, which electricians assumed was due to the disrupting action of the electric current, and hence the conclusion was reached that carbon contained in itself the elements of its own destruction, and was not a suitable material for the burner of an incandescent lamp.

It is admitted that the lamp described in the Sawyer and Man patent is no longer in use, and was never a commercial success; that it does not embody the principle of high resistance with a small illuminating surface; that it does not have the filament burner of the modern incandescent lamp; that the lamp chamber is defective; and that the lamp manufactured by the complainant, and put upon the market, is substantially the Edison lamp; but it is said that, in the conductor used by Edison (a particular part of the stem of the bamboo, lying directly beneath the siliceous cuticle, the peculiar fitness for which purpose was undoubtedly discovered by him), he made use of a fibrous or textile material covered by the patent to Sawyer and Man, and is therefore an infringer. It was admitted, however, that the third claim—for a conductor of carbonized paper—was not infringed.

The two main defenses to this patent are (1) that it is defective upon its face, in attempting to monopolize the use of all fibrous and textile materials for the purpose of electric illuminations; and (2) that Sawyer and Man were not in fact the first to discover that these were better adapted than mineral carbons to such purposes.

Is the complainant entitled to a monopoly of all fibrous and textile materials for incandescent conductors? If the patentees had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad. If, for instance, minerals or porcelains had always been used for a particular purpose, and a person should take out a patent for a similar article of wood, and woods generally were adapted to that purpose, the claim might not be too broad, though defendant used wood of a different kind from that of the patentee. But if woods generally were not adapted to the purpose, and yet the patentee had discovered a wood possessing certain qualities, which gave it a peculiar fitness for such purpose, it would not constitute an infringement for another to discover and use a different kind of wood, which was found to contain similar or superior qualities. The present case is an apt illustration of this principle. Sawyer and Man supposed they had discovered in carbonized paper the best material for an incandescent conductor. Instead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, they made a broad claim for every fibrous or textile material, when in fact an examination of over 6,000 vegetable growths showed that none of them possessed the peculiar qualities that fitted them for that purpose. Was everybody, then, precluded by this broad claim from making further investigation? We think not.

The injustice of so holding is manifest in view of the experiments made, and continued for several months, by Mr. Edison and his assistants, among the different species of vegetable growth, for the purpose of ascertaining the one best adapted to an incandescent conductor. Of these he found suitable for his purpose only about three species of bamboo, one species of cane from the valley of the Amazon (impossible to be procured in quantities on account of the climate), and one or two species of fibers from the agave family. Of the special bamboo, the walls of which have a thickness of about $\frac{3}{8}$ of an inch, he used only about 20/1000 of an inch in thickness. In this portion of the bamboo the fibers are more nearly parallel, the cell walls are apparently smallest, and the pithy matter between the fibers is at its minimum. It seems that carbon filaments cannot be made of wood, that is, exogenous vegetable growth, because the fibers are not parallel, and the longitudinal fibers are intercepted by radial fibers. The cells composing the fibers are all so large that the resulting carbon is very porous and friable. Lamps made of this material proved of no commercial value. After trying as many as 30 or 40 different woods of exo-genous growth, he gave them up as hopeless. But finally, while experimenting with a bamboo strip which formed the edge of a palm-leaf fan, cut into filaments, he obtained surprising results. After microscopic examination of the material, he dispatched a man to Japan to make arrangements for securing the bamboo in quantities. It seems that the characteristic of the bamboo which makes it particularly suitable is that the fibers run more nearly parallel than in other species of wood. Owing to this, it can be cut up into filaments having parallel fibers, running throughout their length, and producing a homogeneous carbon. There is no generic quality, however, in vegetable fibers, because they are fibrous, which adapts them to the purpose. Indeed, the fibers are rather a disadvantage. If the bamboo grew solid, without fibers, but had its peculiar cellular formation, it would be a perfect material, and incandescent lamps would last at least six times as long as at present. All vegetable fibrous growths do not have a suitable cellular structure. In some the cells are so large that they are valueless for that purpose. No exogenous, and very few endogenous, growths are suitable. The messenger whom he dispatched to different parts of Japan and China sent him about 40 different kinds of bamboo, in such quantities as to enable him to make a number of lamps, and from a test of these different species he ascertained which was best for the purpose. From this it appears very clearly that there is no such quality common to fibrous and textile substances generally as makes them suitable for an incandescent conductor, and that the bamboo which was finally pitched upon, and is now generally used, was not selected because it was of vegetable growth, but because it contained certain peculiarities in its fibrous structure which distinguished it from every other fibrous substance. The question really is whether the imperfectly successful experiments of Sawyer and Man, with carbonized paper and wood carbon, conceding all that is claimed for them, authorize them to put under tribute the results of the brilliant discoveries made by others.

It is required by Rev. St. § 4888, that the application shall contain “a written description of the device, and of the manner and process of making constructing, compounding, and using it in such full, clear, concise, and exact terms as to enable any person, skilled in the art or science to which it appertains or with which it is most nearly connected, to make, construct,

compound, and use the same.” The object of this is to apprise the public of what the patentee claims as his own, the courts of what they are called upon to construe, and competing manufacturers and dealers of exactly what they are bound to avoid. *Grant v. Raymond*, [1832]. If the description be so vague and uncertain that no one can tell, except by independent experiments, how to construct the patented device, the patent is void.

It was said by Mr. Chief Justice Taney in *Wood v. Underhill*, [1857], with respect to a patented compound for the purpose of making brick or tile, which did not give the relative proportions of the different ingredients:

But when the specification of a new composition of matter gives only the names of the substances which are to be mixed together, without stating any relative proportion, undoubtedly it would be the duty of the court to declare the patent void. And the same rule would prevail where it was apparent that the proportions were stated ambiguously and vaguely; for in such cases it would be evident, on the face of the specification, that no one could use the invention without first ascertaining, by experiment, the exact proportion of the different ingredients required to produce the result intended to be obtained. . . . And if, from the nature and character of the ingredients to be used, they are not susceptible . . . of such exact description, the inventor is not entitled to a patent.

So in *Tyler v. Boston*, [1868], wherein the plaintiff professed to have discovered a combination of fuel oil with the mineral and earthy oils, constituting a burning fluid, the patentee stated that the exact quantity of fuel oil which is necessary to produce the most desirable compound must be determined by experiment. And the court observed: “Where a patent is claimed for such a discovery, it should state the component parts of the new manufacture claimed with clearness and precision, and not leave a person attempting to use the discovery to find it out ‘by experiment.’”

Applying this principle to the patent under consideration, how would it be possible for a person to know what fibrous or textile material was adapted to the purpose of an incandescent conductor, except by the most careful and painstaking experimentation? If, as before observed, there were some general quality, running through the whole fibrous and textile kingdom, which distinguished it from every other, and gave it a peculiar fitness for the particular purpose, the man who discovered such quality might justly be entitled to a patent; but that is not the case here. An examination of materials of this class carried on for months revealed nothing that seemed to be adapted to the purpose; and even the carbonized paper and wood carbons specified in the patent, experiments with which first suggested their incorporation therein, were found to be so inferior to the bamboo, afterwards discovered by Edison, that the complainant was forced to abandon its patent in that particular, and take up with the material discovered by its rival. Under these circumstances, to hold that one who had discovered that a certain fibrous or textile material answered the required purpose should obtain the right to exclude everybody from the whole domain of fibrous and textile materials, and thereby shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be an unwarranted extension of his monopoly, and operate rather to discourage than to promote invention. If Sawyer and Man had discovered that a certain carbonized paper would answer the purpose, their claim to all carbonized paper would, perhaps, not be extravagant; but

the fact that paper happens to belong to the fibrous kingdom did not invest them with sovereignty over this entire kingdom, and thereby practically limit other experimenters to the domain of minerals.

In fact, such a construction of this patent as would exclude competitors from making use of any fibrous or textile material would probably defeat itself, since, if the patent were infringed by the use of any such material, it would be anticipated by proof of the prior use of any such material. In this connection it would appear, not only that wood charcoal had been constantly used since the days of Sir Humphry Davy for arc lighting, but that in the English patent to Greener and Staite, of 1846, for an incandescent light, “charcoal, reduced to a state of powder,” was one of the materials employed. So also, in the English patent of 1841 to De Moleyns, “a finely pulverized boxwood charcoal or plumbago” was used for an incandescent electric lamp. Indeed, in the experiments of Sir Humphry Davy, early in the century, pieces of well-burned charcoal were heated to a vivid whiteness by the electric current, and other experiments were made which evidently contemplated the use of charcoal heated to the point of incandescence. Mr. Broadnax, the attorney who prepared the application, it seems, was also of opinion that a broad claim for vegetable carbons could not be sustained, because charcoal had been used before in incandescent lighting. There is undoubtedly a good deal of testimony tending to show that, for the past 50 or 60 years, the word “charcoal” has been used in the art, not only to designate carbonized wood, but mineral or hard carbons, such as were commonly employed for the carbon pencils of arc lamps. But we think it quite evident that, in the patents and experiments above referred to, it was used in its ordinary sense of charcoal obtained from wood. The very fact of the use of such word to designate mineral carbons indicates that such carbons were believed to possess peculiar properties required for illumination, that before that had been supposed to belong to wood charcoal.

. . . [W]e are all agreed that the claims of this patent, with the exception of the third, are too indefinite to be the subject of a valid monopoly.

Comments

1. **Enablement, Claim Scope, and Commensurability.** Justices Taney and Grier provide competing perspectives on optimal claim scope. The majority in *Morse* held claim eight invalid because the breadth of the claim was not commensurate with the specification. The commensurability requirement states that a patentee cannot claim more than he discloses; in other words, the claim scope must be commensurate with what is disclosed in the specification. (The *National Recovery* and *Liebel-Flarsheim* cases following these Comments discuss the test for commensurability.) The *Morse* case is perhaps the first time the Supreme Court invoked commensurability, because in a subsequent case, Justice Grier remarked: “Until the [*Morse*] decision was read in court, the patentee [*Morse*] had not the least reason to suspect his claim to be invalid. The decision was a surprise not only to him, but many others more learned in the law, who had carefully examined this claim, and advised the patentee that it was valid.” *Silsby v. Foote*, 61 U.S. 378, 389 (1857) (Grier, J., dissenting).

Recall, the specification did not disclose all uses and improvements of the motive power of the electric or galvanic current. Morse claimed more than he actually invented. The Court employed the enablement requirement to constrain claim scope, limiting Morse to his first seven claims. Justice Taney was very concerned that Morse's claim 8 would capture future improvements or alternatives that Morse did not invent or describe in his patent. But determining the proper scope of Morse's patent (or any patent) is very difficult. (See the *Policy Perspective* after these Comments.) A court must ascertain how much improvement activity patentees such as Morse should be able to capture vis-à-vis improver-competitors. Morse, by all accounts, made a significant inventive contribution, what Justice Grier referred to as "a most wonderful and astonishing invention, requiring tenfold more ingenuity and patient experiment to perfect it, than the art of printing with types and press, as originally invented." By focusing on the significance of Morse's invention, Justice Grier seemed to be making a moral argument based on Morse's just desserts. But he also advanced a policy-based argument by focusing on an improver's ability to obtain patent rights. Grier wrote, "[a]n improvement in a known art is as much the subject of a patent as the art itself," meaning that an improver, whose patent may infringe Morse's claim 8, is not without bargaining power; and, further, granting Morse his claim 8 would be consistent with patent law's goal of promoting technological innovation. As Grier noted, this blocking patent "doctrine has not been found to retard the progress of invention."

In the *Incandescent Lamp* case, the Sawyer and Man specification disclosed that their discovery related to carbonized paper as a good incandescing conductor, but in claim 1 they sought protection for "carbonized fibrous or textile material," language much broader than what was disclosed in the specification. In short, Sawyer and Man claimed a genus, but discovered a species. While they were entitled to protection of the species (as in claim 3), the enablement requirement prevented them from extending their patent protection to all "fibrous or textile material." As Justice Brown wrote, "the fact that paper belongs to the fibrous kingdom did not invest [Sawyer and Man] with sovereignty over this entire kingdom," particularly Edison's bamboo. Echoing Justice Taney's concern in *Morse*, Justice Brown continued:

[T]o hold that one who had discovered that a certain fibrous or textile material answered the required purpose should obtain the right to exclude everybody from the whole domain of fibrous and textile materials, and thereby shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be an unwarranted extension of his monopoly, and operate rather to discourage than to promote invention.

In *In re Fisher*, 427 F.2d 833 (CCPA 1970), the Court of Customs and Patent Appeals captured the role of the enablement requirement and the need for a court to balance competing policy considerations when determining claim scope. The court noted that "an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings." *Id.* at 839. While improvements may be "unobvious" from the patentee's teachings, the improvement is "still within his contribution." But the court also stated that

it is “equally apparent” that a patentee “not be permitted to achieve this dominance by claims which are insufficiently supported” by the specification. The court stressed that the “scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons having ordinary skill in the art.” *Id.*

The Board of Appeal for the European Patent Office has also articulated a commensurability requirement. According to the Board in *Exxon Chemical Patents, Inc.*, the European Patent Convention:

requires that the claims must be supported by the description, in other words it is the definition of the invention in the claims that needs support. In the Board’s judgment, this requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified. This means that the definitions in the claims should essentially correspond to the scope of the invention as disclosed in the description. In other words, the claims should not extend to subject-matter which, after reading the description, would still not be at the disposal of the person skilled in the art.

T 0409/91, 3.3.

2. **The Genus-Species Issue.** As noted in Comment 1, Sawyer and Man claimed generically, but only disclosed one species of the claimed genus. The Court held Sawyer and Man were not entitled to broad protection, as recited in claim 1, because their disclosure was insufficient. But patent law does permit applicants to claim generically without disclosing each and every species as long as the disclosure is sufficient. Where the line is between sufficient and insufficient is sometimes difficult to discern. In *In re Grimme*, 274 F.2d 949, 952 (C.C.P.A. 1960), the applicant claimed generically and the court found the disclosure sufficient because the applicant provided several examples. According to the court, “[i]t is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species. It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it.” Just how many examples or species must be disclosed in a generic-claim context to satisfy the enablement requirement was addressed in *In re Shokal*, 242 F.2d 771, 773 (1957):

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

See also *In re Angstadt*, 537 F.2d 498, 502-03 (deciding that applicants “are not required to disclose every species encompassed by their claims even in an unpredictable art” and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process).

In a biological context, *see Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005) (“Precedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter. . . . It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention.”). Technological unpredictability is indeed an important consideration. *See Bilstad v. Wakalopoulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004) (“If the difference between members of the group is such that the person skilled in the art would not readily discern that other members of the genus would perform similarly to the disclosed members, *i.e.*, if the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus.”).

As a prelude to the novelty section in Chapter 4, it is worth noting here that if the prior art discloses a species, an applicant cannot claim a genus because, by definition, part of the genus is not novel. *See In re Gostelli*, 872 F.2d 1008 (Fed. Cir. 1999). But the reverse is not always true. That is, an applicant may claim a species if the prior art discloses a genus. Courts have held that a prior art genus does not always anticipate a later claimed species, but *may* render the later claimed species obvious under § 103. *See In re Baird*, 16 F.3d 380 (Fed. Cir. 1994) and *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992).

3. ***Samuel Morse’s Patent Troubles.*** Samuel Finley Breese Morse was no stranger to patent litigation, and was not shy in expressing his displeasure about the process. According to Morse, patent litigation “is not the way to encourage the Arts, to drive the Artists into exile or to the insane hospital or to the grave.” KENNETH SILVERMAN, *LIGHTNING MAN: THE ACCURSED LIFE OF SAMUEL F.B. MORSE* 319 (2003). In this vein, historian Joel Mokyr, referring to famed inventors such as Charles Goodyear (rubber vulcanization process) and Eli Whitney (cotton gin), writes that “[l]itigation over patent infringement could sap the creativity of great technical minds, and ruin inventors financially.” JOEL MOKYR, *LEVER OF RICHES* 248-49 (1990). Of course, Morse was not the first to employ the powers of electromagnetism, but compared to his competitors, Morse’s telegraph was “the cheapest, the most rugged, the most reliable, and the simplest to operate.” SILVERMAN, *LIGHTNING MAN*, *supra* at 322.

POLICY PERSPECTIVE

Optimal Claim Scope and Patent Law’s Delicate Balance

Determining the proper scope of Morse’s patent (or any patent) is very difficult. A court must ascertain how much improvement activity patentees such as Morse should be able to capture vis-à-vis improver-competitors. Because of Morse’s inventive contribution, Justice Grier was willing to provide Morse with broader claim scope whereas Chief Justice Taney thought such scope would be ill-advised given the nature of Morse’s disclosure. Grier also noted that improvers could obtain patent

rights, thus providing them with bargaining power. Although under patent doctrine, the improver may have to obtain permission from Morse to practice the improved technology, Grier noted “[t]his doctrine has not been found to retard the progress of invention.” This is largely because the original patentee and the improver will likely cross-license each other.

Thus, a balance must be maintained keeping in mind patent law’s incentives to invent and commercialize, coordination of improvement activity, and transaction costs (*i.e.*, the costs associated with identifying owners of patents, negotiating licensing terms, etc.). On the one hand, a narrower claim scope may allow for more vigorous improvement activity and is particularly useful when transaction costs are high (*e.g.*, licensing terms) between the original and improver patentee relating to the improved technology. See Robert P. Merges & Richard Nelson, *On the Complex Economics of Claim Scope*, 90 COLUM. L. REV. 839 (1990). But a narrow claim scope dilutes the initial incentive to invent, or to follow through in the commercialization process. In particular, improvers (follow-on innovators) will be the beneficiary of a narrow claim scope that is accompanied by an enabling disclosure, one that facilitates follow-on research and lowers costs. On the other hand, a broader claim scope is conducive to efficient coordination efforts that focus on improvement activity and may incentivize the original patent owner himself to invest in sequential R&D. This perspective is known as the “Prospect Theory,” which, as its name suggests, focuses more on encouraging post-patenting (*ex post*) investment in useful prospects and not on rewarding inventive activity before patenting. See Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977). But broad patent rights may also limit competition and the pace of technologic advancement due to high transaction costs. See Mark A. Lemley, *Ex Ante versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 139 (2004) (referring to the prospect theory as “fundamentally anti-market: it trusts the government’s choice of whom to grant control over an area of research and development rather than trusting the market to pick the best researcher”).

The issue of optimal claim scope and the need to balance the interest of inventors and improvers was nicely captured by economist Suzanne Scotchmer, who wrote, “the challenge is to reward early innovators fully for the technological foundation they provide to later innovators, but to reward later innovators adequately for their improvements and new products as well.” Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29, 30 (Winter 1991). See also Clarisa Long, *The Dissonance of Scientific and Legal Norms*, SOC. EPISTEMOLOGY, 1999, Vol. 13, at 167 (characterizing patent law’s incentive dynamic as “trying to allocate fair compensation to the creators of valuable information assets . . . , while assuring that other stakeholders have sufficient access to the same building blocks to provide the broader social benefits that the incentives also have been designed to provide”).

COMPARATIVE PERSPECTIVE
Enablement and Claim Scope in Europe

The most significant international IP treaty—commonly referred to as TRIPS—requires member states to adopt an enablement requirement. Article 29 of TRIPS states:

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

Consistent with TRIPS, the European Patent Convention's disclosure requirements are set forth in Articles 83 and 84, counterparts respectively to 35 U.S.C. § 112, ¶¶ 1 and 2. Article 83 states:

The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

And Article 84 reads:

The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

Article 84's requirement that the claims find support in the description reflects the EPC's commensurability requirement, namely, patent scope should correspond to the technical contribution to the art. In the mid-1990s, the House of Lords addressed the issue of claim scope and enablement in *Biogen Inc. v. Medeva* [1997] RPC 1996. Lord Hoffmann, arguably the U.K.'s most prominent jurist on matters of intellectual property, wrote that "the concept of an enabling disclosure is central to the law of patents." Citing the *Morse* case, he continued:

If the patentee has hit upon a new product which has a beneficial effect but cannot demonstrate that there is a common principle by which that effect will be shared by other products of the same class, he will be entitled to a patent for that product but not for the class, even though some may subsequently turn out to have the same beneficial effect. On the other hand, if he has disclosed a beneficial property which is common to the class, he will be entitled to a patent for all products of that class (assuming them to be new) even though he has not himself made more than one or two of them. . . .

The patent may claim results which it does not enable, such as making a wide class of products when it enables only one of those products and discloses no principle which would enable others to be made. Or it may claim every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention.

I suppose it could be said that Samuel Morse had shown that electric telegraphy could be done. The Wright Brothers showed that heavier-than-air flight was possible, but that did not entitle them to a monopoly of heavier-than-air flying machines. It is inevitable in a young science, like electricity in the early nineteenth century or flying at the turn of the last century or recombinant DNA technology in the 1970s, that dramatically new things will be done for the first time. The technical contribution made in such cases

deserves to be recognised. But care is needed not to stifle further research and healthy competition by allowing the first person who has found a way of achieving an obviously desirable goal to monopolise every other way of doing so. (See Merges & Nelson, *On the Complex Economics of Patent Scope* (1990) 90 COLUM. L. REV. 839.)

2. Enablement and “Undue Experimentation”

Section 112 does not elaborate on how the enablement requirement is satisfied, nor does it set forth a test for compliance. But through the common law process, the courts have developed an “undue experimentation” test, which states a disclosure is sufficient if it enables a person of ordinary skill in the art to make and use the claimed invention without “undue experimentation.” Notably, this common law test uses the adjective “undue,” thereby implying that some experimentation is allowed. Whether undue experimentation was required to make and use the claimed invention was at issue in *National Recovery* and *Liebel-Flarsheim*.

NATIONAL RECOVERY TECHNOLOGIES, INC. v. MAGNETIC SEPARATION SYSTEMS, INC.

166 F.3d 1190 (Fed. Cir. 1999)

GAJARSA, Circuit Judge.

National Recovery Technologies, Inc. (“NRT”) appeals from the judgment of the United States District Court for the Middle District of Tennessee granting summary judgment to Magnetic Separation Systems, Inc. and Garry R. Kenny (collectively “MSS”). The district court held that claim 1 of U.S. Patent No. 5,260,576 (“the ’576 patent”) was invalid for lack of enablement under 35 U.S.C. § 112, paragraph 1 (1994). We affirm the decision of the district court.

BACKGROUND

NRT is engaged in the manufacture and sale of large-scale automated recycling equipment and systems. NRT is also the assignee of the ’576 patent, issued on November 9, 1993, entitled “Method and Apparatus for the Separation of Materials Using Penetrating Electromagnetic Radiation.” The ’576 patent addresses the problem of separating recyclable plastic materials that are virtually indistinguishable to the human eye by using penetrating electromagnetic radiation.

In recycling plastics, it is often useful to separate plastics with similar chemical compositions. A common sorting problem in the recycling industry is the separation of polyvinyl chloride (“PVC”) containers from polyester (“PET”) containers. PVC and PET containers are similar in appearance and are difficult to separate manually.¹ However, PVC and PET containers have

1. Manufacturers of plastic containers in the United States have begun imprinting the base of most plastic containers with identification codes indicating the chemical composition of the container thereby enabling the containers to be sorted manually. However, the ’576 patent states that this process has not found widespread use because it is slow, labor-intensive, and expensive.

different chemical properties (hence the desire to separate them) and thus absorb different amounts of electromagnetic radiation (*e.g.*, x-ray) when irradiated. It is generally well known that PVC containers absorb more electromagnetic radiation than PET containers for an equivalent material thickness. The difference in the ability to absorb for each of the materials can be used to differentiate between the two types of plastic. It is assumed that a high transmittance reading (low absorption) indicates a PET container, and a low transmittance (high absorption) reading indicates a PVC container.

According to the '576 patent, the prior art systems suffered from two drawbacks. First, the prior art systems were only able to scan and classify one container at a time, greatly slowing the processing of containers. Second, the prior art systems were not able to differentiate between radiation that passed through thicker portions of the containers, such as the neck and base, and radiation that passed through the central portions of the containers.

In the separation process disclosed in the preferred embodiment of the '576 patent, containers to be sorted are advanced along a conveyor wide enough to accommodate several containers. Each container is irradiated with a sheet-like beam of electromagnetic radiation as it progresses along the conveyor. A number of detectors spanning the width of the conveyor are positioned below the containers to measure the intensity level of electromagnetic radiation that passes through each of the containers. The patented process then uses a microprocessor to compare the detected values to preset thresholds to classify the container as being made of one type of plastic or another. The containers are then mechanically separated on this basis. If the container is classified as one type of material (*e.g.*, PVC plastic), the container is permitted to fall off the end of the primary conveyor onto a second conveyor. If the container is classified as a second type of material (*e.g.*, PET plastic), air valves located at the end of the primary conveyor are activated, thereby directing the container onto a third conveyor. The '576 patent states that this process is able to classify and separate up to eighty containers per second.

However, the '576 patent recognizes that containers cannot be accurately separated simply upon the assumption that detecting a low transmittance indicates a PVC container and detecting a high transmittance indicates a PET container. Where the PET container is significantly thicker than the PVC container, or where the electromagnetic radiation passes through many layers of PET plastic before detection, the detected transmittance level can be similar to, or even lower than that of a PVC container. This can potentially cause a PET container to be misclassified as a PVC container.

There are often irregularities in container thickness due to both the shape of the container² and the fact that many containers are folded, crushed, or otherwise mangled by the time the containers enter the separation stage of the recycling process. These irregularities may result in a substantial variance in the thickness of the material through which the electromagnetic radiation

2. Generally, the neck, cap and bottom of a plastic container are made of significantly thicker plastic than the sidewalls. The detected intensity of the transmitted electromagnetic radiation will therefore vary depending on which section of the container is irradiated. Further, containers may also be folded, thereby increasing the thickness of the plastic material through which the electromagnetic radiation must travel prior to detection.

passes. The variance in thickness may in turn cause the detected radiation transmittance to vary significantly depending on the section of the container irradiated and measured. As a result, the irregularities and variances in container thickness could cause a PET container to be erroneously classified as a PVC container where the detected transmittance level is reduced because the electromagnetic radiation passed through an abnormally thick portion of the container before detection.

The '576 patent specifically addresses the problem of misclassification due to irregularities in container thickness. The written description of the '576 patent discloses that containers are to be irradiated at several points along their length. Thus, several intensity measurements are recorded for each container. A microprocessor connected to the detectors compares the transmittance measurements for different portions of a particular container to one another, and a subset of the highest readings are selected for processing. The measurements selected are presumed to be measurements of electromagnetic radiation energy that did not pass through an irregularity. The selected measurements are compared to preset threshold values in order to classify the containers as being made of either PET or PVC plastic. The containers are mechanically separated on this basis as described above.

However, given the unpredictability of container orientation and possible damage to a container's "regular" portions, results of this process are not completely accurate in distinguishing between containers of differing materials. If a container is folded several times, or is severely deformed by the time it reaches the scanning process, even those measurements with the highest transmittance intensity may have been taken through irregular portions, thereby leading to a potentially erroneous classification. The ideal solution, therefore, is to ensure that only the regular portions of the container are measured and to use only these measurements in classifying the container.

On February 9, 1996, NRT filed a complaint against MSS in the United States District Court for the Middle District of Tennessee alleging that MSS infringed several of NRT's patents related to the automatic classification and separation of recyclable plastic materials. MSS defended by arguing that the patents at issue were invalid under 35 U.S.C. § 112. . . . [T]he district court issued a Memorandum and Order granting MSS's motion for summary judgment that concluded that claim 1 of the '576 patent was invalid for lack of enablement under 35 U.S.C. § 112, paragraph 1.

DISCUSSION

* * *

3. Enablement under 35 U.S.C. § 112, Paragraph 1

The enablement requirement of § 112 demands that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*). The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed

in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.

In the present case, the district court held that the written description of the '576 patent did not meet the strictures of § 112, paragraph 1. In particular, it held that one of ordinary skill in the art could not "select[] for processing those of said process signals which do not pass through irregularities in the bodies of said material items" without undue experimentation because the written description did not explain how to distinguish between signals that passed through irregular portions of the container and those that did not. The district court had sufficient evidence, including the testimony of one of the inventors, from which it found that NRT failed to determine where irregularities existed in the container. The district court concluded that the specification merely instructed one of ordinary skill in the art to select those signals with the highest transmission measurements, not to select those signals that did not pass through irregularities as required by claim 1.

NRT argues that the district court erred because it required the disclosed embodiment to work perfectly under all circumstances. According to NRT, the district court misinterpreted our decision in *In re Wright*, to require enablement under all possible conditions. NRT is indeed correct that a claim is not invalid for lack of *operability* simply because the invention does not work perfectly under all conditions. See *Hildreth v. Mastoras*, 257 U.S. 27, 34 (1921) ("The machine patented may be imperfect in its operation; but if it embodies the general principle and works . . . it is enough."). However, NRT is incorrect in its characterization of the district court's ruling on enablement as requiring perfect operation from the patented process.

Whether a patented device or process is operable is a different inquiry than whether a particular claim is enabled by the specification. In order to satisfy the enablement requirement of § 112, paragraph 1, the specification must enable one of ordinary skill in the art to practice the *claimed* invention without undue experimentation. Thus, with respect to enablement the relevant inquiry lies in the relationship between the specification, the claims, and the knowledge of one of ordinary skill in the art. If, by following the steps set forth in the specification, one of ordinary skill in the art is not able to replicate the claimed invention without undue experimentation, the claim has not been enabled as required by § 112, paragraph 1.

The case before us presents a classic example of a claim that is broader than the enablement as taught in the specification. The specification of the '576 patent first acknowledges the problem: sometimes radiation intensity readings are misleading because the radiation has passed through abnormally thick portions of the scanned container. The ideal solution to this problem is clear: discard intensity measurements taken through irregularities and use only those measurements taken through the regular portions of the container. Claim 1 claims this ideal solution in the step of "selecting for processing those of said process signals which do not pass through irregularities in the bodies of said material items." However, the specification of the '576 patent does not describe how to perform this ideal selection step. Rather, the specification instructs one of ordinary skill in the art to "use only those measurements of highest transmission rate through the item. . . ." The last sentence of the written description states that:

the most reliable measurements for making a classification are those measurements taken through those portions of the body of an item to be classified which exhibit the greatest rates of transmission of radiation through the item (such as those taken through a relatively thin cross section such as through an unfolded central portion of the container).

'576 Patent, col. 6, ll. 52-58. The specification is clear that in order to obtain the most reliable measurements, a good proxy for intensity measurements that do not pass through irregularities are those measurements with the highest transmission rates. However, enabling a proxy for the claimed invention is not the same as enabling the claimed invention itself.

While the written description does enable one of ordinary skill in the art to approximate the claimed function, this is not the same as enabling one of ordinary skill in the art to perform the actual selection step of claim 1 for which NRT claims patent protection. The written description does not at all purport to enable one of ordinary skill in the art to determine where irregularities exist in the containers. In fact, the '576 patent specification points out that equipment limitations make an actual determination of the location of regular and irregular portions infeasible. It states:

We have found that, in practice, taking a measurement through only a relatively thin cross section of an item requires detailed knowledge of the geometry and orientation of the item (such as a container). Accordingly, placement of an item between a radiation source and a radiation detector such that radiation passing only through a relatively thin cross section is measured requires sophisticated and expensive materials handling means.

'576 Patent, col. 3, ll. 16-24. NRT argues that “[w]hile as a theoretical possibility it might be feasible to construct a system that ignores every single perturbation and flaw in virtually all of the items processed, the '576 patent discloses and claims a workable, practical system, not a theoretical possibility.” However, as we have explained above, claim 1 broadly claims exactly this theoretical possibility that NRT admits is not disclosed in the specification of the '576 patent.

The record before us does not support NRT's contention that one of ordinary skill in the art would be able to construct a machine that is capable of selecting signals based on whether the signals pass through container irregularities without undue experimentation. While the necessity of some experimentation does not preclude enablement, the experimentation must not be unduly extensive. Whether making and using the claimed invention would have required undue experimentation is a legal conclusion based upon underlying facts.

The record shows that as of October 29, 1990, the date the '576 patent was filed, there was no known way for one of ordinary skill in the art of materials processing to distinguish x-ray readings which passed through bottle irregularities from those x-ray readings which did not pass through irregularities. The record moreover indicates that as of the time the '576 patent was filed, even one of the listed inventors of the patent, Dr. Sommers, believed that additional research, development, and experimentation needed to be conducted before a device could be built that would practice the invention as claimed—a device that would selectively identify signals based on whether they passed through sample irregularities. During his deposition testimony,

Dr. Sommers was asked if the '576 patent described any method, technique or algorithm that would tell someone how to determine where irregularities existed in the items to be sorted. Dr. Sommers replied that he believed "what the patent discloses is the need, as a method, to determine that irregularity in the bottle" and at the time the '576 patent was filed, NRT "did not know particularly how to do that . . . [and was] still developing that process." Dr. Sommers further noted that although analyzing the signal transmission measurements would give an indication of where irregularities might exist in the samples being sorted, if "the complete bottle is an irregularity . . . you're not going to get good readings. . . ."

The '576 patent therefore recognizes a specific need in the materials sorting field and suggests a theoretical answer to that need. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement. The specification of the '576 patent therefore does not enable one of ordinary skill in the art to practice the full scope of the invention embodied in claim 1 without undue experimentation. The most that NRT can be credited with is promising the ideal result in claim 1, even though the specification does not completely deliver on this promise.

CONCLUSION

Because the specification of the '576 patent does not enable one of ordinary skill in the art to practice the invention embodied in claim 1 without undue experimentation, we affirm the district court's grant of MSS's motion for summary judgment that claim 1 is not enabled and thus invalid under 35 U.S.C. § 112, paragraph 1.

LIEBEL-FLARSHEIM COMPANY v. MEDRAD, INC.

481 F.3d 1371 (Fed. Cir. 2007)

LOURIE, Circuit Judge.

Liebel-Flarsheim Company and Mallinckrodt Inc. (collectively "Liebel") appeal from the decision of the United States District Court for the Southern District of Ohio granting Medrad's motion for summary judgment that four of Liebel's patents are invalid under 35 U.S.C. § 112. Because we conclude that Liebel's patents are invalid, the front-loading patents for lack of enablement, we affirm the district court's judgment of invalidity.

BACKGROUND

This appeal concerns asserted claims of four of Liebel's patents: claims 10, 11, 13, and 16-19 of U.S. Patent 5,456,669; claims 1, 8, 9, 11-13, 15, 16, 18, 22, 27, 28, 30-33, and 34-37 of U.S. Patent 5,658,261. The '669 and '261 patents (hereinafter the "front-loading patents") share a common specification and are directed to a front-loading fluid injector with a replaceable syringe capable of withstanding high pressures for delivering a contrast agent to a patient.

With regard to the asserted claims of the front-loading patents, this appeal challenges the district court's holding of invalidity following our prior claim construction regarding a pressure jacket.

The claims in the originally-filed application explicitly recited a pressure jacket in front of the syringe receiving opening. During the prosecution of the front-loading patents, Liebel removed all references in the claims to a pressure jacket. Medrad asserted, and the district court agreed, that during the prosecution of the front-loading patents, the applicants became aware of Medrad's jacketless injector system and then deleted all references to a pressure jacket in the asserted claims in order to encompass Medrad's injector within the scope of the claims. The examiner allowed the claims, and the claims as issued do not contain an explicit recitation of a pressure jacket.

Even though the claims do not expressly recite a pressure jacket, the district court initially construed the asserted claims of the front-loading patents as requiring a pressure jacket. In the first appeal to this court, we reversed the district court's claim construction and determined that the asserted claims of the front-loading patents do not require a pressure jacket. . . . On remand and in light of our claim construction, the district court concluded that Medrad's devices did infringe the asserted claims of the front-loading patents, but that those claims were invalid for lack of compliance with the enablement requirement[] of the statute. . . .

The district court also concluded that the asserted claims were invalid for lack of enablement after considering the specification and the factors set forth in *In re Wands*. The court observed that a pressure jacket was necessary to "maintain the integrity of the syringe housing against pressures the syringe encounters during operation of the injector." The court further noted that the inventors themselves testified as to the importance of the pressure jacket around the syringe and that the experiments with and testing of jacketless systems were unsuccessful. The court also relied on testimony of Liebel's engineers that a jacketless system was not a mere design option and that one skilled in the art would not know how to make a jacketless system. The court further found that no prototypes of a jacketless injector had been made or described at the time of filing, and that the state of the art was such that a jacketless system with a disposable syringe would have been a "true innovation." Thus, the court concluded that Medrad had proffered clear and convincing evidence that the specification does not satisfy the written description and enablement requirements.

* * *

DISCUSSION

* * *

A. The Front-Loading '669 and '261 Patents

On appeal, Liebel argues that the court erred in determining that the asserted claims of the front-loading patents are invalid for lack of enablement. With regard to enablement, Liebel contends that the court erroneously considered whether an injector without a pressure jacket was enabled, rather than limiting its inquiry to whether an injector with a pressure jacket was enabled, as it clearly was. Liebel points out that the asserted claims do not recite or require the absence of a pressure jacket and the court improperly focused on such an embodiment. Because it is undisputed that Liebel provided an enabling disclosure of what it calls its preferred embodiment, *viz.*, an injector

with a pressure jacket, Liebel asserts that the court should have held that the disclosure was enabling for the full scope of the claims. Liebel further asserts that the court erred in concluding, after considering the *Wands* factors, that undue experimentation would be required to practice the claimed invention without a pressure jacket. According to Liebel, the testimony that the court relied upon only showed that additional work, not undue experimentation, was required to develop an injector without a pressure jacket. Liebel also ascribes error to the court's consideration of various other pieces of testimony as support for its determination that producing the invention without a pressure jacket would require undue experimentation.

Medrad responds that the district court correctly determined that, under our claim construction, the asserted claims are invalid for lack of enablement. Medrad argues that the court was correct in determining that the full scope of the invention, including the injector without a pressure jacket, is not enabled. According to Medrad, although every embodiment of a claim does not need to be disclosed in the specification, the disclosure must teach the full range of embodiments in order for the claims to be enabled, and here the disclosure does not teach an injector without a pressure jacket. According to Medrad, consideration of the *Wands* factors also supports a determination that the asserted claims are not enabled. Medrad observes that Liebel's own inventors admitted that they could not produce a successful pressure-jacketless system and that that was compelling evidence of lack of enablement. Medrad also cites other testimony that supports a finding of undue experimentation.

We agree with Medrad that the district court correctly determined that the asserted claims of the front-loading patents are invalid for lack of enablement. The enablement requirement is set forth in 35 U.S.C. § 112, ¶ 1 and provides in pertinent part that the specification shall describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]." We have stated that the "enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *AK Steel*, 344 F.3d at 1244.

We have previously construed the claims of the front-loading patents such that they are not limited to an injector with a pressure jacket, and therefore the full scope of the claimed inventions includes injectors with and without a pressure jacket. That full scope must be enabled, and the district court was correct that it was not enabled.

Turning first to consideration of the specification, we find that nowhere does the specification describe an injector with a disposable syringe without a pressure jacket. In fact, the specification teaches away from such an invention. In the "Background of the Invention," the specification describes general injectors and explains that during the injection phase, a plunger is driven forward and pressure develops in the syringe, ranging from 25 psi to over 1000 psi. Without a pressure jacket, syringes that are able to withstand such high pressures are "expensive and therefore impractical where the syringes are to be disposable. Accordingly, many such injectors . . . have been provided with pressure jackets fixed to the injector units and into which the syringes are inserted ." '669 patent, col. 1 ll. 123-31. The specification thus teaches away from a disposable syringe without a pressure jacket by stating that such

syringes are “impractical.” As we have held previously, where the specification teaches against a purported aspect of an invention, such a teaching “is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention.” *AK Steel*, 344 F.3d at 1244. Moreover, consideration of the remainder of the specification reveals that there is no guidance or suggestion of how to make or use a disposable syringe for high pressure use without a pressure jacket. All the figures in the patents depict a pressure jacket and all discussion of them refers to the pressure jacket.

Furthermore, consideration of the testimonial evidence presented supports a conclusion that no genuine issue of material fact exists as to whether undue experimentation would have been required to make and use the injector without a pressure jacket. The inventors admitted that they tried unsuccessfully to produce a pressure-jacketless system and that producing such a system would have required more experimentation and testing. The inventors decided not to pursue such a system because it was “too risky.” The district court relied on various statements in the record by the inventors that testing of a syringe without a pressure jacket proved unsuccessful and that the inventors were not aware of any other similar testing being conducted at that time. Moreover, there was no indication of any prototype of a pressure-jacketless injector having been made.

Liebel argues that language in *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524 (Fed. Cir. 1987), that states that if an invention pertains to an art where the results are predictable, *e.g.*, in the mechanical arts, then disclosure of a single embodiment can enable a broad claim, supports its position. Liebel asserts that because the specification enables one mode of making and using the invention in its preferred embodiment, *viz.*, an injector with a pressure jacket, the enablement requirement is satisfied and the inquiry should end there.

Liebel’s reliance on *Spectra-Physics* is misplaced. In that case, the specification disclosed different “attachment means” for making the claimed invention such as moly-manganese brazing and pulse-soldering, but failed to disclose the best attachment means known to the inventors. . . . [I]n that case, disclosure of one attachment means permitted one skilled in the art to make and use the invention as broadly as it was claimed, which included other attachment means known to one of ordinary skill in the art. In contrast, in this case, disclosure of an injector system with a pressure jacket does not permit one skilled in the art to make and use the invention as broadly as it was claimed, including without a pressure jacket.

The facts of this case are, in fact, more analogous to *AK Steel* than to *Spectra-Physics*. In *AK Steel*, the patentee argued, as it does here, that the patent disclosed several embodiments within the properly construed claim, and that the specification need not teach the full claimed scope in order for the claims to be enabled. 344 F.3d at 1243. The claims in *AK Steel* read on steel strips containing either a Type 1 or a Type 2 aluminum coating. The specification clearly described only Type 2 aluminum coating. We stated, however, that “as part of the *quid pro quo* of the patent bargain, the applicant’s specification must enable one of ordinary skill in the art to practice the *full* scope of the claimed invention.” *Id.* at 1244 (latter emphasis added). We explained that the specification need not necessarily describe how to make and use every embodiment of the invention “because the artisan’s knowledge of the prior art and

routine experimentation can often fill in the gaps.” *Id.* However, because the full scope of the claims included both Type 1 and Type 2 aluminum coating, the relevant inquiry became whether one skilled in the art would have been able to make and use a steel strip containing a Type 1 aluminum coating at the time of the patent’s effective filing date. *Id.* We held that the specification taught against using a Type 1 aluminum coating, and therefore that the claims were invalid for lack of enablement.

Similarly, in this case, the asserted claims read on, and the full scope of the claimed invention includes, an injector system with and without a pressure jacket. There must be “reasonable enablement of the scope of the range” which, in this case, includes both injector systems with and without a pressure jacket. *Id.*

The specification’s reference that teaches away from an injector system with a disposable syringe without a pressure jacket, combined with the testimonial evidence that such a system could not have been produced at the time of filing, supports the district court’s conclusion that the specification fails to fulfill the enablement requirement of § 112. Because we are resolving this issue on the enablement ground, we do not need to consider the written description holding of invalidity.

The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet. The motto, “beware of what one asks for,” might be applicable here.

Comments

1. ***Complying with the Enablement Requirement: Full Scope of the Claimed Invention.*** As part of the quid pro quo of the patent bargain, *Liebel-Flarsheim* holds that the patentee’s specification must enable a person having ordinary skill in the art to practice the *full scope* of the claimed invention. According to the court, there “must be reasonable enablement of the scope of the range,” which meant, in this case, an enabling disclosure of both injector systems—with and without a pressure jacket. In *Automotive Technologies Intern., Inc. v. BMW of North America, Inc.*, 84 U.S.P.Q.2d 1108 (Fed. Cir. 2005), the court added resolution to *Liebel-Flarsheim*’s “reasonable enablement of the scope of the range.” The patent in *Automotive* involved sensing mechanisms for the deployment of airbags. The claim included both mechanical and electronic sensors, but the specification, according to the court, enabled only mechanical sensors. Automotive Technologies argued that “because the specification enables one mode of practicing the invention, viz., mechanical side impact sensors, the enablement requirement is satisfied.” The court, citing *Leibel-Flarsheim*, rejected this argument, stating “[d]isclosure of only mechanical side impact sensors does not permit one skilled in the art to make and use the invention as broadly as it was claimed, which includes electronic side impact sensors. Electronic side impact sensors are not just another known species of a genus consisting of sensors, but are a distinctly different sensor compared with the well-enabled mechanical side impact sensor that is fully discussed in the specification.” *Id.* at 1116. One can infer from *Automotive* that distinctly different embodiments must each be enabled.

The scope of enablement is comprised of what is disclosed in the specification coupled with what is known to a person having ordinary skill in the art. As the *National Recovery* court noted, “with respect to enablement the relevant inquiry lies in the relationship between the specification, the claims, and the knowledge of one of ordinary skill in the art.” Specifically, the test for compliance with the enablement requirement is whether a person of ordinary skill in the art is required to engage in “undue experimentation” to make and use the full scope of the claimed invention. The court considers several factors in determining whether undue experimentation is needed, including: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). (Recall, the *Liebel-Flarsheim* court relied on *Wands*.)

2. **Defining “Undue Experimentation.”** The experimentation must be “undue,” implying that some experimentation—trial and error—is permissible, including routine experimentation. As the *Liebel-Flarsheim* court stated, “the specification need not necessarily describe how to make and use every embodiment of the invention “because the artisan’s knowledge of the prior art and routine experimentation can often fill in the gaps.” See also *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983) (“Assuming some experimentation were needed, a patent is not invalid because of a need for experimentation.”). Moreover, the court in *Automotive Technologies*, *supra*, noted that although enablement is determined through the lens of the skilled artisan, the novel aspects of the invention must be enabled by the patent. The court wrote “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.” 84 U.S.P.Q.2d at 1114. Another issue is the extent to which a patentee may rely on the state of the prior art to “flesh out” an otherwise “bare bones” disclosure. Depending on the nature of the technology, it is clear that “a patent need not teach, and preferably omits, what is well known in the art.” *Hybritech v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). But when nascent technology is involved, the breadth and depth of skilled artisan’s database of knowledge is not as great. Therefore, given the artisan’s almost exclusive reliance on the patentee’s specification, nascent technology “must be enabled with a specific and useful teaching.” *Id.* In *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361 (Fed. Cir. 1997), Judge Lourie criticized reliance on well-known general knowledge not disclosed in the patent specification:

It is true . . . that a specification need not disclose what is well known in the art. . . . However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the

enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.

Id. at 1366. For Judge Lourie “[w]here, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching.” *Id.* at 1367. Indeed, a patentee cannot “bootstrap a vague statement of a problem into an enabling disclosure sufficient to dominate someone else’s solution of the problem.” *Id.* See also *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 1254 (Fed. Cir. 2004) (stating that for nascent technology the specification must be “specific and useful . . . because a person of ordinary skill in the art has little or no knowledge independent from the patentee’s instruction”). This line of reasoning builds on *In re Fisher*, 427 F.2d 833 (CCPA 1970), which recognized “[i]n cases involving predictable factors, such as mechanical or electrical elements, single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.” On the other hand, when an unpredictable factors are at issue, “such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.” *Id.* at 839.

3. **Enablement Measured at Time of Filing.** Congress was silent in defining the temporal dimension of the enablement requirement, namely *when* must a disclosure enable a person having ordinary skill in the art to make and use the claimed invention. In *National Recovery*, the court held that compliance with the enablement requirement is judged as of its filing date — a long-standing common law rule in patent jurisprudence. Technical information or other informative material that arise post-filing cannot be used to satisfy the enablement requirement. See *In re Glass*, 492 F.2d 1228 (CCPA 1974) (stating “the filing date becomes a date of constructive reduction to practice in determining priority of invention and this should not be the case unless at that time, without waiting for subsequent disclosures, any person skilled in the art could practice the invention from the disclosure of the application”). The principle reason for this rule is that the filing date is proof of an inventor’s latest date of invention, a date of crucial importance in American patent law because a patent is awarded to the party who can prove he was the first to invent the claimed invention. Proving date of invention is also important because the earlier one can show date of invention the more likely it is that there will less prior art available to competitors and the PTO. Proving date of invention is discussed in Chapter 4.
4. **The 19th-Century Technical Journal.** In the 19th century, several private technical journals, published by patent agencies, emerged to further the goal of disseminating technical knowledge. For instance, the *Scientific American* was published by Munn and Company, the largest 19th century patent agency; and *American Artisan* and the *American Inventor* were published by the patent agencies Brown, Coombs & Company and American Patent Agency, respectively. These publications and others were also used as a vehicle to bring inventors and capital together. See Naomi R. Lamoreaux & Kenneth L. Sokoloff, *Intermediaries in the U.S. Market for*

Technology, 1870-1920 in FINANCE, INTERMEDIARIES, AND ECONOMIC DEVELOPMENT 214-15 (Engerman et al. eds., 2003).

COMPARATIVE PERSPECTIVE

Complying with the Enablement Requirement in Europe

European disclosure requirements also allow for some trial and error, but instead of “undue experimentation,” the European Patent Office (“EPO”), more specifically, the EPO’s Board of Appeals, requires the claimed invention to be reproducible without “undue burden.” *See* Sericol Limited, T 0327/02. The United Kingdom asks if the specification requires the skilled artisan to “go beyond routine.” For example, in *Mentor v. Hollister*, [1991] FSR 557, 561-62, Justice Aldous wrote:

This section [Article 83 of the EPC transposed into section 14 of the 1977 English Patent Act] requires the skilled man to be able to perform the invention, but does not lay down the limits as to the time and energy that the skilled man must spend seeking to perform the invention before it is insufficient. Clearly there must be a limit. The subsection, by using the words “clearly enough and completely enough,” contemplates that patent specifications need not set out every detail necessary for performance, but can leave the skilled man to use his skill to perform the invention. In so doing he must seek success he should not be required to carry out any prolonged research, enquiry or experiment. He may need to carry out the ordinary methods of trial and error, which involve no inventive step and generally are necessary in applying the particular discovery to produce a practical result.

The section requires the skilled man to be able to perform the invention. Such a man is the ordinary addressee of the patent. He must be assumed to be possessed of the common general knowledge in the art and the necessary skill and expertise to apply that knowledge. He is the man of average skill and intelligence, but is not expected to be able to exercise any invention.

B. WRITTEN DESCRIPTION

The first paragraph of § 112 provides that the “specification shall contain a *written description* of the invention.” The written description requirement (“WD requirement”) serves as a check on patent applicants who wish to retain their original filing date, but also—after filing—amend the originally filed claims, add new claims to a pending application, or file a continuation application. The WD requirement addresses whether the amended claims in the original application or new claims in the subsequent application have support in the original specification and, therefore, are, entitled to the original filing date. Importantly, it is impermissible to add “new matter” to the specification after the application has been filed. *See* 35 U.S.C. § 132. The specification, therefore, must convey that the inventor was in possession of the claimed invention at the time of filing. The filing date, in other words, has a lock-in effect on the specification

The policy underlying the WD requirement becomes clear when we consider the significance of the filing date. The filing date is deemed constructive reduction to practice, which is the applicant's latest date of invention. In this capacity, the WD requirement assures the applicant's claimed invention is entitled a particular priority date (date of invention) and "prevent[s] an applicant from later asserting that he invented that which he did not." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

The WD requirement also applies to originally filed claims, a scenario that has largely been limited to chemical and biotechnology-related inventions. The *University of Rochester* case explores this issue as well as the relationship between the enablement and written description requirements. In the well known case of *Gentry Gallery*, the principal case set forth immediately below, the court explores the policies of the WD requirement.

STATUTE: Specification

35 U.S.C. § 112, ¶ 1

GENTRY GALLERY, INC. v. BERKLINE CORP.

134 F.3d 1473 (Fed. Cir. 1998)

LOURIE, Circuit Judge.

The Gentry Gallery appeals from the judgment of the United States District Court for the District of Massachusetts holding that the Berkline Corporation does not infringe U.S. Patent 5,064,244. Berkline cross-appeals from the decision that the patent was not shown to be invalid. [B]ecause the court clearly erred in finding that the written description portion of the specification supported certain of the broader claims asserted by Gentry, we reverse the decision that those claims are not invalid under 35 U.S.C. § 112, ¶ 1 (1994).

BACKGROUND

Gentry owns the '244 patent, which is directed to a unit of a sectional sofa in which two independent reclining seats ("recliners") face in the same direction. Sectional sofas are typically organized in an L-shape with "arms" at the exposed ends of the linear sections. According to the patent specification, because recliners usually have had adjustment controls on their arms, sectional sofas were able to contain two recliners only if they were located at the exposed ends of the linear sections. Due to the typical L-shaped configuration of sectional sofas, the recliners therefore faced in different directions. *See* '244 patent; col. 1, ll. 15-19. Such an arrangement was "not usually comfortable when the occupants are watching television because one or both occupants must turn their heads to watch the same [television] set. Furthermore, the separation of the two reclining seats at opposite ends of a sectional sofa is not comfortable or conducive to intimate conversation." *Id.* at col. 1, ll. 19-25.

The invention of the patent solved this supposed dilemma by, *inter alia*, placing a "console" between two recliners which face in the same direction. This console "accommodates the controls for both reclining seats," thus eliminating the need to position each recliner at an exposed end of a linear section. *Id.* at col. 1, ll. 36-37. Accordingly, both recliners can then be located

on the same linear section allowing two people to recline while watching television and facing in the same direction. Claim 1, which is the broadest claim of the patent, reads in relevant part:

A sectional sofa comprising:

a pair of reclining seats disposed in parallel relationship with one another in a double reclining seat sectional sofa section being without an arm at one end . . . , each of said reclining seats having a backrest and seat cushions and movable between upright and reclined positions . . . ,

a *fixed console* disposed in the double reclining seat sofa section between the pair of reclining seats and with the console and reclining seats together comprising a unitary structure,

said console including an armrest portion for each of the reclining seats; said arm rests remaining fixed when the reclining seats move from one to another of their positions, and

a *pair of control means*, one for each reclining seat; *mounted on the double reclining seat sofa section*. . . .

Id. at col. 4, line 68 to col. 5, ll. 1-27 (emphasis added to most relevant claim language). Claims 9, 10, 12-15, and 19-21 are directed to a sectional sofa in which the control means are specifically located on the console.

In 1991, Gentry filed suit in the District of Massachusetts alleging that Berkline infringed the patent by manufacturing and selling sectional sofas having two recliners facing in the same direction. In the allegedly infringing sofas, the recliners were separated by a seat which has a back cushion that may be pivoted down onto the seat, so that the seat back may serve as a tabletop between the recliners. . . . After that declaratory judgment action was consolidated with Gentry's infringement suit, Berkline added a counterclaim asserting that the patent was unenforceable because of inequitable conduct. The district court granted Berkline's motion for summary judgment of non-infringement, but denied its motions for summary judgment of invalidity. In construing the language "fixed console," the court relied on, *inter alia*, a statement made by the inventor named in the patent, James Sproule, in a Petition to Make Special (PTMS). *See* 37 C.F.R. § 1.102 (1997). Sproule had attempted to distinguish his invention from a prior art reference by arguing

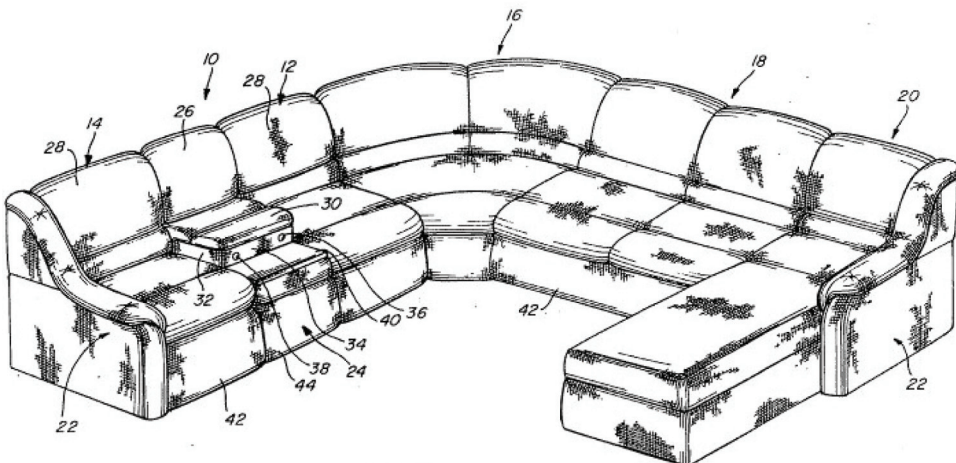


Fig. 1

that that reference, U.S. Patent 3,877,747 to Brennan *et al.* (“Brennan”), “shows a complete center seat with a tray in its back.” *Gentry I*, 30 U.S.P.Q.2d at 1137. Based on Sproule’s argument, the court concluded that, as a matter of law, Berkline’s sofas “contain[] a drop-down tray identical to the one employed by the Brennan product” and therefore did not have a “fixed console” and did not literally infringe the patent. *Id.* The court held that *Gentry* was also “precluded from recovery” under the doctrine of equivalents. *Id.* at 1138. . . .

DISCUSSION

* * *

B. Invalidity

. . . Berkline . . . argues that claims 1-8, 11, and 16-18 are invalid because they are directed to sectional sofas in which the location of the recliner controls is not limited to the console. According to Berkline, because the patent only describes sofas having controls on the console and an object of the invention is to provide a sectional sofa “with a console . . . that accommodates the controls for both the reclining seats,” ’244 patent, col. 1, ll. 35-37, the claimed sofas are not described within the meaning of § 112, ¶ 1. Berkline also relies on Sproule’s testimony that “locating the controls on the console is definitely the way we solved it [the problem of building sectional sofa with parallel recliners] on the original group [of sofas].” *Gentry* responds that the disclosure represents only Sproule’s preferred embodiment, in which the controls are on the console, and therefore supports claims directed to a sofa in which the controls may be located elsewhere. *Gentry* relies on *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1582 n. 7 (Fed. Cir. 1996), and *In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981), for the proposition that an applicant need not describe more than one embodiment of a broad claim to adequately support that claim.

We agree with Berkline that the patent’s disclosure does not support claims in which the location of the recliner controls is other than on the console. Whether a specification complies with the written description requirement of § 112, ¶ 1, is a question of fact, which we review for clear error on appeal from a bench trial. To fulfill the written description requirement, the patent specification “must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). An applicant complies with the written description requirement “by describing *the invention*, with all its claimed limitations.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (1997).

It is a truism that a claim need not be limited to a preferred embodiment. However, in a given case, the scope of the right to exclude may be limited by a narrow disclosure. For example, as we have recently held, a disclosure of a television set with a keypad, connected to a central computer with a video disk player did not support claims directed to “an individual terminal containing a video disk player.” *See id.* (stating that claims directed to a “distinct invention from that disclosed in the specification” do not satisfy the written description requirement); *see also Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (stating that the case law does “not compel the

conclusion that a description of a species always constitutes a description of a genus of which it is a part”).

In this case, the original disclosure clearly identifies the console as the only possible location for the controls. It provides for only the most minor variation in the location of the controls, noting that the control “may be mounted on top or side surfaces of the console rather than on the front wall . . . without departing from this invention.” ’244 patent, col. 2, line 68 to col. 3, line 3. No similar variation beyond the console is even suggested. Additionally, the only discernible purpose for the console is to house the controls. As the disclosure states, identifying the only purpose relevant to the console, “[a]nother object of the present invention is to provide . . . a console positioned between [the reclining seats] that accommodates the controls for both of the reclining seats.” *Id.* at col. 1, ll. 33-37. Thus, locating the controls anywhere but on the console is outside the stated purpose of the invention. Moreover, consistent with this disclosure, Sproule’s broadest original claim was directed to a sofa comprising, *inter alia*, “control means located upon the center console to enable each of the pair of reclining seats to move separately between the reclined and upright positions.” Finally, although not dispositive, because one can add claims to a pending application directed to adequately described subject matter, Sproule admitted at trial that he did not consider placing the controls outside the console until he became aware that some of Gentry’s competitors were so locating the recliner controls. Accordingly, when viewed in its entirety, the disclosure is limited to sofas in which the recliner control is located on the console.

Gentry’s reliance on *Ethicon* is misplaced. It is true, as Gentry observes, that we noted that “an applicant . . . is generally allowed claims, when the art permits, which cover more than the specific embodiment shown.” *Ethicon*, 93 F.3d at 1582 n. 7 (quoting *In re Vickers*, 141 F.2d 522, 525, 61 USPQ2d 122, 125 (CCPA 1944)). However, we were also careful to point out in that opinion that the applicant “was free to draft claim[s] broadly (within the limits imposed by the prior art) to exclude the lockout’s exact location as a limitation of the claimed invention” only because he “did not consider the precise location of the lockout to be an element of his invention.” *Id.* Here, as indicated above, it is clear that Sproule considered the location of the recliner controls on the console to be an essential element of his invention. Accordingly, his original disclosure serves to limit the permissible breadth of his later-drafted claims.

Similarly, *In re Rasmussen* does not support Gentry’s position. In that case, our predecessor court restated the uncontroversial proposition that “a claim may be broader than the specific embodiment disclosed in a specification.” 650 F.2d at 1215. However, the court also made clear that “[a]n applicant is entitled to claims as broad as the prior art *and his disclosure* will allow.” *Id.* at 1214, 650 F.2d 1212 (emphasis added). The claims at issue in *Rasmussen*, which were limited to the generic step of “adheringly applying” one layer to an adjacent layer, satisfied the written description requirement only because “one skilled in the art who read [the] specification would understand that it is unimportant how the layers are adhered, so long as they are adhered.” Here, on the contrary, one skilled in the art would clearly understand that it was not only important, but essential to Sproule’s invention, for the controls to be on the console.

In sum, the cases on which Gentry relies do not stand for the proposition that an applicant can broaden his claims to the extent that they are effectively

bounded only by the prior art. Rather, they make clear that claims may be no broader than the supporting disclosure, and therefore that a narrow disclosure will limit claim breadth. Here, Sproule's disclosure unambiguously limited the location of the controls to the console. Accordingly, the district court clearly erred in finding that he was entitled to claims in which the recliner controls are not located on the console. We therefore reverse the judgment that claims 1-8, 11, and 16-18, were not shown to be invalid.

UNIVERSITY OF ROCHESTER v. G.D. SEARLE & CO., INC.

358 F.3d 916 (Fed. Cir. 2004)

LOURIE, Circuit Judge.

The University of Rochester ("Rochester") appeals from the decision of the United States District Court for the Western District of New York granting summary judgment that United States Patent 6,048,850 is invalid. Because we conclude that the court did not err in holding the '850 patent invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, and in granting summary judgment on that ground, we affirm.

BACKGROUND

Traditional non-steroidal anti-inflammatory drugs ("NSAIDs") such as aspirin, ibuprofen, ketoprofen, and naproxen are believed to function by inhibiting the activity of enzymes called cyclooxygenases. Cyclooxygenases catalyze the production of a molecule called prostaglandin H₂, which is a precursor for other prostaglandins that perform various functions in the human body.

In the early 1990s, scientists discovered the existence and separate functions of two distinct cyclooxygenases, referred to as "COX-1" and "COX-2."¹ COX-1 is expressed (*i.e.*, produced biologically) in the gastrointestinal tract, where it is involved in the production of prostaglandins that serve a beneficial role by, for example, providing protection for the stomach lining. COX-2 is expressed in response to inflammatory stimuli, and is thought to be responsible for the inflammation associated with diseases such as arthritis. It is now known that the traditional NSAIDs inhibit both COX-1 and COX-2, and as a result they not only reduce inflammation, but also can cause undesirable side effects such as stomach upset, irritation, ulcers, and bleeding.

After the separate functions of COX-1 and COX-2 were discovered, it was hypothesized that it would be possible to reduce inflammation without gastrointestinal side effects if a method could be found for selectively inhibiting the activity of COX-2 (*i.e.*, inhibiting the activity of COX-2 without inhibiting COX-1 activity). To that end, Rochester scientists developed a screening assay for use in determining whether a particular drug displayed such selectivity, and filed a U.S. patent application directed to their developments in 1992. After filing a series of continuation, continuation-in-part, and divisional

1. COX-1 and COX-2 are alternatively referred to as "PGHS-1" and "PGHS-2," respectively, where "PGHS" is an abbreviation for "prostaglandin H synthase."

applications derived from that 1992 application, the scientists eventually received United States Patent 5,837,479 in 1998, covering methods “for identifying a compound that inhibits prostaglandin synthesis catalyzed by mammalian prostaglandin H synthase-2 (PGHS-2).”

From a division of the application that led to the ’479 patent, the scientists also obtained, on April 11, 2000, the ’850 patent. The ’850 patent contains three independent claims and five dependent claims. [Claim 1 is representative]:

1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment.

On the day the ’850 patent issued, Rochester sued G.D. Searle & Co., Inc., Monsanto Co., Pharmacia Corp., and Pfizer Inc. (collectively, “Pfizer”), alleging that Pfizer’s sale of its COX-2 inhibitors Celebrex[®] and Bextra[®] for treatment of inflammation infringed the ’850 patent, and seeking injunctive and monetary relief. In May 2002, Pfizer moved for summary judgment of invalidity of the ’850 patent for failure to comply with the written description and enablement requirements of 35 U.S.C. § 112, ¶ 1. Rochester opposed the motion and filed a cross-motion for summary judgment with respect to the written description issue.

In evaluating the parties’ motions, the district court found that, although all of the claims require the use of a “non-steroidal compound that selectively inhibits activity of the PGHS-2 gene,” the ’850 patent neither discloses any such compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research. Indeed, the court found no evidence in the ’850 patent that the inventors themselves knew of any such compound at the time their patent application was filed. Accordingly, the court concluded that the patent’s claims are invalid for lack of written description. . . .

Rochester now appeals.

DISCUSSION

Rochester asserts that the district court erred by granting Pfizer’s motion for summary judgment of invalidity for lack of written description [and] that the court erred by denying its cross-motion for summary judgment with regard to written description.

In its first argument, Rochester asserts that the district court effectively—but erroneously—held that a patent claiming a method of obtaining a biological effect in a human by administering a compound cannot, as a matter of law, satisfy the written description requirement without disclosing the identity of any such compound. Indeed, Rochester contends that “no written description requirement exists independent of enablement.” In any event, Rochester argues that its patent met the requirements of § 112 and is not invalid.³

3. Rochester is supported by *amici curiae* the Regents of the University of California, the University of Texas Southwestern Medical Center at Dallas, and the University of Texas M.D. Anderson Cancer Center, which make essentially the same points.

Pfizer responds to Rochester's argument by pointing out that we have "interpreted § 112 'as requiring a "written description" of an invention separate from enablement,'" (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*), and that "the many prior precedential decisions" contrary to Rochester's position "cannot be overruled except by an *en banc* decision." Pfizer also cites *Vas-Cath Inc. v. Mahurkar*, in which we explained that "[t]he purpose of the written description requirement is broader than to merely explain how to 'make and use' [the invention]," and *Reiffin v. Microsoft Corp.*, in which we stated that the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Pfizer asserts that a patent fails to satisfy the written description requirement if it claims a method of achieving a biological effect, but discloses no compounds that can accomplish that result. It maintains that the district court correctly invalidated Rochester's '850 patent.⁴

We agree with Pfizer that our precedent recognizes a written description requirement and that the '850 patent does not satisfy that requirement. As in any case involving statutory interpretation, we begin with the language of the statute itself. Section 112 provides, in relevant part, that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (2000). Three separate requirements are contained in that provision: (1) "[t]he specification shall contain a written description of the invention"; (2) "[t]he specification shall contain a written description . . . of the manner and process of making and using it [*i.e.*, the invention] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same"; and (3) "[t]he specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention."

In common parlance, as well as in our and our predecessor court's case law, those three requirements are referred to as the "written description requirement," the "enablement requirement," and the "best mode requirement," respectively. The United States Supreme Court also recently acknowledged written description as a statutory requirement distinct not only from the best mode requirement, but also from enablement. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). In addition, the patent application must *describe, enable, and set forth the best mode* of carrying out the invention. § 112. These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public.

Although there is often significant overlap between the three requirements, they are nonetheless independent of each other. Thus, an invention may be described without an enabling disclosure of how to make and use it. A

4. Pfizer is supported by *amicus curiae* Eli Lilly & Co., which makes similar arguments.

description of a chemical compound without a description of how to make and use it, unless within the skill of one of ordinary skill in the art, is an example. Moreover, an invention may be enabled even though it has not been described. See, e.g., *In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971) (“[I]t is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not describe that invention.”). Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B *if* B were described. A specification can likewise describe an invention without enabling the practice of the full breadth of its claims. Finally, still further disclosure might be necessary to satisfy the best mode requirement if otherwise only an inferior mode would be disclosed.

The “written description” requirement serves a teaching function, as a “*quid pro quo*” in which the public is given “meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.” *Enzo*, 323 F.3d at 970. Rochester argues, however, that this teaching, or “public notice,” function,⁵ although “virtually unchanged since the 1793 Patent Act,” in fact “became redundant with the advent of claims in 1870.” We disagree. Statutory language does not become redundant unless repealed by Congress, in which case it no longer exists. In addition, and most significantly, our precedent clearly recognizes a separate written description requirement. See *In re Ruschig*, 379 F.2d 990 (CCPA 1967). . . .

While it is true that this court and its predecessor have repeatedly held that claimed subject matter “need not be described in *haec verba*” in the specification to satisfy the written description requirement, e.g., *In re Smith*, 481 F.2d 910, 914 (CCPA 1973), it is also true that the requirement must still be met in some way so as to “describe the claimed invention so that one skilled in the art can recognize what is claimed.” *Enzo*, 323 F.3d at 968. We have further explained that:

[T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . A description of an anti-inflammatory steroid, *i.e.*, a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [*Regents of the Univ. of Cal. v. Eli Lilly & Co., Inc.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)]. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.

Enzo, 323 F.3d at 968. Similarly, for example, in the nineteenth century, use of the word “automobile” would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, *viz.*, a chassis, an engine, seats, wheels on axles, etc. Thus, generalized language may not suffice if it does not convey the detailed identity of an invention. In this

5. We and the Supreme Court have frequently used the term “public notice” in connection with claims and discussion of the doctrine of equivalents, the point being that the public is entitled to notice of what the inventor has claimed and the Patent and Trademark Office has agreed should be the subject of a patent’s limited right to exclude. However, while the role of the claims is to give public notice of the subject matter that is protected, the role of the specification is to teach, both what the invention is (written description) and how to make and use it (enablement).

case, there is no language here, generalized or otherwise, that describes compounds that achieve the claimed effect. . . .

Rochester's suggestion in its brief that *Lilly* "compounded *Ruschig's* error" by "invoking the written description requirement in a case without priority issues" is similarly deficient. Neither *Wm. Moore* nor *Sus*, for example, involved any priority issues. Moreover, even if the court had never had occasion to apply the written description requirement to original claims prior to the 1987 *Lilly* decision, that requirement was nonetheless always present. As explained in *Enzo*:

It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time. . . . As for the lack of earlier cases on this issue, it regularly happens in adjudication that issues do not arise until counsel raise them, and, when that occurs, courts are then required to decide them.

323 F.3d at 971-72 (Lourie, J., concurring in Denial of Petition for Rehearing En Banc). In any event, the basic requirement of a written description of an invention exists whether a question of priority has arisen or not. The statute does not limit the requirement to cases in which a priority question arises.

Indeed, as early as 1822 the Supreme Court recognized the existence of separate written description and enablement requirements:

[T]he patent act requires . . . that the party [*i.e.*, the inventor] "shall deliver a written description of his invention, in such full, clear, and exact terms, as to distinguish the same from all other things before know[n], and to enable any person skilled in the art or science, & c. & c. to make, compound, and use the same." The specification, then has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [*sic*] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.

Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 433-34 (1822). The Patent Act of 1793, 1 Stat. 318, which was in force at the time *Evans* was decided, required, in relevant part, that every inventor "deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science . . . to make, compound, and use the same. . . ." *In re Barker*, 559 F.2d 588, 592 (CCPA 1977). Although the patent statutes have been extensively revised since 1822, most notably in the addition of the requirement of claims, the language of the present statute is not very different in its articulation of the written description requirement. *Id.* at 592-94.

Rochester also argues that *Fiers*, *Lilly*, and *Enzo* are all distinguishable because they were limited to DNA-based inventions. Rochester asserts that undisputed evidence shows that, based on the '850 patent's teachings, skilled artisans would be able to recognize COX-2-selective inhibitors.

We agree with Rochester that *Fiers*, *Lilly*, and *Enzo* differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester's position. It is irrelevant; the statute applies to all types of inventions. We see no reason for the rule to be any different when non-genetic materials are at issue; in fact, where there might be some basis for finding a written description requirement to be satisfied in a genetics case based on the complementariness of a nucleic acid and, for example, a protein, that correspondence might be less clear in a non-genetic situation. In *Enzo*, we explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are "coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." 323 F.3d at 964 (quoting from the PTO's *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1*, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106). DNA and RNA are each made up of just four building blocks that interact with each other in a highly predictable manner. Each of those building blocks, or "nucleotides," is characterized by a unique "base": In the case of DNA, the four nucleotides include the bases adenine, thymine, cytosine, and guanine; RNA also includes adenine, cytosine, and guanine, but contains the base uracil in place of thymine. Adenine on one strand of DNA binds, or "hybridizes," to thymine on the other; in RNA, adenine binds to uracil; and in either DNA or RNA, cytosine binds to guanine. Given the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a "complementary" strand that will bind to it. Therefore, disclosure of a DNA sequence might support a claim to the complementary molecules that can hybridize to it.

The same is not necessarily true in the chemical arts more generally. Even with the three-dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them, let alone have been within the purview of one of ordinary skill in the art in the 1993-1995 period in which the applications that led to the '850 patent were filed. Rochester and its experts do not offer any persuasive evidence to the contrary. As the district court pointed out:

Tellingly, . . . what plaintiff's experts' [sic] do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds—which, as the patent makes clear, are necessary to practice the claimed method—would be suitable, nor would one know how to find such a compound except through trial and error. . . . Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of the method—a compound that selectively inhibits PGHS-2 activity—was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

Univ. of Rochester, 249 F. Supp. 2d at 229.

Rochester also attempts to distinguish *Fiers*, *Lilly*, and *Enzo* by suggesting that the holdings in those cases were limited to composition of matter claims, whereas the '850 patent is directed to a method. We agree with the district court that that is "a semantic distinction without a difference." Regardless

whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, “[t]he claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment.”

We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure, but the application must nonetheless “describe the claimed subject matter in terms that establish that [the applicant] was in possession of the . . . claimed invention, including all of the elements and limitations.” *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998). *But see Enzo*, 323 F.3d at 969 (“Application of the written description requirement, however, is not subsumed by the ‘possession’ inquiry. A showing of ‘possession’ is ancillary to the statutory mandate that ‘[t]he specification shall contain a written description of the invention,’ and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the invention.”). The specification must teach the invention by describing it.

* * *

In sum, because the ’850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods—an essential element of every claim of that patent—and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art⁹ at the relevant time, Rochester has failed to raise any question of material fact whether the named inventors disclosed the claimed invention. Accordingly, we affirm the district court’s grant of Pfizer’s motion for summary judgment.

Comments

1. **Gentry and the So-Called “Essential-Element” Test.** A key was that the patentee in *Gentry* considered the location of the controls on the console to be an “essential element of his invention.” The *Gentry* case generated a great deal of controversy, because it was thought the court constructed a new test: the essential element test. In *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 993 (Fed. Cir. 1999), for example, the Federal Circuit stated that “*Gentry Gallery* . . . considers the situation where the patent’s disclosure makes crystal clear that a particular (*i.e.*, narrow) understanding

9. In *O’Reilly v. Morse*, 56 U.S. 62, 15 How. 62, 14 L. Ed. 601 (1853), the Supreme Court stated “[Morse] claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of the opinion that the claim is too broad, and not warranted by law.” *Id.* at 113. Likewise, Rochester has claimed a method that could not be adequately described at the time its application was filed. As we explained in *Fiers*, “one cannot describe what one has not conceived.” 984 F.2d at 1171.

of a claim term is an ‘essential element of [the inventor’s] invention.’ Here, however, the patent disclosure provides ample support for the breadth of the term ‘heading;’ it does not unambiguously limit[] the meaning of ‘heading.’” But the court, in *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317 (Fed. Cir. 2002), stated that *Gentry* “did not announce a new ‘essential element’ test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements.” The court continued that *Gentry* “merely expounded upon the unremarkable proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope.” *Id.* at 1323. *See also Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1333 (Fed. Cir. 2003) (stating *Gentry Gallery* does not mandate “an inquiry into what an inventor considers to be essential to his invention and requir[e] that the claims incorporate those elements”).

2. ***Complying with the Written Description Requirement.*** The *Gentry* court stated that to comply with the written description requirement the specification “must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” This is sometimes known as the “possession” test. In *Vas-Cath v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), the court wrote that the test for compliance with the WD requirement is “whether the disclosure of the application relied upon ‘reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.’” *Id.* at 1563. But as the *Rochester* court noted, the specification does not have to disclose “*in haec verba*” (verbatim) support to satisfy the requirement. For instance, in *Application of Wertheim*, 541 F.2d 257, 265 (CCPA 1976), the patent claimed a particular range, “at least 35%,” that was narrower than what was disclosed in the specification, which read “25% to 60%.” The CCPA held that the specification supported the claim even though the precise range claimed was not exactly set forth in the specification.

Importantly, the applicant cannot add “new matter” to the specification and retain the original filing date. 35 U.S.C. § 132(a) (“No amendment shall introduce new matter into the disclosure of the invention.”). *See also TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (“The written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification after the original filing date, . . . the new claims or other added material must find support in the original specification.”). If new matter is added to the specification, the applicant should file a continuation-in-part (C-I-P) application, wherein the new matter (and any claims that the new matter supports) would be entitled to the C-I-P filing date, and the information disclosed in the original application (and any claims that find support in the original disclosure) will retain the original filing date.

3. ***Written Description and Enablement.*** The Federal Circuit rejected *Rochester*’s argument that there is no separate written description requirement independent of the enablement. The written description

and enablement requirements are closely related, and, indeed, the Federal Circuit conceded in *Vas-Cath*, that “[t]here appears to be some confusion in our decisions concerning the extent to which the ‘written description’ requirement is separate and distinct from the enablement requirement.” 935 F.2d at 1563.

The Federal Circuit has distinguished the two doctrines by stressing, as in *Rochester*, that the written description focuses on what the applicant actually invented, proof of which requires a level of specificity in the specification that may be unnecessary for enablement purposes. See *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967) (“[T]he question is not whether [one skilled in the art] would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented.”). Enablement, in contrast, focuses on whether the specification enables a person having ordinary skill in the art could make and use the claimed invention, an inquiry that is more objective than the inventor-centric WD requirement. Thus, it is possible for a specification to enable a skilled artisan to make and use claimed subject matter yet fall short of satisfying the written description requirement. As the Court of Customs and Patent Appeals noted in *In re DiLeone*, 436 F.2d 1404, 1405 (CCPA 1971), a specification that only discloses compound A with no broadening language “might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.” Therefore, an applicant who later amends his claims to add B and C may comply with enablement, but not WD. In short, the “purpose of the ‘written description’ requirement is broader than to merely explain how to ‘make and use’; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” *Vas-Cath*, 935 F.2d at 1563-64.

Nonetheless, as *Rochester* suggests, the relationship between enablement and written description is not without controversy. Beginning with *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) and most recently in *Rochester*, Federal Circuit judges have debated whether there is indeed a distinction between the two. For instance, the court’s refusal to hear *Rochester* en banc produced several opinions, both supporting a separate WD requirement and arguing against such. See 375 F.3d 1303 (Fed. Cir. 2004). Judge Newman agreed with the *Rochester* panel decision that there is a separate WD requirement distinct from enablement and definiteness, stating that “[i]t has always been necessary to disclose and describe what is patented,” [and] [i]t has never been the law that one can claim what is not made known and set forth in the patent. *Id.* at 1304. But she stressed that en banc review was necessary to resolve the “burgeoning conflict in pronouncements of this court concerning the written description and enablement requirements.” *Id.* at 1304. In short, Judge Newman wrote “[t]his question has percolated enough; it is ripe for en banc resolution.” *Id.* at 1305. Judge Rader, on the other hand, wrote a lengthy dissent asserting “contrary to logic and the statute itself, *Eli Lilly* requires one part of the specification (the written description) to provide “adequate support” for another part of the specification (the claims). Neither *Eli Lilly* nor this case

has explained either the legal basis for this new validity requirement or the standard for “adequate support.” *Id.* at 1308-09. According to Judge Rader, *Eli Lilly* “has no basis in the written description language of the original Patent Act.” *Id.* And Judge Linn argued that all § 112, ¶ 1 requires is for the written description to “enable[] any person skilled in the art to which the invention pertains to make and use the claimed invention and sets forth the best mode of carrying out the invention.” The question under § 112, ¶1, is not “Does the written description disclose what the invention is?” Rather, “[t]he question is, ‘Does the written description describe the invention recited in the claims—themselves part of the specification—in terms that are sufficient to enable one of skill in the art to make and use the claimed invention and practice the best mode contemplated by the inventor?’” *Id.* at 1325.

4. ***Written Description and Definiteness.*** The Federal Circuit has distinguished the definiteness requirement from the WD requirement based on both historical and policy grounds. The definiteness requirement, discussed in Section D, below, demands the patentee to particularly point out and distinctly claim his invention; in short, to draft claims clearly. The *Vas-Cath* court offered a historical explanation, noting “the ‘written description’ requirement was a part of the patent statutes at a time before claims were required.” 935 F.2d at 1560. But understanding the persistence of the WD requirement in the light of § 112, ¶ 2 is more challenging. The *Vas-Cath* court, quoting *Rengo Co. v. Molins Mach. Co.*, noted the “subtle” and “complementary” relationship between the policies of the WD and definiteness requirements, but also stressed how these two requirements “approach a similar problem from different directions.” According to the court, the written description requirement “guards against the inventor’s overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation,” whereas the “definiteness requirement shapes the future conduct of persons other than the inventor, by insisting that they receive notice of the scope of the patented device.” While the issue of perspective may be accurate, perhaps a more convincing distinction is that the WD requirement is more informative than the claims. This point was made by Judge Lourie in *University of Rochester*:

The separate written description requirement poses no conflict with the role of the claims. It is well established that the specification teaches an invention, whereas the claims define the right to exclude. While claims must be supported by the written description, the latter contains much material that is not in the claims. The written description contains an elucidation of various aspects of an invention as well as material that is necessary for enablement. Moreover, the written description often contains material that an applicant intended to claim that has been rejected in examination. Thus, the written description and the claims do not duplicate each other.

University of Rochester, 373 F.3d 1303, 1306 (Fed. Cir. 2004) (refusal to hear en banc).

5. ***Written Description Applied to Originally Filed Claims.*** The *University of Rochester* discussion of the written description requirement is one of the more recent cases hotly debating the proper application of the written description requirement. Prior to *University of Rochester*, the Federal

Circuit, in the context of biotechnology-related inventions, held that a specification describing a gene or DNA sequence only in terms of its biological function (*e.g.*, to encode for a known protein) does not comply with the written description requirement, even as to an original claim directed to the functionally-defined DNA sequence. In *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), the court explicitly linked conception with the issue of written description. The court noted that when DNA is at issue, the written description requirement demands “a description of the DNA itself” rather than a method of isolating the DNA. Consistent with *Fiers*, the *Eli Lilly* court wrote that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” Thus, “the description requirement . . . requires a description of an invention, not an indication of a result that one might achieve if one made that invention.” Referring to the DNA simply by its biological function falls short of a sufficient written description, amounting to a mere “wish” or “research plan.”

Some Federal Circuit judges and commentators have argued that applying the written description requirement to originally filed claims is improper because there is no after-filing amendment or continuation application at issue. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 979-80 (Fed. Cir. 2002) (rehearing en banc denied) (Rader, J., dissenting) (asserting that *Eli Lilly* is inconsistent with precedent because “for the first time, this court purported to apply [written description] as a general disclosure doctrine in place of enablement, rather than as a priority doctrine”); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003) (“The purpose of the written description requirement is to prevent an applicant from *later* asserting that he invented that which he did not; the applicant for a patent is therefore required ‘to recount his invention in such detail that his *future* claims can be determined to be encompassed within his *original* creation.’”) (emphasis in original). *See also In re Gardner*, 475 F.2d 1389, 1391 (CCPA 1973) (noting the original claim “itself constituted a description in the original disclosure. . . . Nothing more is necessary for compliance with the description requirement”); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998) (criticizing *Eli Lilly* and application of WD requirement to originally filed claims).

C. BEST MODE

The best mode requirement of § 112, ¶ 1 dictates that in addition to providing an enabling disclosure, the patentee must disclose the best way (or mode) of practicing the claimed invention. (The best mode is sometimes referred to as the preferred embodiment.) For example, the inventor claims “a method of making chemical X wherein A and B are heated between 100 – 110° C.” If the patentee knows, *at the time of filing*, that heating at 107° C provides optimal results, he must disclose that information. An important distinction between

the best mode requirement and the enablement requirement is that failure to comply with best mode requires knowledge of and concealment of a best mode.

The purpose of the best mode requirement is to prevent an inventor from obtaining patent protection while concealing (as a trade secret, for example) from the public preferred embodiments of his claimed invention. The law and policy of the best mode requirement are discussed in *Young Dental*.

STATUTE: Specification

35 U.S.C. § 112, ¶ 1

**YOUNG DENTAL MANUFACTURING COMPANY, INC. v.
Q3 SPECIAL PRODUCTS, INC.**

112 F.3d 1137 (Fed. Cir. 1997)

CLEVENGER, Circuit Judge.

Young Dental Manufacturing Company (Young) appeals the judgment of the United States District Court for the Eastern District of Missouri in favor of Q3 Special Products and David G. Kraenzle (collectively Q3). The court upheld a jury verdict of invalidity of all asserted claims for violation of the best mode requirement of 35 U.S.C. § 112.

I

Young's asserted patents, U.S. Patent Nos. 5,156,547 and 5,423,679 (the '547 and '679 patents), disclose an improved disposable prophy angle (DPA). A prophy angle is the small hand-held device used by dentists to polish teeth. It holds a rubber cup, known as a prophy cup, which the dentist dips into an abrasive paste and then holds against the patient's teeth as the cup rotates. Early prophy angles were not disposable; they were made entirely of metal and had to be sterilized in an autoclave between uses. In the 1970s, plastic DPAs were introduced which could be pushed onto the end of a metal handpiece and locked onto the handpiece's drive shaft. These early DPAs did not replace metal DPAs, however, largely because they often ran roughly, fell apart, and overheated.

In November 1990, Ronald Bailey, an employee of Young, filed a patent application for an improved DPA and assigned the application to Young. The application matured into the patents in suit. Fig. 1 of the '547 patent shows the components of Bailey's DPA in side cross-section.

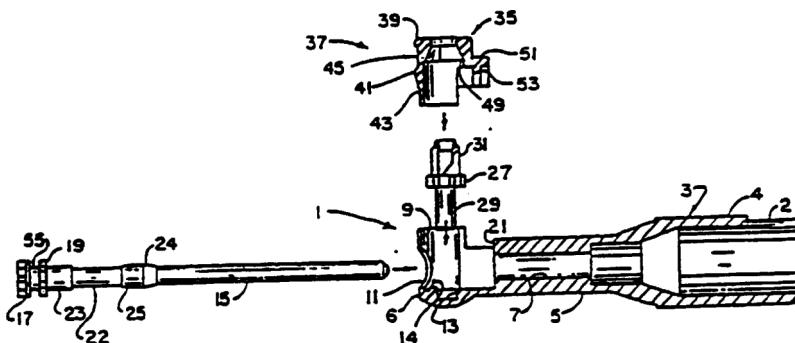


FIG. 1.

The body **3** of the angle includes a sleeve **4**, a neck **5**, and a head **6** formed integrally with each other. The head is formed as a cylinder at right angles to the neck. The body and head have axial bores **7** and **9**, respectively, into which are placed drive shaft **15** and driven shaft **29**, respectively. To assemble the prophy angle, one inserts the drive shaft into the body bore from the distal end of the prophy angle through aperture **11**. One then inserts the driven shaft into the head bore, where the drive gear **17** meshes with the driven gear **27**. A snap cap **35** slides down into head bore **9** to lock the gears and shafts in place. At its front edge, the snap cap has a sheath **43** that covers the aperture and a latch **41** that locks the cap in place.

The '547 patent was the first to issue from Bailey's application. It claims the DPA and a method for assembling the DPA. The '547 patent was followed by the '679 patent, a divisional based on a continuation-in-part application of the '547 patent. . . .

Kraenzle worked as an engineer with Young from December 1990 until his resignation in March 1992. In April 1992, he designed the device accused here of infringing and in July 1992 filed the patent application that matured into the '859 patent. Kraenzle formed Q3 in July 1992 with Chris Carron, another former Young employee, and began selling the accused device in July 1993, the same month in which the '859 patent issued. Kraenzle is the president and majority shareholder of Q3. . . .

II

On November 1, 1993, Young sued Q3, Kraenzle, and Carron, alleging infringement of the '547 patent. . . . Young later added a count for infringement of the '679 patent. Q3 counterclaimed for a declaration of noninfringement and invalidity. . . . The jury returned a verdict in favor of Q3. The jury found noninfringement under the doctrine of equivalents for all asserted claims, and invalidity for obviousness and for failure to comply with the best mode requirement for all asserted claims.

* * *

IV

Young asserts that the district court should not have submitted the best mode issue to the jury. On this point, we agree with Young. Section 112 requires that the specification "set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112 (1994). The purpose of this requirement is to restrain inventors from applying for a patent while at the same time concealing from the public preferred embodiments which the inventor has, in fact, conceived. To establish invalidity for failure to disclose the best mode, the party seeking to invalidate the patent must present clear and convincing evidence that the inventor both knew of and concealed a better mode of carrying out the claimed invention than was set forth in the specification.

Two factual inquiries underlie the determination of whether a patent complies with the best mode requirement. Under the first inquiry, which is entirely subjective, one must ask whether, at the time the patent application was filed, the inventor knew of a mode of practicing the claimed invention that he considered to be better than any other. *United States Gypsum Co. v. National Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996). If the inventor had a best mode of practicing

the claimed invention, one proceeds to the second inquiry. That inquiry involves determining whether the specification adequately disclosed what the inventor contemplated as the best mode so that those having ordinary skill in the art could practice it. *Id.* This latter inquiry is “largely an objective inquiry that depends upon the scope of the claimed invention and the level of skill in the art.” *Id.* (quoting *Chemcast Corp. v. Arco Indus.*, 913 F.2d 923, 928 (Fed. Cir. 1990)).

The best mode requirement does not apply to “production details.” *Wahl Instruments, Inc. v. Acvious, Inc.*, 950 F.2d 1575, 1579-80 (Fed. Cir. 1991). Our precedent has applied the term “production details” in two senses, only one of which truly refers to production details as such. In the first sense, *i.e.*, that of “true” production details, we have referred to commercial considerations that do not relate to the quality or nature of the invention, such as equipment on hand or prior relationships with suppliers. *Id.* In the second sense, under the rubric of production details, we have referred to what more properly are considered routine details. Routine details are details that are apparent to one of ordinary skill in the art. They are appropriately discussed separately from production details because routine details *do* relate to the quality or nature of the invention. Nevertheless, they need not be disclosed because, by definition, their disclosure is not required under the second inquiry of the best mode determination. In other words, to satisfy the second inquiry of the best mode test, an inventor need only disclose information about the best mode that would not have been apparent to one of ordinary skill in the art. Because routine details are apparent to one of ordinary skill, they need not be disclosed.

The details that Q3 asserts are missing from the ’547 and ’679 patents are such routine details. Q3 first asserts that Bailey failed to disclose the gear ratio between the drive gear and the driven gear in Bailey’s DPA. The gear ratio does not escape scrutiny as a production detail because it relates to the quality and nature of the invention—*i.e.*, it affects the stable operation of the DPA at high rotational speeds. However, there is no competent evidence of record indicating that one of skill in the art could not have readily selected a satisfactory gear ratio for this application based on the patent disclosure. Rather, the patent figures disclose the gear shapes and the general design of the gears, and the specification describes the structure of the gears. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991) (“What is required is an adequate disclosure of the best mode, not a guarantee that every aspect of the specification be precisely and universally reproducible.”). We hold that there was no competent evidence to show that the disclosures of the ’547 or ’679 patent were inadequate to satisfy the best mode requirement.

Q3 also asserts that Bailey failed to disclose the grade of plastic used for the body (Lexan 141) and gears (Celcon M-90) of his preferred embodiment. In this regard, Bailey actually disclosed that he preferred that the parts be made from Lexan and Celcon; he merely failed to disclose the particular grades of these two plastics in his contemplated best mode. “A description of particular materials or sources or of a particular method or technique selected for manufacture may or may not be required as part of a best mode disclosure respecting a device.” *Wahl Instruments*, 950 F.2d at 1579.

We do not find any competent evidence of record to show that such detailed disclosure was necessary in the ’547 or ’679 patent to inform one of skill in the art about the inventor’s best mode. Rather, the evidence of record shows that,

given the disclosure of the types of plastic, it would have been readily apparent to one of skill in the art to select the particular grade of plastic that would result in efficient DPA operation. In fact, Kraenzle also selected Lexan 141 and Celcon M-90 for use with his DPAs. He testified that he did so at the suggestion of his mold maker because the grades were “general purpose grades, which are right from the Lexan manual.” In his ’859 patent, Kraenzle, like Bailey, only disclosed the general types of plastics he used and not the particular grades. It thus seems rather curious for Q3 to argue here that disclosure of particular types of plastic are not routine details for purposes of Bailey’s application when Kraenzle did not disclose such information in his own application.

Comments

1. *The Two-Part Test.* Compliance with the best mode requirement entails application of a two-part test. The first part is subjective, and asks whether at the time of filing the inventor knew of a mode of making and using his invention that he considered best. Importantly, the best mode requirement is not an issue if someone other than the inventor knew of a best mode at the time of filing, even if that other person was employed by the same company as the inventor and the company was the assignee. See *Glaxo, Inc. v. Novopharm Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995). If the answer to the first question is yes, the second part of test, which is objective, is reached. This part of the test compares what the inventor knew with what he disclosed by framing the question as follows: Is the disclosure adequate to enable one of ordinary skill in the art to practice the best mode or has the inventor “concealed” his preferred mode? See *Northern Telecom Ltd. v. Samsung Electronics Co., Ltd.*, 215 F.3d 1281, 1286 (Fed. Cir. 2000). Interestingly, there is no duty to update the best mode after the application has been filed. Arguably, this lack of duty to update is inconsistent with the underlying policies of the disclosure requirements.

Failure to comply with the best mode requirement typically occurs in two situations. First, when the patent specification does not adequately disclose a preferred embodiment of the claimed invention, and second, when the patentee fails “to disclose aspects of making or using the claimed invention and the undisclosed matter materially affected the properties of the claimed invention.” *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F.3d 1306, 1319 (Fed. Cir. 2002).

2. *Production Details.* Some information, commonly referred to as “production details,” do not need to be disclosed. As noted in *Young Dental*, there are two types of production details. First, so-called commercial considerations such as the equipment on hand or prior relationships with suppliers are not required to be disclosed. These are considerations that do not relate to the quality of the claimed invention. The second type of production detail are qualitatively significant vis-à-vis the claimed invention, but are deemed routine, such as details of production of which those of ordinary skill in the art are aware. See *Great Northern Corp. v. Henry Molded Products, Inc.*, 94 F.3d 1569 (Fed. Cir. 1996).

3. *Best Mode—An Uncommon Requirement.* The United States is one of a very small minority of countries that has a best mode requirement. Other

countries that have what can be characterized as a best mode requirement include Egypt, Brazil, and Colombia. The Egyptian *Law on Protection of Intellectual Property Rights, Book One, Part I, Article 13*, states the “patent application shall be accompanied by a detailed description of the invention, including a full statement of the subject matter and the best way to enable a person of expertise to execute it.” The Colombian provision, found in *The Andean Community, Decision 486, Article 28(e)* reads the “description shall contain the name of the invention and . . . a description of the best method known to the applicant for carrying out the invention. . . .” And *Article 24 of the Brazilian Industrial Property Code* states the “specification shall clearly and sufficiently describe the object, so as to permit its reproduction by a technician versed in the subject, and shall indicate, when applicable, the best of doing it.” Article 29 of TRIPS permits signatory countries to have a best mode requirement, but does not require such. Article 29.1 states:

Article 29

Conditions on Patent Applicants

1. Members . . . **may** require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date. . . .

(emphasis added).

D. DEFINITENESS

The second paragraph of section 112 is commonly referred to as the “definiteness requirement.” This section—which demands the patentee draft clear and distinct claims—has two purposes. First, a clearly drafted claim provides notice to competitors (and the public generally) of the boundaries of the patentee’s property rights. The second purpose is to distinguish the claimed invention from the prior art.

STATUTE: Specification

35 U.S.C. § 112, ¶ 2

DATAMIZE LLC v. PLUMTREE SOFTWARE, INC.

417 F.3d 1342 (Fed. Cir. 2005)

PROST, Circuit Judge.

Datamize, L.L.C. (“Datamize”) appeals from a decision of the United States District Court for the Northern District of California holding each claim of United States Patent No. 6,014,137 (“the ’137 patent”) invalid as indefinite under 35 U.S.C. § 112, ¶ 2. We affirm.

BACKGROUND

A. The ’137 Patent and Related Prosecution History

The ’137 patent, entitled “Electronic Kiosk Authoring System,” discloses a software program that allows a person to author user interfaces for electronic

kiosks. “The authoring system enables the user interface for each individual kiosk to be customized quickly and easily within wide limits of variation, yet subject to constraints adhering the resulting interface to good standards of aesthetics and user friendliness.” ’137 patent, Abstract; *see also id.* at col. 3, ll. 28-32.

The authoring system gives the system author a limited range of pre-defined design choices for stylistic and functional elements appearing on the screens. *Id.* at col. 3, ll. 52-57. “[M]ajor aesthetic or functional design choices . . . as well as hierarchical methods of retrieving information may be built into the system [while] taking into account the considered opinions of aesthetic design specialists, database specialists, and academic studies on public access kiosk systems and user preferences and problems.” *Id.* at col. 3, ll. 57-64.

At issue in this appeal is the definiteness of “aesthetically pleasing” as it is used in the context of claim 1 of the ’137 patent. The “aesthetically pleasing” claim language was not discussed by the inventor or the patent examiner during prosecution of the application that led to the ’137 patent. The language was discussed, however, during prosecution of a continuation application to the ’137 patent, which eventually issued as United States Patent No. 6,460,040 (“the ’040 patent”). The patent examiner reviewing the application leading to the ’040 patent rejected a claim as being indefinite for using the phrase “aesthetically pleasing.” In response to this rejection, the inventor argued that the phrase is definite, but ultimately deleted it, stating in part that it is “not intended to identify qualities separate and apart from the remainder of this claim element” and is “superfluous and unnecessary.”

* * *

Concluding that the phrase “aesthetically pleasing” in claim 1 is “hopelessly indefinite,” the district court granted Plumtree’s motion for summary judgment of invalidity. Since claim 1 is the ’137 patent’s sole independent claim, the court’s grant of summary judgment of indefiniteness as to claim 1 invalidated each claim in the ’137 patent.

DISCUSSION

* * *

B. The Law of Indefiniteness

Every patent’s specification must “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2 (2000). Because the claims perform the fundamental function of delineating the scope of the invention, the purpose of the definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee’s right to exclude.

According to the Supreme Court, “[t]he statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise.” *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942). The definiteness requirement, however, does not compel absolute clarity. Only claims “not amenable to construction” or “insolubly ambiguous” are indefinite. Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable

meaning. Furthermore, a difficult issue of claim construction does not *ipso facto* result in a holding of indefiniteness. *Exxon Research & Eng'g*, 265 F.3d at 1375. “If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.” *Id.* In this regard it is important to note that an issued patent is entitled to a statutory presumption of validity. See 35 U.S.C. § 282 (2000). “By finding claims indefinite only if reasonable efforts at claim construction prove futile, we accord respect to the statutory presumption of validity and we protect the inventive contribution of patentees, even when the drafting of their patents has been less than ideal.” *Exxon Research & Eng'g*, 265 F.3d at 1375. In this way we also follow the requirement that clear and convincing evidence be shown to invalidate a patent.

In the face of an allegation of indefiniteness, general principles of claim construction apply. Intrinsic evidence in the form of the patent specification and file history should guide a court toward an acceptable claim construction. *Phillips v. AWH Corp.* And while “we have emphasized the importance of intrinsic evidence in claim construction, we have also authorized district courts to rely on extrinsic evidence,” such as expert testimony. *Id.* at 18. In construing claims, “what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.” *Id.* at 31.

C. Analysis

With these principles in mind, we proceed to the question at hand: whether the '137 patent's use of “aesthetically pleasing” meets the standards articulated in our case law concerning definiteness. We begin our analysis by noting our agreement with the district court's understanding that the ordinary meaning of “aesthetically pleasing” includes “having beauty that gives pleasure or enjoyment” or, in other words, “beautiful.” We also recognize that the district court's opinion presents a reasoned and detailed analysis of both the intrinsic evidence, including the specification of the '137 patent and the prosecution history of the '040 patent, and the extrinsic evidence in the form of Datamize's expert testimony. Datamize, however, argues that the district court erred by considering the phrase “aesthetically pleasing” divorced from the context of claim 1.

Datamize is right to point out that the phrase “aesthetically pleasing” should be considered in the context of claim 1. “Aesthetically pleasing” is used three times in claim 1. The first use of “aesthetically pleasing” relates to the look and feel of custom interface screens on kiosks:

providing a plurality of pre-defined interface screen element types, each element type defining a form of element available for presentation on said custom interface screens, wherein each said element type permits limited variation in its on-screen characteristics in conformity with a desired uniform and *aesthetically pleasing* look and feel for said interface screens on all kiosks of said kiosk system.

'137 patent, col. 20, ll. 50-57 (emphasis added).

The second use relies on the first use for antecedent basis and similarly relates to the look and feel of interface screens:

each element type having a plurality of attributes associated therewith, wherein each said element type and its associated attributes are subject to pre-defined

constraints providing element characteristics in conformance with said uniform and *aesthetically pleasing* look and feel for said interface screens.

Id. at col. 20, ll. 58-63 (emphasis added).

The third use provides a slightly different context, relating to the aggregate layout of elements on the interface screen:

assigning values to the attributes associated with each of said selected elements consistent with said pre-defined constraints, whereby the aggregate layout of said plurality of selected elements on said interface screen under construction will be *aesthetically pleasing* and functionally operable for effective delivery of information to a kiosk user.

Id. at col. 21, ll. 6-12 (emphasis added). Thus, in the context of claim 1, “aesthetically pleasing” relates to the look and feel of custom interface screens on kiosks, and the aggregate layout of elements on an interface screen is apparently one example or aspect of the interface screens that may be “aesthetically pleasing.”

This context, while helpful in terms of identifying the components of the claimed invention that must be “aesthetically pleasing,” does not suggest or provide any meaningful definition for the phrase “aesthetically pleasing” itself. Merely understanding that “aesthetically pleasing” relates to the look and feel of interface screens, or more specifically to the aggregate layout of elements on interface screens, fails to provide one of ordinary skill in the art with any way to determine whether an interface screen is “aesthetically pleasing.”

Datamize, however, contends that when construed in the context of claim 1, the phrase “aesthetically pleasing” applies to the process of defining a “desired” result and not the actual result itself. Datamize believes a reasonable construction of “aesthetically pleasing” in the context of the claims involves the intent, purpose, wish, or goal of a person practicing the invention: that person simply must intend to create an “aesthetically pleasing” interface screen; whether that person actually succeeds is irrelevant. In other words, Datamize suggests we adopt a construction of “aesthetically pleasing” that only depends on the subjective opinion of a person selecting features to be included on an interface screen. Indeed, Datamize argues that the district court erred by requiring an objective definition for the phrase “aesthetically pleasing.” Citing our decision in *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1575-76 (Fed. Cir. 1986), Datamize maintains that a claim term need not be subject to a single, objective definition to be definite but rather may include a subjective element. According to Datamize, subjective terms are permissible so long as one of ordinary skill in the art would understand their scope. In this regard, Datamize, citing *Seattle Box Co. v. Industrial Crate & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984), implies that “aesthetically pleasing” includes “words of degree” that are not fatally imprecise. Datamize also contends that the existence of aesthetic constraints in a computer program, as opposed to purely functional constraints, would be circumstantial evidence of a person’s subjective “desire” to achieve an “aesthetically pleasing” look and feel for an interface screen. Related to these arguments, Datamize believes that the person practicing the invention is the “system creator,” defined by Datamize as the person who creates the authoring software. According to Datamize, the appropriate inquiry would focus on

whether a system creator makes aesthetic choices to limit or constrain the possible on-screen characteristics of screen elements since these choices would reflect a subjective intent to create an “aesthetically pleasing” look and feel for an interface screen.

Datamize’s proposed construction of “aesthetically pleasing” in the context of claim 1 is not reasonable for several reasons. First and foremost, the plain meaning of the claim language requires that the look and feel of interface screens actually be “aesthetically pleasing.” The first use of “aesthetically pleasing” in claim 1 clearly sets forth two requirements for the look and feel of interface screens: the look and feel must be (1) uniform and (2) “aesthetically pleasing.” That the uniform and “aesthetically pleasing” look and feel must also be “desired” does not alter that fact.

Furthermore, in *Orthokinetics* we did not conclude, as Datamize suggests, that the absence of an objective definition for a claim term does not render the phrase indefinite. In that case we concluded that the phrase “so dimensioned” in the following limitation is not indefinite: “wherein said front leg portion is *so dimensioned* as to be insertable through the space between the doorframe of an automobile and one of the seats thereof.” *Orthokinetics*, 806 F.2d at 1575. We noted that based on expert testimony it was undisputed that one of ordinary skill in the art would easily have been able to determine the appropriate dimensions that the claim language required. *Id.* at 1576. One desiring to build and use the invention, a travel chair, “must measure the space between the selected automobile’s doorframe and its seat and then dimension the front legs of the travel chair so they will fit in that particular space in that particular automobile.” *Id.* The fact that the claims were intended to cover the use of the invention with various types of automobiles made no difference; we concluded that the phrase “so dimensioned” is as accurate as the subject matter permits since automobiles are of various sizes. *Id.* Thus, in *Orthokinetics* we recognized that an objective definition encompassed by the claim term “so dimensioned” could be applied to innumerable specific automobiles.

In stark contrast to *Orthokinetics*, here Datamize has offered no objective definition identifying a standard for determining when an interface screen is “aesthetically pleasing.” In the absence of a workable objective standard, “aesthetically pleasing” does not just include a subjective element, it is completely dependent on a person’s subjective opinion. To the extent Datamize argues that such a construction of “aesthetically pleasing” does not render the phrase indefinite, we disagree. The scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention. Some objective standard must be provided in order to allow the public to determine the scope of the claimed invention. Even if the relevant perspective is that of the system creator, the identity of who makes aesthetic choices fails to provide any direction regarding the relevant question of how to determine whether that person succeeded in creating an “aesthetically pleasing” look and feel for interface screens. A purely subjective construction of “aesthetically pleasing” would not notify the public of the patentee’s right to exclude since the meaning of the claim language would depend on the unpredictable vagaries of any one person’s opinion of the aesthetics of interface screens. While beauty is in the eye of the beholder, a claim term, to be definite, requires an objective anchor.

Thus, even if we adopted a completely subjective construction of “aesthetically pleasing,” this would still render the ’137 patent invalid.

Furthermore, “aesthetically pleasing” does not exactly compare to words of degree such as “substantially equal to,” see *Seattle Box Co.*, 731 F.2d at 826, “about,” see *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372-73 (Fed. Cir. 2003), or “substantial absence,” see *Exxon Research & Eng’g*, 265 F.3d at 1380-81. The language, however, invokes a similar analysis. “When a word of degree is used the district court must determine whether the patent’s specification provides some standard for measuring that degree.” *Seattle Box Co.*, 731 F.2d at 826. Similarly, when faced with a purely subjective phrase like “aesthetically pleasing,” a court must determine whether the patent’s specification supplies some standard for measuring the scope of the phrase. Thus, we next consult the written description. See *id.*

... [W]hile the description of an embodiment provides examples of aesthetic features of screen displays that can be controlled by the authoring system, it does not explain what selection of these features would be “aesthetically pleasing.” Major aesthetic choices apparently may include some aspect of button styles and sizes, window borders, color combinations, and type fonts. The written description, however, provides no guidance to a person making aesthetic choices such that their choices will result in an “aesthetically pleasing” look and feel of an interface screen. For example, the specification does not explain what factors a person should consider when selecting a feature to include in the authoring system. Left unanswered are questions like: which color combinations would be “aesthetically pleasing” and which would not? And more generally, how does one determine whether a color combination is “aesthetically pleasing”? Again, one skilled in the art reading the specification is left with the unhelpful direction to consult the subjective opinions of aesthetic design specialists, database specialists, and academic studies.

Simply put, the definition of “aesthetically pleasing” cannot depend on an undefined standard. Reference to undefined standards, regardless of whose views might influence the formation of those standards, fails to provide any direction to one skilled in the art attempting to determine the scope of the claimed invention. In short, the definition of “aesthetically pleasing” cannot depend on the undefined views of unnamed persons, even if they are experts, specialists, or academics. Thus, the written description does not provide any reasonable, definite construction of “aesthetically pleasing.”

Comments

1. ***The Policies of Definiteness.*** The policies underlying the definiteness requirement have been part of patent law jurisprudence since at least the late 19th century. As the Supreme Court in *Bates v. Coe*, 98 U.S. 31, 39 (1878), wrote:

Accurate description of the invention is required by law, for several important purposes: (1) That the government may know what is granted, and what will become public property when the term of the monopoly expires; (2) That licensed persons desiring to practice the invention may know during the term

how to make, construct, and use the invention; [and] (3) That other inventors may know what part of the field of invention is unoccupied.

There are two important points to take away from this language. First, patents are written by and for persons of skill in the art, what *Bates* refers to as “inventors” and “persons desiring to practice the invention.” Thus, when interpreting claims, it is the person of technical skill in the art whose perspective and understanding is relevant, not the lay person or judge. (The issue of claim interpretation is explored in detail in Chapter 7.) The key inquiry under definiteness “requires an analysis of whether those persons skilled in the art would understand the bounds of the claim when read in light of the specification,” *Credle v. Bond*, 25 F.3d 1566, 1576 (Fed. Cir. 1994). Recall, this person with technical skill—what is referred to as the “person having ordinary skill in the art”—is central to determining compliance with the three disclosure requirements of § 112, ¶ 1 and, as you will see, is equally central to several other important determinations in patent law.

The second point is that certainty and security in property rights are paramount concerns in any property rights regime, including patent law. See TERRY L. ANDERSON & PETER J. HILL, *THE NOT SO WILD, WILD WEST* 206 (2004) (stating “[w]ell-defined and secure property rights for intellectual property are a key to economic growth in the modern world”). Competitors of the patent owner should be provided with enough notice regarding the metes and bounds of the patent owner’s property interest so that the competitor can make an informed decision as where he should and should not tread.

Certainty is a virtue in numerous areas of law, and in our daily lives. Imagine driving on the interstate when you come upon a sign that reads: “Drive at a Reasonable Speed.” Would you prefer this standard to “Speed Limit—65 m.p.h.”? Most of us (perhaps) would opt for the former because it provides us with more certainty. Unfortunately, it is not that simple in patent law because, as will be explored in Chapter 7, the policies of the definiteness requirement must be counter-balanced with questions of claim scope (as we saw in *Morse*) and the Doctrine of Equivalents, a common law doctrine that permits a patent owner to expand the scope of his literal claim language. In addition, and more fundamentally, language is an imperfect device to describe a non-tangible object; some amount of ambiguity is always going to be present, which is why, as Comment 2 explains, “mathematical precision” is not needed when drafting claims.

2. **“Mathematical Precision” Not Needed.** How precise claim language must be is largely a function of the nature of the subject matter. See *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). Thus, a patentee does not have to “define his invention with mathematical precision” to comply with the definiteness requirement; indeed, terms of degree such as “substantially” or “about” are frequently and properly used in claim drafting. In short, only claims “not amenable to construction” or “insolubly ambiguous” are indefinite. See *Datamize*. The word “substantially” may be ambiguous to a lay person or a judge, but definite to a person of ordinary skill in the art. As the Federal Circuit stated, “when the term ‘substantially’ serves reasonably to describe the subject matter so that its

scope would be understood by persons in the field of invention, and to distinguish the claimed subject matter from the prior art, it is not indefinite.” *Verve, LLC. v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002).

The Federal Circuit relied on *Datamize in Young v. Lumenis, Inc.* 492 F.3d 1336 (Fed. Cir. 2007). In *Lumenis*, Dr. Young invented a surgical method for declawing a domesticated cat. One claim limitation read: “forming a first circumferential incision in the epidermis *near* the edge of the ungual crest of the claw” (emphasis added). The district court found the word “near” to be indefinite under § 112, ¶ 2, and relied on *Amgen Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991), for the “principle that a word of degree can be indefinite when it fails to distinguish the invention over the prior art and does not permit one of ordinary skill to know what activity constitutes infringement.” The Federal Circuit reversed. The court cited *Datamize* for the proposition that claims are indefinite if they “not amenable to construction or are insolubly ambiguous. . . . Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning.” 417 F.3d at 1347. The court wrote: “As used in the claim, the term ‘near’ is not insolubly ambiguous and does not depart from the ordinary and customary meaning of the phrase ‘near’ as meaning ‘close to or at’ the edge of the ungual crest. Reference to the specification shows that it is consistent with that understanding of the term.” 492 F.3d at 1346.

In *Bancorp Services, L.L.C. v. Hartford Life Insurance Co.*, 359 F.3d 1367 (Fed. Cir. 2004). Bancorp owned a patent related to a system for administering and tracking the value of life insurance policies in several accounts. All of the independent claims of the patent referred to “surrender value protected investment credits,” and it is this phrase that Hartford asserted was indefinite. Hartford argued that the term was not defined in the patent and it does not have a commonly understood meaning by persons having ordinary skill in the art. The court agreed with Hartford that “surrender value protected investment credits” was not defined in the patent and Bancorp did not provide an industry publication that defines the term. Nevertheless, said the court, “the components of the term have well-recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence.” The court, citing the presumption of validity that accompanies issued patents, expressed a reluctance to invalidate claims that are not “insolubly ambiguous.” For the court, a claim is not indefinite “if the meaning of the claim is discernible, “even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree.” Another case where the court was reluctant to invalidate a claim based on indefiniteness was *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573 (Fed. Cir. 1996). There the court believed the claim language in question was subject to two interpretations, one narrower than the other, but both enabled by the specification. In this situation, the court adopted the narrower interpretation instead of invalidating the claim. The court based its decision on the notice function of the patent claim and created a canon of construction, as follows:

Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.

Id. at 1581.

3. **History of the Patent Claim.** The claim is an early 19th-century innovation of patent attorneys that was developed to assist clients in proving validity and infringement. See John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 309 (stating the claim “arose not from any administrative, judicial, or legislative requirement. Instead, it was an innovation of patent attorneys, and it was formulated to protect and to expand the rights of patentees”). See also Karl B. Lutz, *Evolution of the Claims of U.S. Patents*, 20 J. PAT. OFF. SOC’Y 134 (1938); William Redin Woodward, *Definiteness and Particularity in Patent Claims*, 46 MICH. L. REV. 755 (1948).

CHAPTER

3

Eligible Subject Matter and Utility

INTRODUCTION

The statutory subject matter requirement—which shares the same statutory section as utility—pertains to the kinds of inventions that are eligible for patent protection.¹ The types of inventions set forth in § 101 include a “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” These terms, characterized as the “great and distinct classes of invention,”² have been part of the American patent system for more than 200 years.³ Like the utility requirement, statutory subject matter is seldom an impediment to patent protection, the heavy lifting being done by §§ 102, 103, and 112. The principal cases of *Chakrabarty* and *Harvard College* relate to living matter; *State Street* and *AT&T* pertain to software and business methods. In *Chakrabarty*, the Supreme Court held that living matter is patentable, famously writing that “‘anything under the sun that is made by man’ constitutes potential subject matter for a patent.” The “made by man” language of *Chakrabarty* is important, because it demands human intervention in the subject matter sought to be patented. Indeed, courts have consistently reaffirmed the principle that laws of nature, physical phenomena, and abstract ideas are not eligible for patent protection.

The utility requirement is, most fundamentally, based on the IP clause of the Constitution, which empowers Congress “to promote the progress of the *useful* arts” by granting patents.⁴ The statutory foundation is set forth in § 101 of the patent code, which requires inventions to be “useful.” But beyond this single word in the Constitution and § 101,⁵ Congress has left the development of

1. See *In re Bergy*, 596 F.2d 952 (CCPA 1979) (referring to § 101, the court stated “[t]he question here, as it has always been, is: are the inventions claimed of a *kind* contemplated by Congress as possibly patentable *if* they turn out to be new, useful, and unobvious within the meaning of those terms as used in the statute”) (emphasis in original).

2. *Ex parte Blythe*, 1885 Comm’n Dec. 82, 86 (Comm’r Pat. 1885).

3. The 1793 Act used the word “art” instead of “process,” but the courts have commonly equated “process” and “art” or subsumed process within “art.” It was not until the 1952 Patent Act, that Congress, for clarification, changed the word “art” to “process.”

4. See *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991).

5. And a more indirect utility requirement in § 112, ¶ 1, which requires the specification enable a person having skill in the art to “make and use” the claimed invention.

what is “useful” to the courts. Judicial interpretation of the utility requirement has evolved to include an operability component and a substantiality component. Operability, which is explored in the *Swartz* case, simply asks does the invention work as claimed and described in the patent. This form of utility is easily satisfied and is rarely a concern for patent applicants or patentees during litigation. Substantial utility, discussed in *Brenner v. Manson* and *In re Fisher*, is a more subjective and controversial inquiry focusing on the degree of usefulness or whether the claimed invention has enough utility given the policies of patent law. (The related doctrine of “specific utility” is also explored in *Fisher* and the Comments.) Substantial utility plays a significant role in genomic- and chemical-related inventions, which commonly involve building blocks of research and upstream research tools.

STATUTE: Inventions patentable

35 U.S.C. § 101

A. ELIGIBLE SUBJECT MATTER

The statutory subject matter requirement is similar to the utility requirement in two ways. First, they both find a home in § 101 of Title 35, and second, neither of them have been—in the past several years, at least—significant obstacles to patentability. (The possible exception is substantial utility applied to biomedical inventions.) Yet they each have generated a great deal of academic discussion and remain conceptually important to our understanding of what types of inventions we want to allow in and subject to the more rigorous requirements embodied in §§ 102, 103, and 112. In addition, it is a distinct possibility that § 101—particularly the statutory subject matter requirement—will become more relevant in the near future.

The courts have taken an expansive view of statutory subject matter; indeed, Chief Justice Burger famously wrote that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” *Diamond v. Chakrabarty*, discussed below. As a result, genetic materials such as DNA sequences, proteins, software, and business methods are eligible subject matter under § 101. It is important to note, however, that there are certain types of things that are not eligible for patent protection, namely laws of nature and abstract ideas such as $E=mc^2$. The Europeans, however, have broader exclusionary rules.

The most important (and interesting) subject matter questions relate to (1) biomedical-related inventions; and (2) software and business methods. The principal cases are devoted to these technologies.

STATUTE: Inventions patentable

35 U.S.C. § 101

1. Biomedical-Related Inventions**DIAMOND v. CHAKRABARTY****447 U.S. 303 (1980)**

Chief Justice BURGER delivered the opinion of the Court.

We granted certiorari to determine whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.

I

In 1972, respondent Chakrabarty, a microbiologist, filed a patent application, assigned to the General Electric Co. The application asserted 36 claims related to Chakrabarty's invention of "a bacterium". . . . This human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills.²

Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves. The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: (1) that micro-organisms are "products of nature," and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101.

Chakrabarty appealed the rejection of these claims to the Patent Office Board of Appeals, and the Board affirmed the Examiner on the second ground. Relying on the legislative history of the 1930 Plant Patent Act, in which Congress extended patent protection to certain asexually reproduced plants, the Board concluded that § 101 was not intended to cover living things such as these laboratory created micro-organisms.

The Court of Customs and Patent Appeals, by a divided vote, [in an opinion by Judge Rich,] reversed on the authority of its prior decision in *In re Bergy*, 563 F.2d 1031, 1038 (1977), which held that "the fact that microorganisms . . . are alive . . . [is] without legal significance" for purposes of the patent law. Subsequently, we granted the Acting Commissioner of Patents and Trademarks' petition for certiorari in *Bergy*, vacated the judgment, and remanded the case "for further consideration in light of *Parker v. Flook*." The Court of Customs and Patent Appeals then vacated its judgment in *Chakrabarty* and consolidated the case with *Bergy* for reconsideration. After re-examining both

2. At present, biological control of oil spills requires the use of a mixture of naturally occurring bacteria, each capable of degrading one component of the oil complex. In this way, oil is decomposed into simpler substances which can serve as food for aquatic life. However, for various reasons, only a portion of any such mixed culture survives to attack the oil spill. By breaking down multiple components of oil, Chakrabarty's micro-organism promises more efficient and rapid oil-spill control.

cases in the light of our holding in *Flook*, that court, with one dissent, [again through Judge Rich,] reaffirmed its earlier judgments.

The Commissioner of Patents and Trademarks again sought certiorari, and we granted the writ as to both *Bergy* and *Chakrabarty*. Since then, *Bergy* has been dismissed as moot, leaving only *Chakrabarty* for decision.

II

The Constitution grants Congress broad power to legislate to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Art. I, § 8, cl. 8. The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. *Kewanee Oil Co. v. Bicron Corp.*; *Universal Oil Co. v. Globe Co.* The authority of Congress is exercised in the hope that “[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.” *Kewanee*, 416 U.S. at 480.

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101, which provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Specifically, we must determine whether respondent’s micro-organism constitutes a “manufacture” or “composition of matter” within the meaning of the statute.

III

In cases of statutory construction we begin, of course, with the language of the statute. *Southeastern Community College v. Davis*. And “unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning.” *Perrin v. United States*, 444 U.S. 37, 42 (1979). We have also cautioned that courts “should not read into the patent laws limitations and conditions which the legislature has not expressed.” *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933).

Guided by these canons of construction, this Court has read the term “manufacture” in § 101 in accordance with its dictionary definition to mean “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.” *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931). Similarly, “composition of matter” has been construed consistent with its common usage to include “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280 (D.C. 1957). In choosing such expansive terms as “manufacture” and “composition of matter,” modified by the comprehensive “any,” Congress plainly contemplated that the patent laws would be given wide scope.

The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as “any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].” Act of Feb. 21, 1793, § 1, 1 Stat. 319. The Act embodied Jefferson’s philosophy that “ingenuity should receive a liberal encouragement.” 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871). See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word “art” with “process,” but otherwise left Jefferson’s language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to “include anything under the sun that is made by man.” S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. See *Parker v. Flook*; *Gottschalk v. Benson*; *Funk Brothers Seed Co. v. Kalo Inoculant Co.*; *O’Reilly v. Morse*; *Le Roy v. Tatham*. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.” *Funk Brothers*, *supra*, 333 U.S., at 130.

Judged in this light, respondent’s micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity “having a distinctive name, character [and] use.” *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887). The point is underscored dramatically by comparison of the invention here with that in *Funk*. There, the patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants. Concluding that the patentee had discovered “only some of the handiwork of nature,” the Court ruled the product nonpatentable:

Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee. 333 U.S., at 131.

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.

IV

Two contrary arguments are advanced, neither of which we find persuasive.

(A)

The petitioner's first argument rests on the enactment of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection. In the petitioner's view, the passage of these Acts evidences congressional understanding that the terms "manufacture" or "composition of matter" do not include living things; if they did, the petitioner argues, neither Act would have been necessary.

We reject this argument. Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. This position appears to have derived from the decision of the patent office in *Ex parte Latimer*, in which a patent claim for fiber found in the needle of the *Pinus australis* was rejected. The Commissioner reasoned that a contrary result would permit "patents [to] be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible." *Id.*, at 126. The *Latimer* case, it seems, came to "se[t] forth the general stand taken in these matters" that plants were natural products not subject to patent protection. The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the "written description" requirement of the patent law. *See* 35 U.S.C. § 112. Because new plants may differ from old only in color or perfume, differentiation by written description was often impossible.

In enacting the Plant Patent Act, Congress addressed both of these concerns. It explained at length its belief that the work of the plant breeder "in aid of nature" was patentable invention. S. Rep. No. 315, 71st Cong., 2d Sess., 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7-9 (1930). And it relaxed the written description requirement in favor of "a description . . . as complete as is reasonably possible." 35 U.S.C. § 162. No Committee or Member of Congress, however, expressed the broader view, now urged by the petitioner, that the terms "manufacture" or "composition of matter" exclude living things. The sole support for that position in the legislative history of the 1930 Act is found in the conclusory statement of Secretary of Agriculture Hyde, in a letter to the Chairmen of the House and Senate Committees considering the 1930 Act, that "the patent laws . . . at the present time are understood to cover only inventions or discoveries in the field of inanimate nature." *See* S. Rep. No. 315, *supra*, at Appendix A; H.R. Rep. No. 1129, *supra*, at Appendix A. Secretary Hyde's opinion, however, is not entitled to controlling weight. His views were solicited on the administration of the new law and not on the scope of patentable subject matter—an area beyond his competence. Moreover, there is language in the House and Senate Committee Reports suggesting that to the extent Congress considered the matter it found the Secretary's dichotomy unpersuasive. The Reports observe:

There is a clear and logical distinction *between the discovery of a new variety of plant and of certain inanimate things*, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man. . . . On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man. . . . (emphasis added).

Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's micro-organism is the result of human ingenuity and research. Hence, the passage of the Plant Patent Act affords the Government no support.

Nor does the passage of the 1970 Plant Variety Protection Act support the Government's position. As the Government acknowledges, sexually reproduced plants were not included under the 1930 Act because new varieties could not be reproduced true-to-type through seedlings. Brief for Petitioner 27, n. 31. By 1970, however, it was generally recognized that true-to-type reproduction was possible and that plant patent protection was therefore appropriate. The 1970 Act extended that protection. There is nothing in its language or history to suggest that it was enacted because § 101 did not include living things.

In particular, we find nothing in the exclusion of bacteria from plant variety protection to support the petitioner's position. The legislative history gives no reason for this exclusion. As the Court of Customs and Patent Appeals suggested, it may simply reflect congressional agreement with the result reached by that court in deciding *In re Arzberger*, which held that bacteria were not plants for the purposes of the 1930 Act. Or it may reflect the fact that prior to 1970 the Patent Office had issued patents for bacteria under § 101. In any event, absent some clear indication that Congress "focused on [the] issues . . . directly related to the one presently before the Court," *SEC v. Sloan*, 436 U.S. 103, 120-121 (1978), there is no basis for reading into its actions an intent to modify the plain meaning of the words found in § 101.

(B)

The petitioner's second argument is that micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. His position rests on the fact that genetic technology was unforeseen when Congress enacted § 101. From this it is argued that resolution of the patentability of inventions such as respondent's should be left to Congress. The legislative process, the petitioner argues, is best equipped to weigh the competing economic, social, and scientific considerations involved, and to determine whether living organisms produced by genetic engineering should receive patent protection. In support of this position, the petitioner relies on our recent holding in *Parker v. Flook*, and the statement that the judiciary "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress." *Id.*, at 596.

It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is "the

province and duty of the judicial department to say what the law is.” *Marbury v. Madison*, 1 Cranch 137, 177 (1803). Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose. Here, we perceive no ambiguity. The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting “the Progress of Science and the useful Arts” with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.

Nothing in *Flook* is to the contrary. That case applied our prior precedents to determine that a “claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101.” 437 U.S., at 595, n. 18. The Court carefully scrutinized the claim at issue to determine whether it was precluded from patent protection under “the principles underlying the prohibition against patents for ‘ideas’ or phenomena of nature.” *Id.*, at 593. We have done that here. *Flook* did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable per se.

To read that concept into *Flook* would frustrate the purposes of the patent law. This Court frequently has observed that a statute is not to be confined to the “particular application[s] . . . contemplated by the legislators.” *Barr v. United States*, 324 U.S. 83, 90 (1945). This is especially true in the field of patent law. A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. See *Graham v. John Deere Co.*, 383 U.S., at 12-17. Mr. Justice Douglas reminded that the inventions most benefiting mankind are those that “push back the frontiers of chemistry, physics, and the like.” *Great A. & P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 154 (1950) (concurring opinion). Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable.

To buttress his argument, the petitioner, with the support of *amicus*, points to grave risks that may be generated by research endeavors such as respondent’s. The briefs present a gruesome parade of horrors. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that with Hamlet, it is sometimes better “to bear those ills we have than fly to others that we know not of.”

It is argued that this Court should weigh these potential hazards in considering whether respondent’s invention is patentable subject matter under

§ 101. We disagree. The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.

What is more important is that we are without competence to entertain these arguments — either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

We have emphasized in the recent past that “[o]ur individual appraisal of the wisdom or unwisdom of a particular [legislative] course . . . is to be put aside in the process of interpreting a statute.” *TVA v. Hill*, 437 U.S., at 194. Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. Cf. 42 U.S.C. § 2181(a), exempting from patent protection inventions “useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.” Or it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of § 101 as it is. The language of that section fairly embraces respondent's invention.

Justice BRENNAN, with whom Justice WHITE, Justice MARSHALL, and Justice POWELL join, dissenting.

I agree with the Court that the question before us is a narrow one. Neither the future of scientific research, nor even, the ability of respondent Chakrabarty to reap some monopoly profits from his pioneering work, is at stake. Patents on the processes by which he has produced and employed the new living organism are not contested. The only question we need decide is whether Congress, exercising its authority under Art. I, § 8, of the Constitution, intended that he be able to secure a monopoly on the living organism itself, no matter how produced or how used. Because I believe the Court has misread the applicable legislation, I dissent.

The patent laws attempt to reconcile this Nation's deep seated antipathy to monopolies with the need to encourage progress. Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there

an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.

In this case, however, we do not confront a complete legislative vacuum. The sweeping language of the Patent Act of 1793, as re-enacted in 1952, is not the last pronouncement Congress has made in this area. In 1930 Congress enacted the Plant Patent Act affording patent protection to developers of certain asexually reproduced plants. In 1970 Congress enacted the Plant Variety Protection Act to extend protection to certain new plant varieties capable of sexual reproduction. Thus, we are not dealing—as the Court would have it—with the routine problem of “unanticipated inventions.” *Ante*. In these two Acts Congress has addressed the general problem of patenting animate inventions and has chosen carefully limited language granting protection to some kinds of discoveries, but specifically excluding others. These Acts strongly evidence a congressional limitation that excludes bacteria from patentability.²

First, the Acts evidence Congress’ understanding, at least since 1930, that § 101 does not include living organisms. If newly developed living organisms not naturally occurring had been patentable under § 101, the plants included in the scope of the 1930 and 1970 Acts could have been patented without new legislation. Those plants, like the bacteria involved in this case, were new varieties not naturally occurring.³ Although the Court, *ante*, rejects this line of argument, it does not explain why the Acts were necessary unless to correct a pre-existing situation.⁴ I cannot share the Court’s implicit assumption that Congress was engaged in either idle exercises or mere correction of the public record when it enacted the 1930 and 1970 Acts. And Congress certainly thought it was doing something significant. The Committee Reports contain expansive prose about the previously unavailable benefits to be derived from

2. But even if I agreed with the Court that the 1930 and 1970 Acts were not dispositive, I would dissent. This case presents even more cogent reasons than *Deepsouth Packing Co.* not to extend the patent monopoly in the face of uncertainty. At the very least, these Acts are signs of legislative attention to the problems of patenting living organisms, but they give no affirmative indication of congressional intent that bacteria be patentable. The caveat of *Parker v. Flook*, 437 U.S. 584, 596 (1978), an admonition to “proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress,” therefore becomes pertinent. I should think the necessity for caution is that much greater when we are asked to extend patent rights into areas Congress has foreseen and considered but has not resolved.

3. The Court refers to the logic employed by Congress in choosing not to perpetuate the “dichotomy” suggested by Secretary Hyde. *Ante*, at 2209. But by this logic the bacteria at issue here are distinguishable from a “mineral . . . created wholly by nature” in exactly the same way as were the new varieties of plants. If a new Act was needed to provide patent protection for the plants, it was equally necessary for bacteria. Yet Congress provided for patents on plants but not on these bacteria. In short, Congress decided to make only a subset of animate “human-made inventions,” *ibid.*, patentable.

4. If the 1930 Act’s only purpose were to solve the technical problem of description referred to by the Court, *ante*, at 2209, most of the Act, and in particular its limitation to asexually reproduced plants, would have been totally unnecessary.

extending patent protection to plants.⁵ Because Congress thought it had to legislate in order to make agricultural “human-made inventions” patentable and because the legislation Congress enacted is limited, it follows that Congress never meant to make items outside the scope of the legislation patentable.

Second, the 1970 Act clearly indicates that Congress has included bacteria within the focus of its legislative concern, but not within the scope of patent protection. Congress specifically excluded bacteria from the coverage of the 1970 Act. 7 U.S.C. § 2402(a). The Court’s attempts to supply explanations for this explicit exclusion ring hollow. It is true that there is no mention in the legislative history of the exclusion, but that does not give us license to invent reasons. The fact is that Congress, assuming that animate objects as to which it had not specifically legislated could not be patented, excluded bacteria from the set of patentable organisms.

The Court protests that its holding today is dictated by the broad language of § 101, which cannot “be confined to the ‘particular application[s] . . . contemplated by the legislators.’” *Ante*, quoting *Barr v. United States*, 324 U.S. 83, 90 (1945). But as I have shown, the Court’s decision does not follow the unavoidable implications of the statute. Rather, it extends the patent system to cover living material even though Congress plainly has legislated in the belief that § 101 does not encompass living organisms. It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

Comments

1. *Chakrabarty and Its Dissent.* In *Chakrabarty*, the Court held that a living, genetically-altered microorganism constituted patentable subject matter. Such a modified microorganism, due to human intervention, was not a product of nature and fell within the broadly defined concepts of manufacture or composition of matter. This momentous decision was important for several reasons, namely in held that life can be patented and it gave a significant boost to the nascent biotechnology industry.

5. Secretary Hyde’s letter was not the only explicit indication in the legislative history of these Acts that Congress was acting on the assumption that legislation was necessary to make living organisms patentable. The Senate Judiciary Committee Report on the 1970 Act states the Committee’s understanding that patent protection extended no further than the explicit provisions of these Acts:

Under the patent law, patent protection is limited to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. S. Rep. No.91-1246, p. 3 (1970).

Similarly, Representative Poage, speaking for the 1970 Act, after noting the protection accorded asexually developed plants, stated that “for plants produced from seed, there has been no such protection.” 116 Cong.Rec. 40295 (1970).

Despite *Chakrabarty*'s significance, there were strong dissenting arguments that garnered four of the nine Justices. Perhaps the most persuasive argument from the dissent was *expressio unius est exclusio alterius*, which is a canon of construction that holds "to express or include one thing implies the exclusion of the other." BLACK'S LAW DICTIONARY (7th ed. 1999). The applicability of this doctrine to *Chakrabarty* was that living matter, namely plants in this instance, was not patentable until Congress enacted the 1930 and 1970 plant acts; and since Congress only spoke to plants, living matter other than plants, such as microorganisms, are not patentable. This argument was also made below, unsuccessfully.

2. ***The Then Nascent Biotechnology Industry.*** Patents play an extremely important role in the biotechnology industry. As two economists observed, "[t]he" collection of small and medium sized firms in the American biotechnology industry is . . . a striking example of enterprises that would not have come into existence without the prospect of a patent, and which depend on patent protection to make their profits, and to attract capital. Robert Mazzoleni & Richard Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RESEARCH POLICY 273, 276 (1998). Patents are also extremely important to biotech's close cousin, the pharmaceutical industry. See Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, Nat'l Bureau of Econ. Research, Working Paper No. 7552 (2004) (finding pharmaceutical industry relies heavily on the patent system).

The cost of developing a new drug is extremely expensive, although estimates vary. Compare Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003) (estimating new drug development cost at \$802 million) with Public Citizen, *Tufts Drug Study Sample Is Skewed; True Figure of R&D Costs Likely Is 75 Percent Lower* (Dec. 4, 2001) (estimating figure to be much less). Because of the high R & D costs, patent protection is essential, even though it contributes to the high costs of drugs. See ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT? 40-41 (2004) ("Patents make new drugs expensive, which is bad. But if they were not expensive, the revenue from selling them would not justify the large cost of developing them. So nobody would undertake such development. And expensive new drugs are better than no new drugs. This is the tradeoff at the heart of the patent system."). Thus, the issue for many commentators is not whether the patent system has a role to play in the pharmaceutical and biotechnology industries, but where on the developmental continuum should patent law be inserted. That is, is patent policy best served by allowing patent protection on upstream biotech research (e.g., genes and proteins) or downstream research (e.g., marketable therapeutics). This issue is explored in Comment 1, *supra*, after *In re Fisher*.

3. ***"Laws of Nature, Physical Phenomena, and Abstract Ideas" Not Patentable.*** Despite noting that Congress, in enacting section 101, "intended statutory subject matter to 'include anything under the sun that is made my man,'" the Court also stated there were limits on section 101. For instance, section

101 does not embrace “laws of nature, physical phenomena, and abstract ideas.” Interestingly, unlike the European Patent Convention, which specifically sets out what is not available for patent protection, section 101 is positive in its approach and leaves it to the common law to carve out exceptions.

So why is it that one may not patent a principle (e.g., $E=mc^2$), abstract ideas, or law or product of nature (e.g., law of gravity or a naturally occurring mineral or plant)—Public policy dictates that there are some things that are so fundamental to the advancement of technology that they must remain in the public domain. Also, laws or products of nature, for example, do not constitute a machine, composition of matter, or manufacture; that is, there is no invention or human intervention, only discovery. Moreover, allowing patent protection on abstract ideas and laws of nature would lead to excessive rent seeking and extremely high transaction costs. See WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 305-06 (2004) (noting transaction costs would be “enormous because the scope” of protection “often is extremely difficult to pin down, and this would make it difficult for newcomers to know when they needed to get a license”). Justice Breyer had this to say about the prohibition:

The justification for the principle does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection.

* * *

Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others.

LabCorp v. Metabolite Laboratories, Inc., 126 S. Ct. 2921, 2922 (2006) (dissenting from dismissal of certiorari).

4. **DNA, Proteins, and Notions of Purity and Isolation.** If naturally occurring substances are not patentable, then how is it that firms obtain patents on DNA sequences (*i.e.*, genes) and proteins—The answer is human intervention, which allows, for instance, one to claim a purified and isolated gene itself or claim the gene as part of a vector or transformed cell. In other words, a gene as it exist in the human body is not subject to patent protection, but a gene “isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associate with it” is eligible for patent protection under § 101.

Historically, courts expressed skepticism that purified, naturally occurring substances were not always patentable. See, *e.g.*, *American Wood Paper Co. v. Fiber Disintegrating Co.*, 90 U.S. 566 (1874) (responding to the

assertion that the claimed subject matter (cellulose) was purified, the Court wrote: “There are many things well known and valuable in medicine or in the arts which may be extracted from diverse substances. But extract is the same, no matter from what it has been taken. . . . Whether a slight difference in the degree of purity of an article produced by several processes justifies denominating the products different manufactures, so that different patents may be obtained for each, may well be doubted, and it is not necessary to decide”).

In the early part of the 20th century, however, arguments based on human intervention and purification in the context of chemical and biological inventions were receive more generously by the courts. One of the most important cases in this regard was *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F.95 (S.D.N.Y. 1911), a case that provided the doctrinal foundation for the patenting of purified DNA sequences and proteins. The subject matter at issue in *Parke-Davis* was an adrenalin compound derived from the suprarenal glands of various animals. But the patentee’s (Takamine) claimed compound was a purified version, which was an important factor for Judge Learned Hand:

[E]ven if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. . . . Everyone, not already saturated with scholastic distinctions, would recognize that Takamine’s crystals were not merely the old dried glands in a purer state, nor would his opinion change if he learned that the crystals were obtained from the glands by a process of eliminating the inactive organic substances. The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic.

Id. at 103. See generally, Linda H. Demaine and Aaron X. Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303 (2002).

HARVARD COLLEGE v. CANADA (COMMISSIONER OF PATENTS)

2002 Supreme Court of Canada 76, [2002] 4 S.C.R. 45

BASTARACHE, J.

I. INTRODUCTION

118 This appeal raises the issue of the patentability of higher life forms within the context of the *Patent Act*, R.S.C. 1985. The respondent, the President and Fellows of Harvard College, seeks to patent a mouse that has been genetically altered to increase its susceptibility to cancer, which makes it useful for cancer research. The patent claims also extend to all non-human mammals which have been similarly altered.

119 The Commissioner of Patents upheld the Patent Examiner's refusal to grant the patent. This decision was in turn upheld by the Federal Court, Trial Division, but was overturned by a majority of the Federal Court of Appeal. . . .

120 [T]he sole question is whether Parliament intended the definition of "invention", and more particularly the words "manufacture" or "composition of matter", within the context of the *Patent Act*, to encompass higher life forms such as the oncomouse. In my opinion, Parliament did not intend higher life forms to be patentable. Had Parliament intended every conceivable subject matter to be patentable, it would not have chosen to adopt an exhaustive definition that limits invention to any "art, process, machine, manufacture or composition of matter". In addition, the phrases "manufacture" and "composition of matter" do not correspond to common understandings of animal and plant life. Even accepting that the words of the definition can support a broad interpretation, they must be interpreted in light of the scheme of the Act and the relevant context. The Act in its current form fails to address many of the unique concerns that are raised by the patenting of higher life forms, a factor which indicates that Parliament never intended the definition of "invention" to extend to this type of subject matter. Given the unique concerns associated with the grant of a monopoly right over higher life forms, it is my view that Parliament would not likely choose the *Patent Act* as it currently exists as the appropriate vehicle to protect the rights of inventors of this type of subject matter.

II. FACTUAL BACKGROUND

121 On June 21, 1985, the respondent, the President and Fellows of Harvard College ("Harvard"), applied for a patent on an invention entitled "transgenic animals". The invention aims to produce animals with a susceptibility to cancer for purposes of animal carcinogenic studies. The animals can be used to test a material suspected of being a carcinogen by exposing them to the material and seeing if tumours develop. Because the animals are already susceptible to tumour development, the amount of material used can be smaller, thereby more closely approximating the amounts to which humans are actually exposed. In addition, the animals will be expected to develop tumours in a shorter time period. The animals can also be used to test materials thought to confer protection against the development of cancer.

122 The technology by which a cancer-prone mouse ("oncomouse") is produced is described in the patent application disclosure. The oncogene (the cancer-promoting gene) is obtained from the genetic code of a non-mammal source, such as a virus. A vehicle for transporting the oncogene into the mouse's chromosomes is constructed using a small piece of bacterial DNA referred to as a plasmid. The plasmid, into which the oncogene has been "spliced", is injected into fertilized mouse eggs, preferably while they are at the one-cell stage. The eggs are then implanted into a female host mouse, or "foster mother", and permitted to develop to term. After the offspring of the foster mother are delivered, they are tested for the presence of the oncogene; those that contain the oncogene are called "founder" mice. Founder mice are mated with mice that have not been genetically altered. In accordance with Mendelian inheritance principles, 50 percent of the offspring will have all of

their cells affected by the oncogene, making them suitable for the uses described above.

123 In its patent application, the respondent seeks to protect both the process by which the oncomice are produced and the end product of the process, i.e. the founder mice and the offspring whose cells are affected by the oncogene. The process and product claims also extend to all non-human mammals. In March 1993, by Final Action, a Patent Examiner rejected the product claims (claims 1 to 12) as being outside the scope of the definition of “invention” in s. 2 of the *Patent Act*, but allowed the process claims (claims 13 to 26). In August 1995, after a review by the Commissioner of Patents and a hearing before the Patent Appeal Board, the Commissioner confirmed the refusal to grant a patent for claims 1 to 12. The Federal Court, Trial Division dismissed the respondent’s appeal from the decision of the Commissioner. The respondent’s further appeal to the Federal Court of Appeal was allowed by a majority of the court, Isaac J.A. dissenting. The Commissioner of Patents appeals from that decision.

III. RELEVANT STATUTORY PROVISIONS

124 *Patent Act*, R.S.C. 1985:

2. In this Act, except as otherwise provided, . . .

“invention” means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;

* * *

126 The Patent Examiner’s rejection of claims 1 to 12 was based on his conclusion that higher life forms fall outside the definition of “invention” as given in s. 2 of the *Patent Act*, and therefore are not patentable subject matter. . . . In addition, the Patent Examiner noted that neither the Patent Appeal Board nor the courts have expressly stated that higher life forms constitute patentable subject matter.

B. Decision of the Commissioner of Patents (August 4, 1995)

* * *

130 Turning to the issue at hand, the Commissioner expressed the view that the words “manufacture” and “composition of matter” as found in s. 2 apply to something that has been made under the control of the inventor. At the same time, the resulting product must be reproducible in a consistent manner. Considering the invention in question, the Commissioner determines that there are two distinct phases. The first phase involves the preparation of the genetically engineered plasmid. The second involves the development of a genetically engineered mouse in the uterus of the host mouse. The Commissioner concluded that while the first phase is controlled by human intervention, in the second phase it is the laws of nature that take over to produce the mammalian end product. He was therefore unwilling to extend the meaning of “manufacture” or “composition of matter” to include a non-human mammal. In his view, the inventors do not have full control over all of the characteristics of the resulting mouse, and human intervention ensures that reproducibility extends only so far as the cancer-forming gene.

* * *

V. ANALYSIS

* * *

B. The Definition of “Invention”: Whether a Higher Life Form Is a “Manufacture” or a “Composition of Matter”

153 The sole question in this appeal is whether the words “manufacture” and “composition of matter”, in the context of the *Patent Act*, are sufficiently broad to include higher life forms. If these words are not sufficiently broad to include higher life forms, it is irrelevant whether this Court believes that higher life forms such as the oncomouse ought to be patentable. The grant of a patent reflects the interest of Parliament to promote certain manifestations of human ingenuity. As Binnie J. indicates in his reasons, there are a number of reasons why Parliament might want to encourage the sort of biomedical research that resulted in the oncomouse. But there are also a number of reasons why Parliament might want to be cautious about encouraging the patenting of higher life forms. In my view, whether higher life forms such as the oncomouse ought to be patentable is a matter for Parliament to determine. This Court’s views as to the utility or propriety of patenting non-human higher life forms such as the oncomouse are wholly irrelevant.

154 This Court has on many occasions expressed the view that statutory interpretation cannot be based on the wording of the legislation alone. Rather, the Court has adopted E. A. Driedger’s statement in his text *Construction of Statutes* (2nd ed. 1983), at p. 87: “[T]he words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament.”

155 Having considered the relevant factors, I conclude that Parliament did not intend to include higher life forms within the definition of “invention” found in the *Patent Act*. In their grammatical and ordinary sense alone, the words “manufacture” and “composition of matter” are somewhat imprecise and ambiguous. However, it is my view that the best reading of the words of the Act supports the conclusion that higher life forms are not patentable. As I discuss below, I do not believe that a higher life form such as the oncomouse is easily understood as either a “manufacture” or a “composition of matter”. For this reason, I am not satisfied that the definition of “invention” in the *Patent Act* is sufficiently broad to include higher life forms. This conclusion is supported by the fact that the patenting of higher life forms raises unique concerns which do not arise in respect of non-living inventions and which are not addressed by the scheme of the Act. Even if a higher life form could, scientifically, be regarded as a “composition of matter”, the scheme of the Act indicates that the patentability of higher life forms was not contemplated by Parliament. Owing to the fact that the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, ethical and environmental concerns that the Act does not contemplate, I conclude that the Commissioner was correct to reject the patent application. This is a policy issue that raises questions of great significance and importance and that would appear to require a dramatic expansion of the traditional patent regime. Absent explicit legislative direction, the Court should not order the Commissioner to grant a patent on a higher life form.

(1) *The Words of the Act*

156 The definition of “invention” in s. 2 of the *Patent Act* lists five categories of invention: art (*réalisation*), process (*procédé*), machine (*machine*), manufacture (*fabrication*) or composition of matter (*composition de matières*). The first three, “art”, “process” and “machine”, are clearly inapplicable when considering claims directed toward a genetically engineered non-human mammal. If a higher life form is to fit within the definition of “invention”, it must therefore be considered to be either a “manufacture” or a “composition of matter”.

157 Rothstein J.A. concluded that the oncomouse was a “composition of matter”, and therefore did not find it necessary to consider whether it was also a “manufacture”. In coming to this conclusion, he relied, at para. 115, on the following definition of “composition of matter” adopted by the majority of the U.S. Supreme Court in *Chakrabarty*, *supra*, at p. 308:

... all compositions of two or more substances and ... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.

In *Chakrabarty*, the majority attributed the widest meaning possible to the phrases “composition of matter” and “manufacture” for the reason that inventions are, necessarily, unanticipated and unforeseeable. Burger C.J., at p. 308, also referred to the fact that the categories of invention are prefaced by the word “any” (“any new and useful process, machine, manufacture, or composition of matter”). Finally, the Court referred to extrinsic evidence of Congressional intent to adopt a broad concept of patentability, noting at p. 309 that: “The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”

158 I agree that the definition of “invention” in the *Patent Act* is broad. Because the Act was designed in part to promote innovation, it is only reasonable to expect the definition of “invention” to be broad enough to encompass unforeseen and unanticipated technology. I cannot however agree with the suggestion that the definition is unlimited in the sense that it includes “anything under the sun that is made by man”. In drafting the *Patent Act*, Parliament chose to adopt an exhaustive definition that limits invention to any “art, process, machine, manufacture or composition of matter”. Parliament did not define “invention” as “anything new and useful made by man”. By choosing to define invention in this way, Parliament signaled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the Act. This should be kept in mind when determining whether the words “manufacture” and “composition of matter” include higher life forms.

159 With respect to the meaning of the word “manufacture” (*fabrication*), although it may be attributed a very broad meaning, I am of the opinion that the word would commonly be understood to denote a non-living mechanistic product or process. For example, the *Oxford English Dictionary* (2nd ed. 1989), vol. IX, at p. 341, defines the noun “manufacture” as the following:

The action or process of making by hand. ... The action or process of making articles or material (in modern use, on a large scale) by the application of physical labour or mechanical power.

The *Grand Robert de la langue française* (2nd ed. 2001), vol. 3, at p. 517, defines thus the word “*fabrication*”:

[TRANSLATION] Art or action or manufacturing. . . . The manufacture of a technical object (by someone). Manufacturing by artisans, by hand, by machine, industrially, by mass production. . . .

In *Chakrabarty*, *supra*, at p. 308, “manufacture” was defined as

the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.

These definitions use the terminology of “article”, “material”, and “*objet technique*”. Is a mouse an “article”, “material”, or an “*objet technique*”—In my view, while a mouse may be analogized to a “manufacture” when it is produced in an industrial setting, the word in its vernacular sense does not include a higher life form. The definition in *Hornblower v. Boulton* (1799), 8 T.R. 95, 101 E.R. 1285 (K.B.), cited by the respondent, is equally problematic when applied to higher life forms. In that case, the English courts defined “manufacture” as “something made by the hands of man” (p. 1288). In my opinion, a complex life form such as a mouse or a chimpanzee cannot easily be characterized as “something made by the hands of man”.

160 As regards the meaning of the words “composition of matter”, I believe that they must be defined more narrowly than was the case in *Chakrabarty*, *supra*, at p. 308 namely “all compositions of two or more substances and . . . all composite articles”. If the words “composition of matter” are understood this broadly, then the other listed categories of invention, including “machine” and “manufacture”, become redundant. This implies that “composition of matter” must be limited in some way. Although I do not express an opinion as to where the line should be drawn, I conclude that “composition of matter” does not include a higher life form such as the oncomouse.

161 The phrase “composition of matter” (*composition de matières*) is somewhat broader than the term “manufacture” (*fabrication*). It is a well-known principle of statutory interpretation that the meaning of questionable words or phrases in a statute may be ascertained by reference to the meaning of the words or phrases associated with them (P.-A. Côté, *The Interpretation of Legislation in Canada* (3rd ed. 2000), at pp. 313-14). Also, a collective term that completes an enumeration is often restricted to the same genus as those words, even though the collective term may ordinarily have a much broader meaning (p. 315). The words “machine” and “manufacture” do not imply a conscious, sentient living creature. This provides *prima facie* support for the conclusion that the phrase “composition of matter” is best read as not including such life forms. This argument is bolstered by the fact that there are a number of factors that make it difficult to regard higher life forms as “composition[s] of matter”.

162 First, the *Oxford English Dictionary*, *supra*, vol. III, at p. 625, defines the word “composition” as “[a] substance or preparation formed by combination or mixture of various ingredients”, the *Grand Robert de la langue française*, *supra*, vol. 2, at p. 367, defines “*composition*” as [TRANSLATION] “[a]ction or manner of forming a whole, a set by assembling several parts, several elements”. Within the context of the definition of “invention”, it does not seem

unreasonable to assume that it must be the inventor who has combined or mixed the various ingredients. Owing to the fact that the technology by which a mouse predisposed to cancer is produced involves injecting the oncogene into a fertilized egg, the genetically altered egg would appear to be cognizable as “[a] substance or preparation formed by combination or mixture of various ingredients” or as [TRANSLATION] “[a]ction or manner of forming a whole . . . by assembling several parts”. However, it does not thereby follow that the oncomouse itself can be understood in such terms. Injecting the oncogene into a fertilized egg is the but-for cause of a mouse predisposed to cancer, but the process by which a fertilized egg becomes an adult mouse is a complex process, elements of which require no human intervention. The body of a mouse is composed of various ingredients or substances, but it does not consist of ingredients or substances that have been combined or mixed together by a person. Thus, I am not satisfied that the phrase “composition of matter” includes a higher life form whose genetic code has been altered in this manner.

163 It also is significant that the word “matter” captures but one aspect of a higher life form. As defined by the *Oxford English Dictionary*, *supra*, vol. IX, at p. 480, “matter” is a “[p]hysical or corporeal substance in general . . . , contradistinguished from immaterial or incorporeal substance (spirit, soul, mind), and from qualities, actions, or conditions”. “*Matière*” is defined by the *Grand Robert de la langue française*, *supra*, vol. 4, p. 1260, as [TRANSLATION] “corporeal substance ‘that is perceptible in space and has mechanical mass’”. Although some in society may hold the view that higher life forms are mere “composition[s] of matter”, the phrase does not fit well with common understandings of human and animal life. Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed. A person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilized egg cell; it simply would not be predisposed to cancer. The fact that it has this predisposition to cancer that makes it valuable to humans does not mean that the mouse, along with other animal life forms, can be defined solely with reference to the genetic matter of which it is composed. The fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualize higher life forms as mere “composition[s] of matter”. It is a phrase that seems inadequate as a description of a higher life form.

164 Lastly, I wish also to address Rothstein J.A.’s assertion that “[t]he language of patent law is broad and general and is to be given wide scope because inventions are, necessarily, unanticipated and unforeseeable” (para. 116). In my view, it does not thereby follow that all proposed inventions are patentable. On the one hand, it might be argued that, in this instance, Parliament could foresee that patents might be sought in higher life forms. Although Parliament would not have foreseen the genetically altered mouse and the process of genetic engineering used to produce it, Parliament was well aware of animal husbandry or breeding. While the technologies used to produce a crossbred animal and a genetically engineered animal differ substantially, the end result, an animal with a new or several new features, is the same. Yet Parliament chose to define the categories of invention using lan-

guage that does not, in common usage, refer to higher life forms. One might thus infer that Parliament did not intend to include higher life forms in the definition of “invention”.

* * *

166 Patenting higher life forms would involve a radical departure from the traditional patent regime. Moreover, the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues. If higher life forms are to be patentable, it must be under the clear and unequivocal direction of Parliament. For the reasons discussed above, I conclude that the current Act does not clearly indicate that higher life forms are patentable. Far from it. Rather, I believe that the best reading of the words of the Act supports the opposite conclusion—that higher life forms such as the oncomouse are not currently patentable in Canada.

(2) *The Scheme of the Act*

167 This interpretation of the words of the Act finds support in the fact that the patenting of higher life forms raises unique concerns which do not arise with respect to non-living inventions and which cannot be adequately addressed by the scheme of the Act. In *Pioneer Hi-Bred* (F.C.A.), Marceau J.A. discussed the intention of Parliament to include crossbred plants in the following terms (at p. 14):

... it seems to me that the inclusion of plants within the purview of the legislation would have led ... to the enactment of special provisions capable of better adapting the whole scheme to a subject matter, the essential characteristic of which is that it reproduces itself as a necessary result of its growth and maturity. I do not dispute the appellant's contention that those who develop new types of plants by cross breeding should receive in this country, as they do elsewhere, some kind of protection and reward for their efforts but it seems to me that, to assure such result, the legislator will have to adopt special legislation, as was done a long time ago in the United States and in many other industrialized countries.

Marceau J.A.'s observation in this regard is compelling. The patenting of higher life forms raises special concerns that do not arise in respect of non-living inventions. Unlike other inventions, biologically based inventions are living and self-replicating. In addition, the products of biotechnology are incredibly complex, incapable of full description, and can contain important characteristics that have nothing to do with the invention. In my view, the fact that the *Patent Act* in its current state is ill-equipped to deal appropriately with higher life forms as patentable subject matter is an indication that Parliament never intended the definition of “invention” to extend to this type of subject matter.

168 The respondent argues that the concerns arising out of higher life forms as patentable subject matter are “external to the *Patent Act* and its jurisprudence” and that there is therefore no statutory basis to reject the patentability of higher life forms on moral, ethical or environmental grounds. I agree with the respondent that some of the policy concerns raised by the interveners are more appropriately dealt with outside the patent system. For example, some interveners expressed concern for the environmental and animal welfare implications of biotechnology. These issues are only tenuously linked to the patentability of higher life forms and are more directly related to

the development and use of the technology itself. With regard to research and experimentation involving animals, by the time a researcher is in a position to file for a patent, any harm to the animal resulting from research will already have been done. Correspondingly, it is preferable to address this issue through existing or new regimes for protecting animal welfare. Similarly, if it is determined that additional measures are needed to protect the environment from the products of biotechnology, this may be effected through the *Canadian Environmental Protection Act*, R.S.C. 1985, c. 16 (4th Supp.), or other comparable regulatory mechanisms.

169 While the above-mentioned concerns are only indirectly related to the *Patent Act*, several of the issues raised by the interveners and in the literature are more directly related to patentability and to the scheme of the *Patent Act* itself. These issues, which pertain to the scope and content of the monopoly right accorded to the inventor by a patent, have been explored in depth by the Canadian Biotechnology Advisory Committee (CBAC), a body created in 1999 with a mandate to provide the government with advice on policy issues associated with biotechnology. In June 2002, the CBAC released its final report, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*. The report recommends that higher life forms should be patentable. Nonetheless, it concludes, at p. 7, that given the importance of issues raised by the patenting of higher life forms and the significant “values” content of the issues raised, Parliament and not the courts should determine whether and to what degree patent rights ought to extend to plants and animals.

170 Two of the issues addressed by the CBAC (farmers’ privilege and innocent bystanders) arise out of the unique ability of higher life forms to self-replicate. Because higher life forms reproduce by themselves, the grant of a patent covers not only the particular plant, seed or animal sold, but also all of its progeny containing the patented invention. In the CBAC’s view, this represents a significant increase in the scope of rights offered to patent holders that is not in line with the scope of patent rights provided in other fields (*Patenting of Higher Life Forms and Related Issues*, *supra*, at p. 12).

171 One significant concern arising out of the increased scope of patent protection is the impact that it will have on Canada’s agricultural industry. The CBAC recommends that a farmers’ privilege provision be included in the Act. The privilege would permit farmers to collect and reuse seeds harvested from patented plants and to breed patented animals for their own use, so long as these were not sold for commercial breeding purposes. Although the CBAC puts forward suggestions pertaining to the general nature of such a provision, it nonetheless recognizes that more work would need to be done to identify the extent of the privilege in relation to plants and animals.

172 Another concern identified by the CBAC in respect to self-replication pertains to infringement. The CBAC observes that since plants and animals are often capable of reproducing on their own, it must be recognized that they will not always do so under the control or with the knowledge of those who grow the plants or raise the animals. Patent law does not currently require a patent holder to prove that an alleged infringer knew or ought to have known about the reproduction of a patented invention. An “innocent bystander” may therefore be faced with high costs to defend a patent infringement suit and an award of damages for infringement without a

countervailing remedy against the patent holder. The CBAC correspondingly recommends that the *Patent Act* contain a provision that would allow the so-called “innocent bystander” to rebut the usual presumption concerning knowledge of infringement in respect of inventions capable of reproducing, such as plants, seeds and animals.

173 In its recommendations, the CBAC also deals with a concern that was raised before this Court by the intervener Canadian Environmental Law Association. The intervener submitted that patents on life forms may actually deter further innovation in the biomedical field by foreclosing opportunities for research and product development to those that do not hold the patent. Arguably, this potential is inherent in the nature of a patent system. Yet the impact may be more significant with respect to the products of biotechnology. As noted by the CBAC, at p. 14: “Access to basic or platform technology such as DNA sequences, cell lines, plants and animals at reasonable cost is crucial to research”. High research costs can be expected to drive up the price of the end product, which in the case of biotechnology includes diagnostic tests and therapeutic agents important to the health of Canadians (see T. Schrecker et al., *Ethical Issues Associated with the Patenting of Higher Life Forms* (1997), at p. 44).

* * *

175 Perhaps the most significant issue addressed by the CBAC is the patentability of human life. The CBAC recommends that if Canada decides to permit patents over higher life forms, human bodies at all stages of development should be excluded. It observes in this regard that although humans are also animals, no country, including Canada, allows patents on the human body. According to the CBAC, this understanding derives from the universal principle of respect for human dignity, one element of which is that humans are not commodities (see CBAC, *supra*, at p. 8).

176 The potential for commodification of human life arises out of the fact that the granting of a patent is, in effect, a declaration that an invention based on living matter has the potential to be commercialized. The commodification of human beings is not only intrinsically undesirable; it may also engender a number of troubling consequences. Many of the consequentialist concerns (i.e., the creation of “designer human beings” or features) are directed at genetic engineering in general and not at patenting *per se*, and are perhaps better dealt with outside the confines of the *Patent Act* (see Schrecker, *supra*, at pp. 64-65). Nonetheless, there remains a concern that allowing patents on the human body will lead to human life being reconceptualized as genetic information. A related concern is the potential for objectification. As noted by Schrecker, *supra*, at p. 62: “[t]o objectify something is implicit in treating it as a market commodity, but what is disturbing about objectifying a person or organism is not so much the exchange of money as it is the notion that a subject, a moral agent with autonomy and dignity, is being treated as if it can be used as an instrument for the needs or desires of others without giving rise to ethical objections”.

177 Whatever justification is used to support the assumption, there seems to be little debate that human life is not patentable. In response to the hypothetical question of whether patentability could be extended to human beings, Rothstein J.A. replied, at para. 207: “The answer is clearly that the *Patent Act* cannot be extended to cover human beings”. He based this con-

clusion on the fact that patenting is a form of ownership of property and that ownership concepts cannot be extended to human beings pursuant to s. 7 of the *Charter*. He concluded the topic by remarking that “[t]here is, therefore, no concern by including non-human mammals under the definition of ‘invention’ in the *Patent Act*, that there is any implication that a human being would be patentable in the way that the oncomouse is” (para. 207).

178 In my view, this general response to concerns over the implications for human beings of patenting higher life forms is an oversimplification. Reference to the *Charter* does not address the issue of whether the definition of “invention” in s. 2 applies to human subject matter as a matter of statutory interpretation. Should this Court determine that higher life forms are within the scope of s. 2, this must necessarily include human beings. There is no defensible basis within the definition of “invention” itself to conclude that a chimpanzee is a “composition of matter” while a human being is not. As noted by this Court in *Bell ExpressVu Limited Partnership v. Rex*, [2002] 2 S.C.R. 559, 2002 SCC 42, at para. 62, “*Charter* values” are to be used as an interpretative principle only in circumstances of genuine ambiguity, i.e. where a statutory provision is subject to differing but equally plausible interpretations. To read legislation in conformity with the *Charter* in cases where there is no real ambiguity is to deprive the government the opportunity to justify a provision that appears to conflict with the *Charter* under s. 1.

179 In addition, while it is likely that s. 7 of the *Charter* would have some impact on the patenting of human life, it is unlikely to resolve many of the more specific issues that may arise. Section 7 states that everyone has the right to “life, liberty and security of the person”. Because the section deals only with “person[s]”, it leaves the status of foetuses uncertain. In its report to Parliament, the CBAC recommends that the *Patent Act* be amended to say that no patent shall be granted on human bodies “at any stage of development” (p. x). In its view, this wording would demonstrate an intention not only to include human bodies of infants, children and adults, but also all precursors to the human body from zygotes to foetuses. Recognition by the CBAC of the necessity of specifically addressing this issue supports the view that reference to s. 7 of the *Charter* alone cannot dispose of concerns associated with the patenting of human life.

* * *

181 The problem posed by the above technology with respect to locating the defining line which separates humans from animals is not insurmountable. It does, however, call into question Rothstein J.A.’s assumption that s. 7 of the *Charter* is capable of addressing the issues associated with the patenting of human life. In my view, it is not an appropriate judicial function for the courts to create an exception from patentability for human life given that such an exception requires one to consider both what is human and which aspects of human life should be excluded.

182 The scenarios above demonstrate that the issue of patenting of human life forms is a complex one that cannot be readily dismissed by reference to the *Charter*. Once again, it is an issue that demands a comprehensive Parliamentary response. Illustrative in this regard is *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*, which sets out several detailed exceptions to pat-

entability pertaining to the human body. The first paragraph of article 5 of the Directive sets out the primary exception:

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

The second paragraph allows for a patent on “[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene . . . even if the structure of that element is identical to that of a natural element”. Paragraph 1 of article 6 sets out a general exception to patentability for inventions where their commercial exploitation would be contrary “to *ordre public* or morality”. Paragraph 2 further specifies that processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes are all considered unpatentable as being contrary to “*ordre public* or morality”.

183 As noted earlier, the CBAC has recommended that higher life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable. The concerns above therefore are not raised to justify a position that higher life forms should not be patentable, but rather serve to illustrate that the *Patent Act* in its current form is not well suited to address the unique characteristics possessed by higher life forms. The lack of direction currently in the *Patent Act* to deal with issues that might reasonably arise signals a legislative intention that higher life forms are currently not patentable. In addition, the discussion of the issues raised by the CBAC and other groups illustrates the complexity of the concerns. In my view, this Court does not possess the institutional competence to deal with issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing societal interests and intricate legislative drafting.

(3) *The Object of the Act*

184 The respondent submits that the object of the *Patent Act* is to encourage and reward the development of innovations and technology. In its view, this objective supports a broad reading of the definition of “invention” that does not exclude any area of technology save for the statutory exclusion in s. 27(3).

185 There is no doubt that two of the central objects of the Act are “to advance research and development and to encourage broader economic activity” (see *Free World Trust v. Electro Santé Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66, at para. 42). As noted earlier, this does not, however, imply that “anything under the sun that is made by man” is patentable. Parliament did not leave the definition of “invention” open, but rather chose to define it exhaustively. Regardless of the desirability of a certain activity, or the necessity of creating incentives to engage in that activity, a product of human ingenuity must fall within the terms of the Act in order for it to be patentable. The object of the Act must be taken into account, but the issue of whether a proposed invention *ought* to be patentable does not provide an answer to the question of whether that proposed invention *is* patentable. In addition, the manner in which Canada has administered its patent regime in the past reveals that the promotion of

ingenuity has at times been balanced against other considerations. For example, under the former provisions of the *Patent Act*, a licence could be granted to manufacture a patented medicine seven years after the patent first appeared on the market. The existence of this compulsory licence scheme demonstrates that other objectives, including fairness and the promotion of Canada's universal healthcare system, have at times existed as part of the patent regime (see Chong, *supra*; see also Rudolph, *supra*, at p. 35, note 74).

186 Given the above, the respondent's argument that the object of the Act leads inexorably to the broadest reading of the definition of "invention" possible is problematic and is, in my view, based on an oversimplification of the patent regime. In the court below, Rothstein J.A. preferred the approach taken by the majority of the U.S. Supreme Court in *Chakrabarty*, *supra*. The majority read the language of the Act expansively on the basis that the Act embodied Thomas Jefferson's philosophy that "ingenuity should receive a liberal encouragement" (p. 308). The minority of the court did not wholly accept this characterization, commenting in respect to the objective of the Act, at p. 319 of the reasons:

The patent laws attempt to reconcile this Nation's deep-seated antipathy to monopolies with the need to encourage progress. Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.

187 Based on the language and the scheme of the Act, both of which are not well accommodated to higher life forms, it is reasonable to assume that Parliament did not intend the monopoly right inherent in the grant of a patent to extend to inventions of this nature. It simply does not follow from the objective of promoting ingenuity that all inventions must be patentable, regardless of the fact that other indicators of legislative intention point to the contrary conclusion.

* * *

C. Drawing the Line: Is It Defensible to Allow Patents on Lower Life Forms While Denying Patents on Higher Life Forms —

197 The respondent notes that the Commissioner of Patents has since 1982 accepted that lower life forms come within the definitions of "composition of matter" and "manufacture" and has granted patents on such life forms accordingly. It adds that the *Patent Act* does not distinguish, in its definition of "invention", between subject matter that is less complex (lower life forms) and subject matter that is more complex (higher life forms). It submits that there is therefore no evidentiary or legal basis for the distinction the Patent Office has made between lower life forms such as bacteria, yeast and moulds, and higher life forms such as plants and animals.

198 The patentability of lower life forms is not at issue before this Court, and was in fact never litigated in Canada. In *Abitibi*, *supra*, the Patent Appeal Board, the Commissioner concurring, rejected the prior practice of the Patent Office and issued a patent on a microbial culture that was used to digest, and thereby purify, a certain waste product that emanates from pulp mills. The

decision, in this regard, was based largely on the U.S. Supreme Court's decision in *Chakrabarty*, *supra*, and on the practice in Australia, Germany and Japan. Having noted that judicial bodies in these countries altered their interpretation of patentable subject matter to include micro-organisms, the Board observed, at p. 88: "[o]bviously the answer to the question before us, which once had seemed so clear and definite has become clouded and uncertain". The Board was careful to limit the subject matter to which the decision would apply (at p. 89):

... this decision will extend to all micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.

199 Though this Court is not faced with the issue of the patentability of lower life forms, it must nonetheless address the respondent's argument that the line between higher and lower life forms is indefensible. As discussed above, I am of the opinion that the unique concerns and issues raised by the patentability of plants and animals necessitate a parliamentary response. Only Parliament has the institutional competence to extend patent rights or another form of intellectual property protection to plants and animals and to attach appropriate conditions to the right that is granted. In the interim, I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two. Perhaps more importantly, there appears to be a consensus that human life is not patentable; yet this distinction is also not explicit in the Act. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other higher life forms.

200 The appellant submits that a fully developed non-human mammal is worlds apart from a yeast, a mould, or even the single-celled egg leading to its development. Whereas simple organisms are easily defined or identified by reference to a limited number of properties, complex life forms are not. In addition, simple organisms are often produced by processes similar to the manufacture of chemicals, while complex intelligent life forms are not.

201 As I stated above, the issue of whether a lower life form is a "composition of matter" or "manufacture" was never challenged in the courts in this country and it is difficult to say whether the Canadian courts would have followed the approach of the majority of the U.S. Supreme Court in *Chakrabarty*, or whether the approach of the minority would have been preferred. Regardless of the wisdom of the decision, it is now accepted in Canada that lower life forms are patentable. Nonetheless, I agree with the appellant that this does not necessarily lead to the conclusion that higher life forms are patentable, at least in part for the reasons that it is easier to conceptualize a lower life form as a "composition of matter" or "manufacture" than it is to conceptualize a higher life form in these terms.

* * *

BINNIE, J., dissenting.

1 The biotechnology revolution in the 50 years since discovery of the structure of DNA has been fuelled by extraordinary human ingenuity and financed in significant part by private investment. Like most revolutions, it has wide ramifications, and presents potential and serious dangers as well as past and future benefits. In this appeal, however, we are only dealing with a small corner of the biotechnology controversy. We are asked to determine whether the oncomouse, a genetically modified rodent with heightened genetic susceptibility to cancer, is an invention. The legal issue is a narrow one and does not provide a proper platform on which to engage in a debate over animal rights, or religion, or the arrogance of the human race.

2 The oncomouse has been held patentable, and is now patented in jurisdictions that cover Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, the United Kingdom and the United States. A similar patent has been issued in Japan. New Zealand has issued a patent for a transgenic mouse that has been genetically modified to be susceptible to HIV infection. Indeed, we were not told of any country with a patent system comparable to Canada's (or otherwise) in which a patent on the oncomouse had been applied for and been refused.

3 If Canada is to stand apart from jurisdictions with which we usually invite comparison on an issue so fundamental to intellectual property law as what constitutes an "invention", the respondent, successful everywhere but in Canada, might expect to see something unique in our legislation. However, one looks in vain for a difference in definition to fuel the Commissioner's contention that, *as a matter of statutory interpretation*, the oncomouse is not an invention. The truth is that our legislation is not unique. The Canadian definition of what constitutes an invention, initially adopted in pre-Confederation statutes, was essentially taken from the United States *Patent Act* of 1793, a definition generally attributed to Thomas Jefferson. The United States patent on the oncomouse was issued 14 years ago. My colleague, Bastarache J., acknowledges that the fertilized, genetically altered oncomouse *egg* is an invention under our *Patent Act*, R.S.C. 1985, c. P-4 (para. 162). Thereafter, we part company, because my colleague goes on to conclude that the resulting *oncomouse*, that grows from the patented egg, is not itself patentable because it is not an invention. Subject matter patentability, on this view, is lost between two successive stages of a transgenic mouse's genetically pre-programmed growth. In my opinion, with respect, such a "disappearing subject-matter" exception finds no support in the statutory language.

4 A patent, of course, does not give its holder a license to practise the invention free of regulatory control (any more than an *unpatented* invention enjoys such immunity). On the contrary, the grant of a patent simply reflects the public interest in promoting the disclosure of advancements in learning by rewarding human ingenuity. Innovation is said to be the lifeblood of a modern economy. We neglect rewarding it at our peril. Having disclosed to the public the secrets of how to make or use the invention, the inventor can prevent *unauthorized* people for a limited time from taking a "free ride" in exploiting the information thus disclosed. At the same time, persons skilled in the art of the patent are helped to further advance the frontiers of knowledge by standing on the shoulders of those who have gone before.

C. The Commercial and Scientific Context

16 Biotechnology is global in scope. Worldwide demand is expected to more than double from \$20 billion in 1995 to \$50 billion by 2005. Canada is a significant player. Statistics Canada reports that Canada's biotechnology sector in 1999 generated almost \$2 billion in revenues, including \$718 million in exports. These revenues are expected to exceed \$5 billion in 2002. The Canadian Biotechnology Advisory Committee (CBAC), formed in 1999 to advise the federal government on these matters, recently reported that Canada has more biotechnology companies *per capita* than any other country: *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*, June 2002, p. 2. It was calculated by Ernst & Young in its *Seventh Annual European Life Sciences Report 2000*, that Canada is second behind the U.S. in terms of number of companies, third behind the U.S. and U.K. in revenues, and first in R & D *per* employee.

17 Genetic tests and "engineered" products hold out the possibility of modifying genetic mutations that either cause a disorder (e.g., Tay-Sachs disease, cystic fibrosis, Huntington's disease) or are responsible for increasing an individual's risk to develop, at some point during his or her lifetime, a particular disease (e.g., breast cancer). In addition, some research indicates a genetic element in some "behavioural illnesses" such as schizophrenia, Alzheimer's, autism, attention-deficit hyperactivity disorder, and Tourette's syndrome.

18 This is not to suggest that because something is beneficial it is necessarily patentable. As stated, such value judgments have been excluded from the administration of the *Patent Act*. It is to say, however, that the massive investment of the private sector in biotechnical research is exactly the sort of research and innovation that the *Patent Act* was intended to promote.

D. Financing Research and Development

19 As this case demonstrates, even university research has to be paid for, and intellectual property rights are an important contributor.

20 We are told that in the United States (comparable statistics do not seem to be available in Canada), a health-related biotechnology product on average costs between 200 and 350 million dollars (U.S.) to develop, and takes 7 to 10 years from the research and development stage to bring it to market (Statistics Canada, *Biotechnology Use and Development—1999* (March 2001), at p. 25). One would think it in the public interest to shorten the time and reduce the cost of research designed to minimize human suffering, and to reward those who develop research tools (such as the oncomouse) that might make this possible, provided the inventors disclose their work for others to build on.

* * *

F. Patenting of "Higher Life Forms" in Comparable Jurisdictions

33 In 1873, Louis Pasteur was granted a patent in the United States on a certain yeast, which is a living organism.

34 A patent for the Harvard oncomouse was issued by the United States Patent Office on April 12, 1988 and by the European Patent Office on May 13, 1992, despite the explicit power under the *European Patent Convention* to re-

fuse a patent based on “morality” or “*ordre public*”. As mentioned earlier, a similar patent has been issued in Japan, and New Zealand has issued a patent for a transgenic mouse.

35 The appellant Commissioner’s principal argument is that to allow the oncomouse patent would be to “expand” the scope of the *Patent Act* (i.e., his factum, paras. 2, 3, 35 and 73), but the opposite conclusion reached in so many countries with comparable legislation suggests the contrary. In those jurisdictions, patents for the oncomouse have been issued without any need for legislative amendment, including the United States where the language of our definition of “invention” originated. The Commissioner seeks to *re-strict* the legislative definition of invention, and he does so (in my view) for policy reasons unrelated to the *Patent Act* or to its legitimate role and function.

* * *

Comments

1. ***The Influence of Chakrabarty on the Canadian Supreme Court.*** The *Chakrabarty* case has been very influential, not only within the United States, but in foreign jurisdictions. But the majority in the above Canadian Supreme Court case was not swayed by *Chakrabarty*’s reasoning. The Canadian Supreme Court considered and rejected the rationale in *Chakrabarty*. In particular, the Court refused to recognize that a higher life form is a “composition of matter.” For the Canadian Justices, “anything under the sun that is made my man” is not eligible for patent protection.
2. ***The European Approach to Transgenic Animals.*** The oncomouse was a research tool, genetically designed to possess a predisposition to breast cancer. While patenting the oncomouse was essentially uncontroversial in the United States (see U.S. Pat. No. 4,736,866), the same was not true during the European experience, which ultimately resulted in European Patent No. 0169672. The principal argument asserted by European opponents on patenting the oncomouse were grounded in public order and morality, two concepts finding textual support in Article 53(a) of the European Patent Convention. This argument was ultimately unsuccessful, as reflected in the following statement by the Examining Division of the EPO:

[The oncomouse] cannot be considered immoral or contrary to public order. The provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals together with a low risk connected with the handling of the animals by qualified staff can generally be regarded as beneficial to mankind. A patent should therefore not be denied for the present invention on the ground of Article 53(a) EPC.

Harvard/Oncomouse, 1992 O.J. E.P.O. at 593 (Examining Div.).

A Note on Patents, Biotechnology, and the Bayh-Dole Act

In addition to the *Chakrabarty* decision, another significant event occurred in 1980 that positively affected the biotechnology industry. In that year, Congress enacted the Bayh-Dole Act, which allows universities and other non-profit entities to “elect to retain title” for inventions that resulted from federal funding. See 35 U.S.C. §§ 200-205. The goal of this legislation was to encourage “private industry to utilize government funded inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application.” H.R. Rep. No. 96-1307, pt. 1, at 3 (1980). According to Rebecca Eisenberg, the “Act has been consistently hailed as an unqualified success in stimulating the commercial development of discoveries emerging from government-sponsored research in universities.” Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research*, 82 U. VA. L. REV. 1663, 1708-09 (1996). See also *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, Congressional Research Service Report of Congress 8 (June 10, 2005) (stating the Bayh-Dole Act “appears to have met its expressed goals of using ‘the patent system to promote the utilization of inventions arising from federally-supported research or development; . . . and to promote collaboration between commercial concerns and nonprofit organizations, including universities”); DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN N. SAMPAT & ARVIDS A. ZIEDONIS, *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES* (2004) (observing an increase in licensing activity by research universities after the enactment of Bayh-Dole, but also attributing factors in addition to Bayh-Dole to increase in research university innovations such as federal funding and traditional university-industry interaction). For criticisms of the Bayh-Dole Act, see DEREK BOK, *UNIVERSITIES IN THE MARKETPLACE* 77 (2003) (While acknowledging Bayh-Dole is not without benefits, Bok states that “[u]niversities have paid a price for industry support through excessive secrecy, periodic expose’s of financial conflict, and corporate efforts to manipulate or suppress research results”). See also Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217 (2006).

Several noteworthy surveys have revealed that the biotechnology and pharmaceutical industries rely quite heavily on patents as a means of appropriation. See Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, Nat’l Bureau of Econ. Research, Working Paper No. 7552 (2004); Robert Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL’Y 273, 276 (1998) (noting that small and medium size biotechnology firms provide “a striking example of enterprises that would not have come into existence without the prospect of a patent”). Much of the upstream research for these industries occurs in research universities.

In a higher-education setting, The University of Wisconsin was at the forefront of commercializing inventions. In the 1920s, Henry Steenbock, a UW scientist, discovered how to enrich milk with vitamin D. Once his research

was published, Quaker Oats offered to purchase Steenbock's patented invention for \$900,000. Steenbock declined this offer, instead proposing a foundation be established that would both hold title and license the patent to Quaker Oats. This foundation—named the Wisconsin Alumni Research Foundation (WARF)—was created in 1925 with the help of Quaker lawyers. Today, WARF is one of the giants of university technology-transfer.

COMPARATIVE PERSPECTIVE
Biotechnology and Patents in Europe

The eligibility requirements in Europe and the U.S. provide an interesting point of comparison. In contrast to the American statutory approach, which defines what can be patented, the Europeans offer a negative expression of eligible subject matter. *See* EPC Article 57. Of note for biotech-related inventions, Article 53(a) denies patent protection for “inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality. . .”

Toward to end of the 20th century, the European Parliament sought to provide a competitive boost to the European biotech industry by issuing a *directive* codifying patent protection for biotech-related inventions. *See* Directive 98/44/EC. Several concerns were raised about the Directive, and it “was a source of friction for a decade between the European Union and its Member States as a result of differences in the national law implementing it.” Laurent Manderieux, *Europe's IP Architecture*, in *THE HANDBOOK OF EUROPEAN INTELLECTUAL PROPERTY MANAGEMENT* 3-10 (Jolly & Philpott eds., 2007). The aforementioned public morality provision in the EPC was used as tool to fight (ultimately unsuccessfully) the Directive by countries such as The Netherlands and political parties such as the Green Party. What is particularly interesting is that the European Patent Office issued biotech-related patents prior to the Directive, and certainly subsequent to its adoption.

2. Software and Business Methods

**STATE STREET BANK AND TRUST CO. v.
SIGNATURE FINANCIAL GROUP, INC.**

149 F.3d 1368 (Fed. Cir. 1998)

RICH, Circuit Judge.

Signature Financial Group, Inc. (Signature) appeals from the decision of the United States District Court for the District of Massachusetts granting a motion for summary judgment in favor of State Street Bank & Trust Co. (State Street), finding U.S. Patent No. 5,193,056 (the '056 patent) invalid on the ground that the claimed subject matter is not encompassed by 35 U.S.C. § 101 (1994). We reverse and remand because we conclude that the patent claims are directed to statutory subject matter.

BACKGROUND

Signature is the assignee of the '056 patent which is entitled "Data Processing System for Hub and Spoke Financial Services Configuration." The '056 patent issued to Signature on 9 March 1993, naming R. Todd Boes as the inventor. The '056 patent is generally directed to a data processing system (the system) for implementing an investment structure which was developed for use in Signature's business as an administrator and accounting agent for mutual funds. In essence, the system, identified by the proprietary name Hub and Spoke (R), facilitates a structure whereby mutual funds (Spokes) pool their assets in an investment portfolio (Hub) organized as a partnership. This investment configuration provides the administrator of a mutual fund with the advantageous combination of economies of scale in administering investments coupled with the tax advantages of a partnership.

State Street and Signature are both in the business of acting as custodians and accounting agents for multi-tiered partnership fund financial services. State Street negotiated with Signature for a license to use its patented data processing system described and claimed in the '056 patent. When negotiations broke down, State Street brought a declaratory judgment action asserting invalidity, unenforceability, and noninfringement in Massachusetts district court, and then filed a motion for partial summary judgment of patent invalidity for failure to claim statutory subject matter under § 101. The motion was granted and this appeal followed.

DISCUSSION

The following facts pertinent to the statutory subject matter issue are either undisputed or represent the version alleged by the nonmovant. The patented invention relates generally to a system that allows an administrator to monitor and record the financial information flow and make all calculations necessary for maintaining a partner fund financial services configuration. As previously mentioned, a partner fund financial services configuration essentially allows several mutual funds, or "Spokes," to pool their investment funds into a single portfolio, or "Hub," allowing for consolidation of, inter alia, the costs of administering the fund combined with the tax advantages of a partnership. In particular, this system provides means for a daily allocation of assets for two or more Spokes that are invested in the same Hub. The system determines the percentage share that each Spoke maintains in the Hub, while taking into consideration daily changes both in the value of the Hub's investment securities and in the concomitant amount of each Spoke's assets.

In determining daily changes, the system also allows for the allocation among the Spokes of the Hub's daily income, expenses, and net realized and unrealized gain or loss, calculating each day's total investments based on the concept of a book capital account. This enables the determination of a true asset value of each Spoke and accurate calculation of allocation ratios between or among the Spokes. The system additionally tracks all the relevant data determined on a daily basis for the Hub and each Spoke, so that aggregate year end income, expenses, and capital gain or loss can be determined for accounting and for tax purposes for the Hub and, as a result, for each publicly traded Spoke.

It is essential that these calculations are quickly and accurately performed. In large part this is required because each Spoke sells shares to the public and the price of those shares is substantially based on the Spoke's percentage interest in the portfolio. In some instances, a mutual fund administrator is required to calculate the value of the shares to the nearest penny within as little as an hour and a half after the market closes. Given the complexity of the calculations, a computer or equivalent device is a virtual necessity to perform the task.

The '056 patent application was filed 11 March 1991. It initially contained six "machine" claims, which incorporated means-plus-function clauses, and six method claims. According to Signature, during prosecution the examiner contemplated a § 101 rejection for failure to claim statutory subject matter. However, upon cancellation of the six method claims, the examiner issued a notice of allowance for the remaining present six claims on appeal. Only claim 1 is an independent claim.

The district court began its analysis by construing the claims to be directed to a process, with each "means" clause merely representing a step in that process. However, "machine" claims having "means" clauses may only be reasonably viewed as process claims if there is no supporting structure in the written description that corresponds to the claimed "means" elements. See *In re Alappat*. This is not the case now before us.

When independent claim 1 is properly construed in accordance with § 112, ¶ 6, it is directed to a machine, as demonstrated below, where representative claim 1 is set forth, the subject matter in brackets stating the structure the written description discloses as corresponding to the respective "means" recited in the claims.

1. A data processing system for managing a financial services configuration of a portfolio established as a partnership, each partner being one of a plurality of funds, comprising:

(a) computer processor means [a personal computer including a CPU] for processing data;

(b) storage means [a data disk] for storing data on a storage medium;

(c) first means [an arithmetic logic circuit configured to prepare the data disk to magnetically store selected data] for initializing the storage medium;

(d) second means [an arithmetic logic circuit configured to retrieve information from a specific file, calculate incremental increases or decreases based on specific input, allocate the results on a percentage basis, and store the output in a separate file] for processing data regarding assets in the portfolio and each of the funds from a previous day and data regarding increases or decreases in each of the funds, [sic, funds'] assets and for allocating the percentage share that each fund holds in the portfolio;

(e) third means [an arithmetic logic circuit configured to retrieve information from a specific file, calculate incremental increases and decreases based on specific input, allocate the results on a percentage basis and store the output in a separate file] for processing data regarding daily incremental income, expenses, and net realized gain or loss for the portfolio and for allocating such data among each fund;

(f) fourth means [an arithmetic logic circuit configured to retrieve information from a specific file, calculate incremental increases and decreases based on specific input, allocate the results on a percentage basis and store

the output in a separate file] for processing data regarding daily net unrealized gain or loss for the portfolio and for allocating such data among each fund; and

(g) fifth means [an arithmetic logic circuit configured to retrieve information from specific files, calculate that information on an aggregate basis and store the output in a separate file] for processing data regarding aggregate year-end income, expenses, and capital gain or loss for the portfolio and each of the funds.

Each claim component, recited as a “means” plus its function, is to be read, of course, pursuant to § 112, ¶ 6, as inclusive of the “equivalents” of the structures disclosed in the written description portion of the specification. Thus, claim 1, properly construed, claims a machine, namely, a data processing system for managing a financial services configuration of a portfolio established as a partnership, which machine is made up of, at the very least, the specific structures disclosed in the written description and corresponding to the means-plus-function elements (a)–(g) recited in the claim. A “machine” is proper statutory subject matter under § 101. We note that, for the purposes of a § 101 analysis, it is of little relevance whether claim 1 is directed to a “machine” or a “process,” as long as it falls within at least one of the four enumerated categories of patentable subject matter, “machine” and “process” being such categories.

This does not end our analysis, however, because the court concluded that the claimed subject matter fell into one of two alternative judicially-created exceptions to statutory subject matter. The court refers to the first exception as the “mathematical algorithm” exception and the second exception as the “business method” exception. . . .

The plain and unambiguous meaning of § 101 is that any invention falling within one of the four stated categories of statutory subject matter may be patented, provided it meets the other requirements for patentability set forth in Title 35, i.e., those found in §§ 102, 103, and 112, ¶ 2.

The repetitive use of the expansive term “any” in § 101 shows Congress’s intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in § 101. Indeed, the Supreme Court has acknowledged that Congress intended § 101 to extend to “anything under the sun that is made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Thus, it is improper to read limitations into § 101 on the subject matter that may be patented where the legislative history indicates that Congress clearly did not intend such limitations. See *Chakrabarty*, 447 U.S. at 308 (“We have also cautioned that courts ‘should not read into the patent laws limitations and conditions which the legislature has not expressed.’”)

THE “MATHEMATICAL ALGORITHM” EXCEPTION

The Supreme Court has identified three categories of subject matter that are unpatentable, namely “laws of nature, natural phenomena, and abstract ideas.” *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). Of particular relevance to this case, the Court has held that mathematical algorithms are not patentable subject matter to the extent that they are merely abstract ideas. See *Diehr*; *Parker v. Flook*; *Gottschalk v. Benson*. In *Diehr*, the Court explained that certain types of mathematical subject matter, standing alone, represent nothing more

than abstract ideas until reduced to some type of practical application, *i.e.*, “a useful, concrete and tangible result.” *In re Alappat*, 33 F.3d at 1544.

Unpatentable mathematical algorithms are identifiable by showing they are merely abstract ideas constituting disembodied concepts or truths that are not “useful.” From a practical standpoint, this means that to be patentable an algorithm must be applied in a “useful” way. In *Alappat*, we held that data, transformed by a machine through a series of mathematical calculations to produce a smooth waveform display on a rasterizer monitor, constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation), because it produced “a useful, concrete and tangible result”—the smooth waveform.

Similarly, in *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, we held that the transformation of electrocardiograph signals from a patient’s heart-beat by a machine through a series of mathematical calculations constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation), because it corresponded to a useful, concrete or tangible thing—the condition of a patient’s heart.

Today, we hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces “a useful, concrete and tangible result”—a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

The district court erred by applying the *Freeman-Walter-Abele* test to determine whether the claimed subject matter was an unpatentable abstract idea. The *Freeman-Walter-Abele* test was designed by the Court of Customs and Patent Appeals, and subsequently adopted by this court, to extract and identify unpatentable mathematical algorithms in the aftermath of *Benson* and *Flook*. See *In re Freeman* as modified by *In re Walter*. The test has been thus articulated:

First, the claim is analyzed to determine whether a mathematical algorithm is directly or indirectly recited. Next, if a mathematical algorithm is found, the claim as a whole is further analyzed to determine whether the algorithm is “applied in any manner to physical elements or process steps,” and, if it is, it “passes muster under § 101.”

In re Pardo, 684 F.2d 912, 915 (CCPA 1982).

After *Diehr* and *Chakrabarty*, the *Freeman-Walter-Abele* test has little, if any, applicability to determining the presence of statutory subject matter. As we pointed out in *Alappat*, application of the test could be misleading, because a process, machine, manufacture, or composition of matter employing a law of nature, natural phenomenon, or abstract idea is patentable subject matter even though a law of nature, natural phenomenon, or abstract idea would not, by itself, be entitled to such protection. The test determines the presence of, for example, an algorithm. Under *Benson*, this may have been a sufficient indicium of nonstatutory subject matter. However, after *Diehr* and *Alappat*, the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless, of course, its operation does

not produce a “useful, concrete and tangible result.” *Alappat*, 33 F.3d at 1544. After all, as we have repeatedly stated,

every step-by-step process, be it electronic or chemical or mechanical, involves an algorithm in the broad sense of the term. Since § 101 expressly includes processes as a category of inventions which may be patented and § 100(b) further defines the word “process” as meaning “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material,” it follows that it is no ground for holding a claim is directed to non-statutory subject matter to say it includes or is directed to an algorithm. This is why the proscription against patenting has been limited to mathematical algorithms. . . .

In re Iwahashi, 888 F.2d 1370, 1374 (Fed. Cir. 1989).

The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to⁹—process, machine, manufacture, or composition of matter—but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other “conditions and requirements” of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. *See In re Warmerdam*. For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a “useful, concrete, and tangible result.” This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

THE BUSINESS METHOD EXCEPTION

As an alternative ground for invalidating the '056 patent under § 101, the court relied on the judicially-created, so-called “business method” exception to statutory subject matter. We take this opportunity to lay this ill-conceived exception to rest. Since its inception, the “business method” exception has merely represented the application of some general, but no longer applicable legal principle, perhaps arising out of the “requirement for invention”—which was eliminated by § 103. Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.

The business method exception has never been invoked by this court, or the CCPA, to deem an invention unpatentable. Application of this particular exception has always been preceded by a ruling based on some clearer concept of Title 35 or, more commonly, application of the abstract idea exception based on finding a mathematical algorithm. Illustrative is the CCPA’s analysis in *In re Howard*, wherein the court affirmed the Board of Appeals’ rejection of the claims for lack of novelty and found it unnecessary to reach the Board’s section 101 ground that a method of doing business is “inherently unpatentable.” 394 F.2d at 872.

Similarly, *In re Schrader*, while making reference to the business method exception, turned on the fact that the claims implicitly recited an abstract idea in the form of a mathematical algorithm and there was no “transformation or

9. Of course, the subject matter must fall into at least one category of statutory subject matter.

conversion of subject matter representative of or constituting physical activity or objects.” 22 F.3d at 294.

State Street argues that we acknowledged the validity of the business method exception in *Alappat* when we discussed *Maucorps* and *Meyer*:

Maucorps dealt with a business methodology for deciding how salesmen should best handle respective customers and *Meyer* involved a “system” for aiding a neurologist in diagnosing patients. Clearly, neither of the alleged “inventions” in those cases falls within any § 101 category.

Alappat, 33 F.3d at 1541. However, closer scrutiny of these cases reveals that the claimed inventions in both *Maucorps* and *Meyer* were rejected as abstract ideas under the mathematical algorithm exception, not the business method exception.

Even the case frequently cited as establishing the business method exception to statutory subject matter, *Hotel Security Checking Co. v. Lorraine Co.*, did not rely on the exception to strike the patent. In that case, the patent was found invalid for lack of novelty and “invention,” not because it was improper subject matter for a patent. The court stated “the fundamental principle of the system is as old as the art of bookkeeping, i.e., charging the goods of the employer to the agent who takes them.” 160 F. at 469. “If at the time of [the patent] application, there had been no system of bookkeeping of any kind in restaurants, we would be confronted with the question whether a new and useful system of cash registering and account checking is such an art as is patentable under the statute.” *Id.* at 472.

This case is no exception. The district court announced the precepts of the business method exception as set forth in several treatises, but noted as its primary reason for finding the patent invalid under the business method exception as follows:

If Signature’s invention were patentable, any financial institution desirous of implementing a multi-tiered funding complex modelled (sic) on a Hub and Spoke configuration would be required to seek Signature’s permission before embarking on such a project. This is so because the ’056 Patent is claimed [sic] sufficiently broadly to foreclose virtually any computer-implemented accounting method necessary to manage this type of financial structure.

927 F. Supp. 502, 516. Whether the patent’s claims are too broad to be patentable is not to be judged under § 101, but rather under §§ 102, 103 and 112. Assuming the above statement to be correct, it has nothing to do with whether what is claimed is statutory subject matter.

AT&T CORP. v. EXCEL COMMUNICATIONS, INC.

172 F.3d 1352 (Fed. Cir. 1999)

PLAGER, Circuit Judge.

This case asks us once again to examine the scope of section 1 of the Patent Act, 35 U.S.C. § 101 (1994). The United States District Court for the District of Delaware granted summary judgment to Excel Communications, Inc., holding U.S. Patent No. 5,333,184 (the ’184 patent) invalid under § 101 for failure to claim statutory subject matter. AT&T Corp. (“AT&T”), owner of the ’184

patent, appeals. Because we find that the claimed subject matter is properly within the statutory scope of § 101, we reverse the district court's judgment of invalidity on this ground and remand the case for further proceedings.

BACKGROUND

A.

The '184 patent, entitled "Call Message Recording for Telephone Systems," issued on July 26, 1994. It describes a message record for long-distance telephone calls that is enhanced by adding a primary interexchange carrier ("PIC") indicator. The addition of the indicator aids long-distance carriers in providing differential billing treatment for subscribers, depending upon whether a subscriber calls someone with the same or a different long-distance carrier.

The invention claimed in the '184 patent is designed to operate in a telecommunications system with multiple long-distance service providers. The system contains local exchange carriers ("LECs") and long-distance service (interexchange) carriers ("IXCs"). The LECs provide local telephone service and access to IXCs. Each customer has an LEC for local service and selects an IXC, such as AT & T or Excel, to be its primary long-distance service (interexchange) carrier or PIC. IXCs may own their own facilities, as does AT&T. Others, like Excel, called "resellers" or "resale carriers," contract with facility-owners to route their subscribers' calls through the facility-owners' switches and transmission lines. Some IXCs, including MCI and U.S. Sprint, have a mix of their own lines and leased lines.

The system thus involves a three-step process when a caller makes a direct-dialed (1+) long-distance telephone call: (1) after the call is transmitted over the LEC's network to a switch, and the LEC identifies the caller's PIC, the LEC automatically routes the call to the facilities used by the caller's PIC; (2) the PIC's facilities carry the call to the LEC serving the call recipient; and (3) the call recipient's LEC delivers the call over its local network to the recipient's telephone.

When a caller makes a direct-dialed long-distance telephone call, a switch (which may be a switch in the interexchange network) monitors and records data related to the call, generating an "automatic message account" ("AMA") message record. This contemporaneous message record contains fields of information such as the originating and terminating telephone numbers, and the length of time of the call. These message records are then transmitted from the switch to a message accumulation system for processing and billing.

Because the message records are stored in electronic format, they can be transmitted from one computer system to another and reformatted to ease processing of the information. Thus the carrier's AMA message subsequently is translated into the industry-standard "exchange message interface," forwarded to a rating system, and ultimately forwarded to a billing system in which the data resides until processed to generate, typically, "hard copy" bills which are mailed to subscribers.

B.

The invention of the '184 patent calls for the addition of a data field into a standard message record to indicate whether a call involves a particular PIC

(the “PIC indicator”). This PIC indicator can exist in several forms, such as a code which identifies the call recipient’s PIC, a flag which shows that the recipient’s PIC is or is not a particular IXC, or a flag that identifies the recipient’s and the caller’s PICs as the same IXC. The PIC indicator therefore enables IXCs to provide differential billing for calls on the basis of the identified PIC.

The application that issued as the ’184 patent was filed in 1992. The U.S. Patent and Trademark Office (“PTO”) initially rejected, for reasons unrelated to § 101, all forty-one of the originally filed claims. Following amendment, the claims were issued in 1994 in their present form. The ’184 patent contains six independent claims, five method claims and one apparatus claim, and additional dependent claims. The PTO granted the ’184 patent without questioning whether the claims were directed to statutory subject matter under § 101.

AT&T in 1996 asserted ten of the method claims against Excel in this infringement suit. The independent claims at issue (claims 1, 12, 18, and 40) include the step of “generating a message record for an interexchange call between an originating subscriber and a terminating subscriber,” and the step of adding a PIC indicator to the message record. Independent claim 1, for example, adds a PIC indicator whose value depends upon the call recipient’s PIC:

A method for use in a telecommunications system in which interexchange calls initiated by each subscriber are automatically routed over the facilities of a particular one of a plurality of interexchange carriers associated with that subscriber, said method comprising the steps of:

generating a message record for an interexchange call between an originating subscriber and a terminating subscriber, and

including, in said message record, a primary interexchange carrier (PIC) indicator having a value which is a function of whether or not the interexchange carrier associated with said terminating subscriber is a predetermined one of said interexchange carriers.

(Emphasis added.) Independent claims 12 and 40 add a PIC indicator that shows if a recipient’s PIC is the same as the IXC over which that particular call is being made. Independent claim 18 adds a PIC indicator designed to show if the caller and the recipient subscribe to the same IXC. The dependent claims at issue add the steps of accessing an IXC’s subscriber database (claims 4, 13, and 19) and billing individual calls as a function of the value of the PIC indicator (claims 6, 15, and 21).

The district court concluded that the method claims of the ’184 patent implicitly recite a mathematical algorithm. The court was of the view that the only physical step in the claims involves data-gathering for the algorithm. Though the court recognized that the claims require the use of switches and computers, it nevertheless concluded that use of such facilities to perform a non-substantive change in the data’s format could not serve to convert non-patentable subject matter into patentable subject matter. Thus the trial court, on summary judgment, held all of the method claims at issue invalid for failure to qualify as statutory subject matter.

DISCUSSION

A.

The issue on appeal, whether the asserted claims of the '184 patent are invalid for failure to claim statutory subject matter under 35 U.S.C. § 101, is a question of law which we review without deference. In matters of statutory interpretation, it is this court's responsibility independently to determine what the law is.

B.

Our analysis of whether a claim is directed to statutory subject matter begins with the language of 35 U.S.C. § 101, which reads:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Supreme Court has construed § 101 broadly, noting that Congress intended statutory subject matter to "include anything under the sun that is made by man." See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); see also *Diamond v. Diehr*, 450 U.S. 175, 182 (1981). Despite this seemingly limitless expanse, the Court has specifically identified three categories of unpatentable subject matter: "laws of nature, natural phenomena, and abstract ideas." See *Diehr*, 450 U.S. at 185.

In this case, the method claims at issue fall within the "process"¹ category of the four enumerated categories of patentable subject matter in § 101. The district court held that the claims at issue, though otherwise within the terms of § 101, implicitly recite a mathematical algorithm, and thus fall within the judicially created "mathematical algorithm" exception to statutory subject matter.

A mathematical formula alone, sometimes referred to as a mathematical algorithm, viewed in the abstract, is considered unpatentable subject matter. See *Diehr*; *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63 (1972). Courts have used the terms "mathematical algorithm," "mathematical formula," and "mathematical equation," to describe types of nonstatutory mathematical subject matter without explaining whether the terms are interchangeable or different. Even assuming the words connote the same concept, there is considerable question as to exactly what the concept encompasses. See, e.g., *Diehr*, 450 U.S. at 186 n. 9 ("The term 'algorithm' is subject to a variety of definitions . . . [Petitioner's] definition is significantly broader than the definition this Court employed in *Benson* and *Flook*.").

This court recently pointed out that any step-by-step process, be it electronic, chemical, or mechanical, involves an "algorithm" in the broad sense of the term. See *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1374-75 (Fed. Cir. 1998). Because § 101 includes processes as a category of patentable subject matter, the judicially-defined proscription against patenting of a "mathematical algorithm," to the extent such a proscription still

1. "Process" is defined in 35 U.S.C. § 100(b) to encompass: "[a] process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

exists, is narrowly limited to mathematical algorithms in the abstract. *See id.*; *see also Benson*, 409 U.S. at 65 (describing a mathematical algorithm as a “procedure for solving a given type of mathematical problem”).

Since the process of manipulation of numbers is a fundamental part of computer technology, we have had to reexamine the rules that govern the patentability of such technology. The sea-changes in both law and technology stand as a testament to the ability of law to adapt to new and innovative concepts, while remaining true to basic principles. In an earlier era, the PTO published guidelines essentially rejecting the notion that computer programs were patentable. As the technology progressed, our predecessor court disagreed, and, overturning some of the earlier limiting principles regarding § 101, announced more expansive principles formulated with computer technology in mind.³ In our recent decision in *State Street*, this court discarded the so-called “business method” exception and reassessed the “mathematical algorithm” exception, both judicially-created “exceptions” to the statutory categories of § 101. As this brief review suggests, this court (and its predecessor) has struggled to make our understanding of the scope of § 101 responsive to the needs of the modern world.

The Supreme Court has supported and enhanced this effort. In *Diehr*, the Court expressly limited its two earlier decisions in *Flook* and *Benson* by emphasizing that these cases did no more than confirm the “long-established principle” that laws of nature, natural phenomena, and abstract ideas are excluded from patent protection. 450 U.S. at 185. The *Diehr* Court explicitly distinguished *Diehr*’s process by pointing out that “the respondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber.” *Id.* at 187. The Court then explained that although the process used a well-known mathematical equation, the applicants did not “pre-empt the use of that equation.” *Id.* Thus, even though a mathematical algorithm is not patentable in isolation, a process that applies an equation to a new and useful end “is at the very least not barred at the threshold by § 101.” *Id.* at 188. In this regard, it is particularly worthy of note that the argument for the opposite result, that “the term ‘algorithm’ . . . is synonymous with the term ‘computer program,’” *id.* at 219 (Stevens, J., dissenting), and thus computer-based programs as a general proposition should not be patentable, was made forcefully in dissent by Justice Stevens; his view, however, was rejected by the *Diehr* majority.

As previously noted, we most recently addressed the “mathematical algorithm” exception in *State Street*. In *State Street*, this court, following the Supreme Court’s guidance in *Diehr*, concluded that “[u]npatentable mathematical algorithms are identifiable by showing they are merely abstract ideas constituting disembodied concepts or truths that are not ‘useful.’ . . . [T]o be patentable an algorithm must be applied in a ‘useful’ way.” *Id.* at 1373. In that case, the claimed data processing system for implementing a financial management structure satisfied the § 101 inquiry because it constituted a “practical application of a mathematical algorithm, . . . [by] produc[ing] ‘a useful, concrete and tangible result.’” *Id.* at 1373.

3. For a more detailed review of this history, with extensive citation to the secondary literature, see Justice Stevens’s dissent in *Diehr*, 450 U.S. at 193.

The *State Street* formulation, that a mathematical algorithm may be an integral part of patentable subject matter such as a machine or process if the claimed invention as a whole is applied in a “useful” manner, follows the approach taken by this court en banc in *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994). In *Alappat*, we set out our understanding of the Supreme Court’s limitations on the patentability of mathematical subject matter and concluded that:

[The Court] never intended to create an overly broad, fourth category of [mathematical] subject matter excluded from § 101. Rather, at the core of the Court’s analysis . . . lies an attempt by the Court to explain a rather straightforward concept, namely, that certain types of mathematical subject matter, *standing alone*, represent nothing more than *abstract ideas until reduced to some type of practical application*, and thus that subject matter is not, in and of itself, entitled to patent protection.

Id. at 1543 (emphasis added). Thus, the *Alappat* inquiry simply requires an examination of the contested claims to see if the claimed subject matter as a whole is a disembodied mathematical concept representing nothing more than a “law of nature” or an “abstract idea,” or if the mathematical concept has been reduced to some practical application rendering it “useful.” *Id.* at 1544. In *Alappat*, we held that more than an abstract idea was claimed because the claimed invention as a whole was directed toward forming a specific machine that produced the useful, concrete, and tangible result of a smooth waveform display.

In both *Alappat* and *State Street*, the claim was for a machine that achieved certain results. In the case before us, because Excel does not own or operate the facilities over which its calls are placed, AT&T did not charge Excel with infringement of its apparatus claims, but limited its infringement charge to the specified method or process claims. Whether stated implicitly or explicitly, we consider the scope of § 101 to be the same regardless of the form—machine or process—in which a particular claim is drafted. *See, e.g., In re Alappat*, 33 F.3d at 1581 (Rader, J., concurring) (“Judge Rich, with whom I fully concur, reads *Alappat*’s application as claiming a machine. In fact, whether the invention is a process or a machine is irrelevant. The language of the Patent Act itself, as well as Supreme Court rulings, clarifies that *Alappat*’s invention fits comfortably within 35 U.S.C. § 101 whether viewed as a process or a machine.”); *State Street*, 149 F.3d at 1372 (“[F]or the purposes of a § 101 analysis, it is of little relevance whether claim 1 is directed to a ‘machine’ or a ‘process,’ . . .”). Furthermore, the Supreme Court’s decisions in *Diehr*, *Benson*, and *Flook*, all of which involved method (*i.e.*, process) claims, have provided and supported the principles which we apply to both machine—and process-type claims. Thus, we are comfortable in applying our reasoning in *Alappat* and *State Street* to the method claims at issue in this case.

C.

In light of this review of the current understanding of the “mathematical algorithm” exception, we turn now to the arguments of the parties in support of and in opposition to the trial court’s judgment. We note that, at the time the trial court made its decision, that court did not have the benefit of this court’s explication in *State Street* of the mathematical algorithm issue.

As previously explained, AT&T's claimed process employs subscribers' and call recipients' PICs as data, applies Boolean algebra to those data to determine the value of the PIC indicator, and applies that value through switching and recording mechanisms to create a signal useful for billing purposes. In *State Street*, we held that the processing system there was patentable subject matter because the system takes data representing discrete dollar amounts through a series of mathematical calculations to determine a final share price—a useful, concrete, and tangible result.

In this case, Excel argues, correctly, that the PIC indicator value is derived using a simple mathematical principle (p and q). But that is not determinative because AT&T does not claim the Boolean principle as such or attempt to forestall its use in any other application. It is clear from the written description of the '184 patent that AT&T is only claiming a process that uses the Boolean principle in order to determine the value of the PIC indicator. The PIC indicator represents information about the call recipient's PIC, a useful, non-abstract result that facilitates differential billing of long-distance calls made by an IXC's subscriber. Because the claimed process applies the Boolean principle to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle, on its face the claimed process comfortably falls within the scope of § 101.

Excel argues that method claims containing mathematical algorithms are patentable subject matter only if there is a “physical transformation” or conversion of subject matter from one state into another. The physical transformation language appears in *Diehr*, see 450 U.S. at 184 (“That respondents' claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing cannot be disputed.”), and has been echoed by this court in *Schrader*, 22 F.3d at 294 (“Therefore, we do not find in the claim any kind of data transformation.”).

The notion of “physical transformation” can be misunderstood. In the first place, it is not an invariable requirement, but merely one example of how a mathematical algorithm may bring about a useful application. As the Supreme Court itself noted, “when [a claimed invention] is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.” *Diehr*, 450 U.S. at 192.

This understanding of transformation is consistent with our earlier decision in *Arrhythmia*, 958 F.2d 1053 (Fed. Cir. 1992). *Arrhythmia*'s process claims included various mathematical formulae to analyze electrocardiograph signals to determine a specified heart activity. The *Arrhythmia* court reasoned that the method claims qualified as statutory subject matter by noting that the steps transformed physical, electrical signals from one form into another form—a number representing a signal related to the patient's heart activity, a non-abstract output. The finding that the claimed process “transformed” data from one “form” to another simply confirmed that *Arrhythmia*'s method claims satisfied § 101 because the mathematical algorithm included within the process was applied to produce a number which had specific meaning—a useful, concrete, tangible result—not a mathematical abstraction.

Excel also contends that because the process claims at issue lack physical limitations set forth in the patent, the claims are not patentable subject matter. This argument reflects a misunderstanding of our case law. Since the claims at

issue in this case are directed to a process in the first instance, a structural inquiry is unnecessary. The argument that physical limitations are necessary may also stem from the second part of the *Freeman-Walter-Abele* test, an earlier test which has been used to identify claims thought to involve unpatentable mathematical algorithms. That second part was said to inquire “whether the claim is directed to a mathematical algorithm that is not applied to or limited by physical elements.” *Arrhythmia*, 958 F.2d at 1058. Although our en banc *Alappat* decision called this test “not an improper analysis,” we then pointed out that “the ultimate issue always has been whether the claim as a whole is drawn to statutory subject matter.” 33 F.3d at 1543 n. 21. Furthermore, our recent *State Street* decision questioned the continuing viability of the *Freeman-Walter-Abele* test, noting that, “[a]fter *Diehr* and *Chakrabarty*, the *Freeman-Walter-Abele* test has little, if any, applicability to determining the presence of statutory subject matter.” 149 F.3d at 1374. Whatever may be left of the earlier test, if anything, this type of physical limitations analysis seems of little value because “after *Diehr* and *Alappat*, the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless, of course, its operation does not produce a ‘useful, concrete and tangible result.’” *Id.* at 1374.

D.

In his dissent in *Diehr*, Justice Stevens noted two concerns regarding the § 101 issue, and to which, in his view, federal judges have a duty to respond:

First, the cases considering the patentability of program-related inventions do not establish rules that enable a conscientious patent lawyer to determine with a fair degree of accuracy which, if any, program-related inventions will be patentable. Second, the inclusion of the ambiguous concept of an “algorithm” within the “law of nature” category of unpatentable subject matter has given rise to the concern that almost any process might be so described and therefore held unpatentable.

Diehr, 450 U.S. at 219 (Stevens, J., dissenting).

Despite the almost twenty years since Justice Stevens wrote, these concerns remain important. His solution was to declare all computer-based programming unpatentable. That has not been the course the law has taken. Rather, it is now clear that computer-based programming constitutes patentable subject matter so long as the basic requirements of § 101 are met. Justice Stevens’s concerns can be addressed within that framework.

His first concern, that the rules are not sufficiently clear to enable reasonable prediction of outcomes, should be less of a concern today in light of the refocusing of the § 101 issue that *Alappat* and *State Street* have provided. His second concern, that the ambiguous concept of “algorithm” could be used to make any process unpatentable, can be laid to rest once the focus is understood to be not on whether there is a mathematical algorithm at work, but on whether the algorithm-containing invention, as a whole, produces a tangible, useful, result.

In light of the above, and consistent with the clearer understanding that our more recent cases have provided, we conclude that the district court did not apply the proper analysis to the method claims at issue. Accordingly, we hold

as a matter of law that Excel was not entitled to the grant of summary judgment of invalidity of the '184 patent under § 101.

Comments

1. ***Defining Software and the Software Patent.*** It is common to think of software as part of a CD-ROM or that which forms part of a computer and provides it with functional applications. But it is more accurate to think of software as a series of instructions, known as source code and object code, “that directs a computer to perform specified functions or operations.” *Fantasy Sports Props., Inc. v. Sportslines.com, Inc.*, 287 F.3d 1108, 1118 (Fed. Cir. 2002). Indeed, the PTO’s Manual of Patent Examination Procedure (MPEP) states “a computer program is merely a set of instructions capable of being executed by a computer.” MPEP § 2106.IV.B.1(a) (8th ed. 2001).

It is particularly difficult to define a software patent and there is no universally accepted definition. Perhaps the reason for this elusiveness has something to do with software’s pervasiveness across many industries that make categorization quite difficult. See Stuart J.H. Graham & David C. Mowery, *Software Patents: Good News or Bad News*, http://tiger.gatech.edu/files/gt_tiger_software.pdf at 29 (May 2004) (stating “[o]ne of the thorniest problems in analyzing software patenting, of course, is defining and measuring software patents”).

2. ***“Useful, Concrete and Tangible Result.”*** The *State Street* court broadly opened the doors of § 101’s subject matter requirement and held that patent eligibility is satisfied regardless of format as long as the claimed invention produces a “useful, concrete, and tangible result,” which in this case was a final share price. The *AT&T* court extended *State Street*. The court rejected the physical transformation requirement for claims comprising algorithms. This requirement, according to the court, is “but merely one example of how a mathematical algorithm may bring about a useful application.” 172 F.3d at 1358.

In the light of *State Street* and *AT&T*, the PTO adopted examination guidelines relating to patentable subject matter. In these guidelines, embodied in the Manual of Patent Examination Procedure (“MPEP”), physical transformation is not a requirement and the agency gives definition to “useful, concrete, and tangible.” To be “useful,” the claimed invention must satisfy § 101’s utility requirement and have “practical application.” The term “concrete” is defined as an invention that is “substantially repeatable or . . . can “substantially produce the same result again.” And “tangible” means “not abstract” and that which “produce[s] a real-world result.” MPEP § 2106 (September 2007).

In *Gottschalk v. Benson*, 409 U.S. 63 (1972), the Supreme Court’s first foray into the patentability of inventions related to mathematical algorithms and computer-related inventions, the Court held that a method for converting binary-code decimal numerals into binary numerals was not eligible for patent protection under § 101. The patent in *Benson* related to processing data and the “conversion of numerical information.” *Id.* at 64. According to the *Benson* Court, “a patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the

algorithm itself.” *Id.* at 72. Thus, the Court was concerned with patenting abstract ideas and overly broad claims. (Indeed, *Benson* quoted extensively from *O’Reilly v. Morse*.) In important dicta, however, the Court stated, “transformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” *Id.* at 70.

Nine years later, in *Diamond v. Diehr*, 450 U.S. 175 (1981), the Court emphasized this “transformation” language and held that a claimed process that included use of a mathematical algorithm and use of a computer to calculate cure time in a molding process to be eligible for patent protection under § 101. Also, the *Diehr* Court stressed that an § 101 eligibility examination must view “claims as a whole.” As the Court wrote:

When a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws are designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.

Id. at 192. In *State Street* (and *Alappat* before), the Federal Circuit adopted the “claims as a whole approach,” which included algorithms that are part of a specific machine, rather than a series of disembodied mathematical formulae that in and of themselves would not be patentable subject matter. Moreover, the *State Street* court embraced the importance of transformation—here the transformation of data into discrete dollar amounts, a transformation that employs algorithms in a “useful way.” And the *Alappat/State Street/AT&T* trilogy remains the doctrinal Federal Circuit’s doctrinal framework.

3. **AT&T and Reconciling Diehr.** In *Diamond v. Diehr*, Justice Stevens delivered a powerful dissent arguing software should be per se unpatentable. The *State Street* case, while certainly an important opinion regarding software eligibility, did not address Stevens’ dissent in *Diehr*. But *AT&T*—an important case, but one that has been in *State Street*’s shadow—did try to reconcile the “useful, concrete, and tangible” language of *State Street* with Stevens’s concern about uncertainty and ambiguity. In language worth restating, the *AT&T* court wrote that Justice Stevens’s

first concern, that the rules are not sufficiently clear to enable reasonable prediction of outcomes, should be less of a concern today in light of the refocusing of the § 101 issue that *Alappat* and *State Street* have provided. His second concern, that the ambiguous concept of “algorithm” could be used to make any process unpatentable, can be laid to rest once the focus is understood to be not on whether there is a mathematical algorithm at work, but on whether the algorithm-containing invention, as a whole, produces a tangible, useful, result.

4. **The Resurgence of § 101’s Eligibility Requirement?** Recent Federal Circuit case law suggests that the court may be putting more bite into § 101 eligibility requirements. In *In re Comiskey*, the applicant claimed method and system for mandatory arbitration involving legal documents. The claimed invention did not require a machine, nor does it describe a process of manufacture or a process for the alteration of a composition of matter.

The court characterized Comiskey's patent as claiming "the mental process of resolving a legal dispute between two parties by the decision of a human arbitrator." In support of its conclusion that "Comiskey's independent claims 1 and 32 seek to patent the use of human intelligence in and of itself," the court recited the legal principles of eligibility:

It is thus clear that the present statute does not allow patents to be issued on particular business systems—such as a particular type of arbitration—that depend entirely on the use of mental processes. In other words, the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable.

In re Comiskey, 499 F.3d 1365 (Fed. Cir. 2007). *See also In re Nuijten*, — F.3d —, 2007 WL 2728397 (Fed. Cir. 2007) (holding patent claiming electrical signal unpatentable under § 101 subject matter requirements); *Ex parte Lundgren*, 76 U.S.P.Q.2d 1385 (B.P.A.I. 2005) (asserting "there is currently no judicially recognized separate 'technological arts' test to determine patent eligible subject matter under Section 101"). These cases parallel the Supreme Court's recently expressed skepticism on certain types of inventions, a topic discussed in the following Comment.

5. ***The Supreme Court's Growing Skepticism.*** Concomitant with the USPTO's and Federal Circuit's recent push into § 101, the Supreme Court has expressed an interest in subject matter eligibility. In 2006, for example, the Court was poised to decide a § 101 eligibility case. *See LabCorp v. Metabolite*. The Court ultimately dismissed the certiorari as improvidently granted, 126 S. Ct. 2921 (2006), but the question presented and the dissent from the dismissal are telling. The question presented was:

Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

Justice Breyer, joined by Justices Souter and Stevens, dissented from the dismissal, and signaled his concerns with the Federal Circuit's "useful, concrete, and tangible" test:

[T]he Federal Circuit's decision in *State Street Bank* help respondents. That case does say that a process is patentable if it produces a "useful, concrete, and tangible result." But this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary. The Court, for example, has invalidated a claim to the use of electromagnetic current for transmitting messages over long distances even though it produces a result that seems "useful, concrete, and tangible." *Morse*. Similarly the Court has invalidated a patent setting forth a system for triggering alarm limits in connection with catalytic conversion despite a similar utility, concreteness, and tangibility. *Flook*. And the Court has invalidated a patent setting forth a process that transforms, for computer-programming purposes, decimal figures into binary figures—even though the result would

seem useful, concrete, and at least arguably (within the computer's wiring system) tangible. *Gottschalk*.

126 S. Ct. at 2928.

6. ***Software and Patents: A Complex and Controversial Relationship.*** The patenting of software has always been controversial. Software firms, especially during the 1980s, turned to copyright law as a means of appropriating their innovations. Code was considered a form of expression. But by the early 1990s, copyrights became less important as courts began narrowly interpreting copyright law as applied to software. *See, e.g., Apple Computer, Inc. v. Microsoft, Inc.*, 35 F.3d 1435 (9th Cir. 1994) (denying copyright protection for Apple's graphical user interface); *Lotus Development Corp. v. Borland International, Inc.*, 49 F.3d 807 (1st Cir. 1995) (holding no copyright protection for pull-down menus). As such, copyright doctrine was seen as an increasingly poor fit for software. Copyright law protects the expression of the software code, not functional elements of the software. And reverse engineering is a rather straightforward means of obtaining access to software's functionality. Unlike a patent, a copyright does not protect its owner against reverse engineering, which is considered a form of fair use. *See Sony Computer Entertainment, Inc. v. Connectix Corp.*, 203 F.3d 596 (9th Cir. 2000). *See also* Robert J. Mann, *Do Patents Facilitate Financing in the Software Industry*, 83 TEX. L. REV. 961, 1013, 1015 (2005) (stating "[t]he most obvious problem with copyright protection for software relates to reverse engineering" by competitors, but copyright law does have an important role in preventing piracy by customers and code "theft" from departing employees); Peter S. Menell, *Envisioning Copyright Law's Digital Future*, 36 N.Y.L. SCH. L. REV. 63, 65-66 (2003) ("Copyright law provides a thin layer of protection for computer software, effectively prohibiting wholesale piracy of computer programs without affording control for interface specifications and other essential elements of computer functionality."). Thus, in many respects, patent law is a much more attractive option for software firms.

Diehr was decided in 1981, but it was not until the 1990s that software patents became more commonplace. *See, e.g., Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed. Cir. 1992). In fact, the number of software patent applications and issued patents increased dramatically in the 1990s. *See* Stuart J.H. Graham & David C. Mowery, *Intellectual Property Protection in the U.S. Software Industry*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 219 (Wesley A. Cohen & Stephen A. Merrill eds., 2003). As Cohen and Lemley write, "the past three decades have witnessed an about-face on the question of software's eligibility for patent protection . . . [as] software's status as patentable subject matter was first doubted, then grudgingly admitted, and finally embraced." Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 7 (2001).

But software patents remain controversial. Some economists have argued patents are not needed to incentivize software innovation, and indeed, are harmful to software innovation because the sheer number of software patents makes it difficult for innovators to obtain permission to pursue their research. Software patents can present significant barriers to entry for small entities, imposing a tax of sorts, either in the form of due diligence (*e.g.*, money spent on infringement studies of existing patents). As a group of

economists recently wrote in opposition to the failed European Software Directive, “[s]oftware patents damage innovation by raising costs and uncertainties in assembling the many components needed for complex computer programs and constraining the speed and effectiveness of innovation.” <http://www.researchineurope.org/policy/patentdirltr.pdf>. Moreover, large entities in the software industry have argued they are being plagued by low-quality patents owned by smaller entities. For criticisms of software patents, see James Bessen & Eric Maskin, *Sequential Innovation, Patents and Imitation*, available at <http://ssrn.com/abstract=206189> (Jan. 2000); PATENTS IN THE KNOWLEDGE-BASED ECONOMY 2 (Wesley M. Cohen & Stephen A. Merrill eds., 2003); James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=327760. The attitude within the IT industry generally has been described as one of mutually assured destruction, meaning that Firm 1 arms itself with patents because Firms 2, 3, and 4 have done the same. The first firm to sue another will be hit with counter-infringement suits. Of course, this can give rise to cross-licensing opportunities, assuming transaction costs are not prohibitively.

But other commentators have contested these claims. See John R. Allison & Robert J. Mann, *The Disputed Quality of Software Patents*, <http://ssrn.com/abstract=970083> (March 2007) (disputing the notion that software patents are of a lower quality than other types of patents, and also stating that “the data substantially undermine the traditional story that large firms in the software industry are plagued by a large number of low-quality patents obtained by the smaller firms in the industry”). See also Mann, *Facilitate Financing*, *supra*, at 1004-09 (rejecting software thicket thesis); Robert P. Merges, *Patents, Entry and Growth in the Software Industry*, at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=926204 (asserting that patents have not damaged the software industry and new firm entry remains robust).

7. **Business Method and Other “Non-Traditional” Patents.** In addition to software, the *State Street* and *AT&T* cases have spurred patenting in business methods, financial tools, and the like. Indeed, the PTO has been flooded with business method patents in the wake of *State Street* and its rejection of the “ill-conceived exception.” This increase in patent applications has posed problems for the PTO. See Robert P. Merges, *As Many as Six Possible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999). One patent that received a great deal of publicity was Amazon.com’s “one-click” ordering method. In fact, Amazon successfully obtained a preliminary injunction against Barnes & Noble, although the injunction was reversed on appeal. See *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343 (Fed. Cir. 2001).

In addition, commentators have criticized business method patents. According to two commentators:

Beyond the issue of permissible subject matter, settled by *State Street*, critics raise essentially two objections. First, some BMPs appear to be based on ideas that can not reasonably be considered novel because similar methods have existed in various unprotected forms for some time. For example, Price-line.com’s “reverse auction,” in which purchasers list a maximum price and

the software auctioneer finds a willing supplier, has antecedents in Dutch auctions and other selling methods. Similarly, Barnes & Noble contested the validity of Amazon's "one-click" patent on the grounds that other techniques involving a single operation by the consumer, contingent on the seller's ability to identify the consumer uniquely, were in operation prior to the patent's issuance in 1999. . . .

Second, many patents cover remarkably broad claims that could permit patentees to exclude competition in a wide swath of Internet applications. . . . In brief, [business method patents] are controversial because they provide broad and lengthy exclusivity for inventions that may not be particularly novel or non-obvious.

Keith E. Maskus & Eina Vivian Wong, *Searching For Economic Balance in Business Method Patents*, 8 WASH. U. J.L. & POL'Y 289, 291-92 (2002). Rochelle Dreyfuss asserts that incentives other than patents are more germane to business method innovations:

Business methods are . . . hard to free ride on. They depend in strong ways on the social structure within the firms utilizing them. Compensation schemes, lines of reporting, supervising policies, and other business factors. Moreover, as we saw, sticky business methods are their own reward. With lock in, network effects, and even good old fashioned loyalty, lead time (the first mover advantage) goes a long way to assuring returns adequate to recoup costs and earn substantial profit. In sum, while business innovations are certainly desirable, it is not clear that business method patents are needed to spur people to create them.

Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad For Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 274-75 (2000). See also Michael J. Meurer, *Business Method Patents and Patent Floods*, 8 WASH. U. J.L. & POL'Y 309 (2002); John R. Thomas, *Liberty and Property in Patent Law*, 39 HOUS. L. REV. 569 (2002). But some commentators have argued that the criticism of business method patents lacks empirical support, which has "led to undesirable results." See, e.g., John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERKELEY TECH. L.J. 987, 990 (2003) (comparing Internet business method patents to large random sample of general patents and finding business method patents "actually fare quite well statistically").

Yet another concern about patenting business methods and financial tools is that these types of inventions are far removed from patent law's traditional technological subject matter. See John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139 (1999) (criticizing the patenting of non-technological arts). See also *Ex parte Lundgren*, 76 U.S.P.Q.2d 1385 (B.P.A.I. 2004), which provides a lengthy debate about whether § 101's patent eligibility requirement has an inherent "technological arts" component. The patent in *Lundgren* claimed a method for compensating a manager. The patent application was rejected by the Examiner as failing to satisfy § 101's "technological arts" requirement. The Board reversed, but the case engendered a strong dissent.

COMPARATIVE PERSPECTIVE

Software and Business Method Patents in Europe

Under Section 52(2)(c) of the European Patent Convention, methods of “doing business and programs for computers” are not eligible for patent protection. Article 52(3) states:

The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Although the Europeans continue to view business method patents skeptically, the patent office in Europe has not shown the same skepticism toward software. The claimed invention satisfies the eligibility requirements as long as it reveals a “technical character.” *See* EPO Guidelines for Substantive Examination, Part C, Chapter IV, §§ 2.1, 2.2. *See also Computer Program Product/IBM*, T 1173/97-3.5.1 (EPO Bd. of App. July 1, 1998). For instance, in 2005, 8,664 applications were filed in the “computing” field, doubling the amount of applications filed in 1999 (3,955), and doubling the number of applications in biochemistry/genetic engineering, which generated 4,098 applications in 2005. EPO 2005 ANNUAL REPORT (Business Report, p. 22). Indeed, Microsoft was a top 10 filer of applications in 2005 with 879.

While it is clear that the EPO issues patents on software-related inventions, despite Article 52 apparent prohibition, there remains a degree of uncertainty regarding enforcement as numerous national courts are less enthusiastic about software patents. Recall that there is no European-wide patent or community patent. Because of this disparate treatment of software-related patents among the EU member states, the software industry, much like the biotechnology industry before it, wanted to enhance certainty for software patents throughout Europe. To this end, the European Parliament considered a directive on European software patents in 2005, but rejected it overwhelmingly. In a study commissioned by the Parliament, the authors wrote that “conclusive evidence supporting a liberalization of existing European patent law and practice in respect of software . . . , on the basis of U.S. experience, does not exist.” BNA Patent, Trademark & Copyright Law Daily (September 26, 2003).

B. UTILITY

1. Operability and the Basic Utility Test

The utility requirement demands the invention be operable. While there are examples of inoperable inventions (*e.g.*, perpetual motion machines and the invention in *Swartz*), the operability requirement is easily satisfied.

IN RE SWARTZ**232 F.3d 862 (Fed. Cir. 2000)**

PER CURIAM.

Mitchell R. Swartz appeals from the decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), affirming the examiner's final rejection of claims 25-48 of application Serial No. 07/760,970 for lack of operability or utility under 35 U.S.C. § 101. . . .

* * *

The PTO has the initial burden of challenging a patent applicant's presumptively correct assertion of utility. If the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility, however, the burden shifts to the applicant to submit evidence sufficient to convince such a person of the invention's asserted utility. Here the PTO provided several references showing that results in the area of cold fusion were irreproducible. Thus the PTO provided substantial evidence that those skilled in the art would "reasonably doubt" the asserted utility and operability of cold fusion. *See In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995). The examiner found that Mr. Swartz had not submitted evidence of operability that would be sufficient to overcome reasonable doubt. After its review of the evidence, the Board found that Mr. Swartz had "produced no persuasive objective evidence, in our view, that overcomes the examiner's position."

On this appeal, Mr. Swartz complains that the Board "ignored" evidence that he submitted and disregarded his arguments, and he invites this Court to examine voluminous record material that he urges supports his position on the issue of utility. Such conclusory allegations in an appeal brief are quite insufficient to establish that the Board's decision on the issue of utility is not supported by substantial evidence or to establish that the Board's ultimate conclusion of a lack of enablement is incorrect as a matter of law.

Finally, Mr. Swartz's attempt to show that his claims are directed to a process other than cold fusion must fail. In his written description and throughout prosecution of his application, Mr. Swartz continually represented his invention as relating to cold fusion.

For the reasons discussed above, the Board did not err in concluding that the utility of Mr. Swartz's claimed process had not been established and that his application did not satisfy the enablement requirement. Accordingly, the judgment of the Board is affirmed.

Comments

1. **The Utility of Fusion.** The utility requirement of *Swartz* looks to whether the claimed invention simply works; in other words, is the invention operable. Swartz's claims to cold fusion were not reproducible. Similarly, the Federal Circuit has affirmed utility rejections based on inoperability in *Newman v. Quigg*, 877 F.2d 1575 (Fed. Cir. 1989) (perpetual motion machine) and *Fregeau v. Mossinghoff*, 776 F.2d 1034 (Fed. Cir. 1985) (method for enhancing the flavor of a beverage by passing it through a magnetic field).

A great deal of money and time have been (and continues to be) expended on studying fusion, the process whereby heavy versions of hydrogen atoms (*e.g.*, deuterium and tritium) fuse together forming helium. The reaction produces an immense amount of energy. Indeed, fusion occurs at the center of the sun, whereby hydrogen atoms collide under very high pressures resulting in intense light and heat of 30 million degrees Fahrenheit. The commercial benefit of fusion would be substantial because of the near limitless “clean” energy it would produce as compared to coal and because of the prospect of gas and oil depletion. But fusion, thus far, has not proven to be practical because of the enormous amount of energy required to begin the reaction. And although the International Thermonuclear Experimental Reactor Consortium has decided to build the world’s first large-scale nuclear fusion reactor in France beginning in 2008, many advocates agree that practical application of fusion is not likely until 2040.

2. ***Operability and Utility’s Modern Application.*** The *Swartz* case represents the modern analytical approach to utility that can be traced to *In re Brana*. In *Brana*, the Federal Circuit articulated a two-step test for determining whether the utility requirement has been met. First, the PTO “has the initial burden of challenging a *presumptively* correct assertion of utility in the disclosure.” Second, “[o]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant” to prove utility. *Brana*, 51 F.3d at 1566 (Fed. Cir. 1995) (emphasis added).

Under the operability requirement, the claim invention must be “capable of being used to effect the object proposed.” *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873). But not every objective stated in the specification must be met before operability is satisfied. Indeed, “[w]hen a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958 (Fed. Cir. 1983). Moreover, the claimed invention need not be the best or only way to accomplish the stated objectives.

3. ***Beneficial Utility and Patent Law’s Erstwhile Morality Consideration.*** In the 19th century, there was a morality component to the utility requirement, sometimes referred to as beneficial utility. Justice Story’s opinion in *Bedford v. Hunt*, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) is largely considered the progenitor of the morality requirement. In *Hunt*, Justice Story wrote:

By useful invention, in the statute, is meant such a one as may be applied to some beneficial use in society, in contradistinction to an invention, which is injurious to the morals, the health, or the good order of society.

Unlike the Europeans, the morality requirement is a relic of a bygone era, no longer a player in patent law. See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (“To be sure, since Justice Story’s opinion in *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817), it has been stated that inventions that are ‘injurious to the well-being, good policy, or sound morals of society’ are unpatentable. . . . [But this principle] has not been applied broadly in recent years. . . . As the Supreme Court put the point more generally, ‘Congress never intended that the patent laws

should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted.”). For a discussion on the role of ethics and morality in patent law, see Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men*, 2 WASH. U. J.L. & POL’Y 247 (2000).

2. Substantial Utility

The most relevant and controversial aspect of the utility requirement relates to what is known as “substantial utility.” It is in this form that the utility requirement retains practical significance, particularly as applied to chemical and biotechnology-related inventions. Over the past 10 years the PTO, although inconsistently, has turned to the utility requirement to cast doubt on the patentability of certain genomic-related inventions. For example, while patents on fully sequenced genes and proteins are regularly patented, the PTO has denied patents on so-called ESTs or express sequence tags as lacking utility. ESTs are partial gene sequences, and the PTO’s position is that these partial sequences are *insufficiently useful* under § 101, despite applicants’ arguments that ESTs could be used as a probe to discover the entire gene of which it was a part. The *In re Fisher* case, which relies on *Brenner v. Manson*, explores this issue.

BRENNER v. MANSON

383 U.S. 519 (1966)

Justice FORTAS delivered the opinion of the Court.

[Manson’s request for an interference was denied by the examiner based on Manson’s failure to comply with the utility requirement. The Court of Customs and Patent Appeals (CCPA) reversed, stating that “‘where a claimed process produces a known product it is not necessary to show utility for the product.’” The Commissioner of Patents, Brenner, petitioned the Supreme Court — successfully — to grant certiorari.]

In December 1957, Howard Ringold and George Rosenkranz applied for a patent on an allegedly novel process for making certain known steroids. They claimed priority as of December 17, 1956, the date on which they had filed for a Mexican patent. . . .

In January 1960, Manson, a chemist engaged in steroid research, filed an application to patent precisely the same process described by Ringold and Rosenkranz. He asserted that it was he who had discovered the process, and that he had done so before December 17, 1956. Accordingly, he requested that an “interference” be declared in order to try out the issue of priority between his claim and that of Ringold and Rosenkranz.

A Patent Office examiner denied Manson’s application, and the denial was affirmed by the Board of Appeals within the Patent Office. The ground for rejection was the failure “to disclose any utility for” the chemical compound produced by the process. This omission was not cured, in the opinion of the Patent Office, by Manson’s reference to an article in the November 1956 issue of the *Journal of Organic Chemistry*, 21 J. Org. Chem. 1333-1335, which

revealed that steroids of a class which included the compound in question were undergoing screening for possible tumor-inhibiting effects in mice, and that a homologue adjacent to Manson's steroid had proven effective in that role. Said the Board of Appeals, "It is our view that the statutory requirement of usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful."

The Court of Customs and Patent Appeals (hereinafter CCPA) reversed. The court held that "where a claimed process produces a known product it is not necessary to show utility for the product," so long as the product "is not alleged to be detrimental to the public interest." *Certiorari* was granted to resolve this running dispute over what constitutes "utility" in chemical process claims.

II.

Our starting point is the proposition, neither disputed nor disputable, that one may patent only that which is "useful." [U]tility has maintained a central place in all of our patent legislation, beginning with the first patent law in 1790 and culminating in the present law's provision that

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

As is so often the case, however, a simple, everyday word can be pregnant with ambiguity when applied to the facts of life. That this is so is demonstrated by the present conflict between the Patent Office and the CCPA over how the test is to be applied to a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—has not yet been evidenced. It was not long ago that agency and court seemed of one mind on the question. In *Application of Bremner*, 182 F.2d 216, 217, the court affirmed rejection by the Patent Office of both process and product claims. It noted that "no use for the products claimed to be developed by the processes had been shown in the specification." It held that "It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful."

The Patent Office has remained steadfast in this view. The CCPA, however, has moved sharply away from *Bremner*. The trend began in *Application of Nelson*. There, the court reversed the Patent Office's rejection of a claim on a process yielding chemical intermediates "useful to chemists doing research on steroids," despite the absence of evidence that any of the steroids thus ultimately produced were themselves "useful." The trend has accelerated, culminating in the present case where the court held it sufficient that a process produces the result intended and is not "detrimental to the public interest."

Respondent does not—at least in the first instance—rest upon the extreme proposition, advanced by the court below, that a novel chemical process is patentable so long as it yields the intended product and so long as the product is not itself "detrimental." Nor does he commit the outcome of his claim to the slightly more conventional proposition that any process is "useful" within the meaning of § 101 if it produces a compound whose potential usefulness is under investigation by serious scientific researchers, although he urges this position, too, as an alternative basis for affirming the decision of the

CCPA. Rather, he begins with the much more orthodox argument that his process has a specific utility which would entitle him to a declaration of interference even under the Patent Office's reading of § 101. The claim is that the supporting affidavits filed pursuant to Rule 204(b), by reference to Ringold's 1956 article, reveal that an adjacent homologue of the steroid yielded by his process has been demonstrated to have tumor-inhibiting effects in mice, and that this discloses the requisite utility. We do not accept any of these theories as an adequate basis for overriding the determination of the Patent Office that the "utility" requirement has not been met.

Even on the assumption that the process would be patentable were respondent to show that the steroid produced had a tumor-inhibiting effect in mice, we would not overrule the Patent Office finding that respondent has not made such a showing. The Patent Office held that, despite the reference to the adjacent homologue, respondent's papers did not disclose a sufficient likelihood that the steroid yielded by his process would have similar tumor-inhibiting characteristics. Indeed, respondent himself recognized that the presumption that adjacent homologues have the same utility has been challenged in the steroid field because of "a greater known unpredictability of compounds in that field." In these circumstances and in this technical area, we would not overturn the finding of the Primary Examiner, affirmed by the Board of Appeals and not challenged by the CCPA.

The second and third points of respondent's argument present issues of much importance. Is a chemical process "useful" within the meaning of § 101 either (1) because it works—*i.e.*, produces the intended product—or (2) because the compound yielded belongs to a class of compounds now the subject of serious scientific investigation? These contentions present the basic problem for our adjudication. Since we find no specific assistance in the legislative materials underlying § 101, we are remitted to an analysis of the problem in light of the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other.

In support of his plea that we attenuate the requirement of "utility," respondent relies upon Justice Story's well-known statement that a "useful" invention is one "which may be applied to a beneficial use in society, in contradistinction to an invention injurious to the morals, health, or good order of society, or frivolous and insignificant"—and upon the assertion that to do so would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge. Justice Story's language sheds little light on our subject. Narrowly read, it does no more than compel us to decide whether the invention in question is "frivolous and insignificant"—a query no easier of application than the one built into the statute. Read more broadly, so as to allow the patenting of any invention not positively harmful to society, it places such a special meaning on the word 'useful' that we cannot accept it in the absence of evidence that Congress so intended. There are, after all, many things in this world which may not be considered "useful" but which, nevertheless, are totally without a capacity for harm.

It is true, of course, that one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions. And it may be that inability to patent a process to some extent discourages disclosure and leads to greater secrecy than would otherwise be the

case. The inventor of the process, or the corporate organization by which he is employed, has some incentive to keep the invention secret while uses for the product are searched out. However, in light of the highly developed art of drafting patent claims so that they disclose as little useful information as possible—while broadening the scope of the claim as widely as possible—the argument based upon the virtue of disclosure must be warily evaluated. Moreover, the pressure for secrecy is easily exaggerated, for if the inventor of a process cannot himself ascertain a “use” for that which his process yields, he has every incentive to make his invention known to those able to do so. Finally, how likely is disclosure of a patented process to spur research by others into the uses to which the product may be put? To the extent that the patentee has power to enforce his patent, there is little incentive for others to undertake a search for uses.

Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

These arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process. Respondent appears to concede that with respect to a product, as opposed to a process, Congress has struck the balance on the side of nonpatentability unless “utility” is shown. Indeed, the decisions of the CCPA are in accord with the view that a product may not be patented absent a showing of utility greater than any adduced in the present case. We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole “utility” consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.

This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something “useful,” or that we are blind to the prospect that what now seems without “use” may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. “(A) patent system must be related to the world of commerce rather than to the realm of philosophy. . . .”

The judgment of the CCPA is reversed.

Justice HARLAN, concurring in part and dissenting in part.

* * *

What I find most troubling about the result reached by the Court is the impact it may have on chemical research. Chemistry is a highly interrelated field and a tangible benefit for society may be the outcome of a number of different discoveries, one discovery building upon the next. To encourage one chemist or research facility to invent and disseminate new processes and products may be vital to progress, although the product or process be without “utility” as the Court defines the term, because that discovery permits someone else to take a further but perhaps less difficult step leading to a commercially useful item. In my view, our awareness in this age of the importance of achieving and publicizing basic research should lead this Court to resolve uncertainties in its favor and uphold the respondent’s position in this case.

This position is strengthened, I think, by what appears to have been the practice of the Patent Office during most of this century. While available proof is not conclusive, the commentators seem to be in agreement that until *Application of Bremner*, 182 F.2d 216 in 1950, chemical patent applications were commonly granted although no resulting end use was stated or the statement was in extremely broad terms. Taking this to be true, *Bremner* represented a deviation from established practice which the CCPA has now sought to remedy in part only to find that the Patent Office does not want to return to the beaten track. If usefulness was typically regarded as inherent during a long and prolific period of chemical research and development in this country, surely this is added reason why the Court’s result should not be adopted until Congress expressly mandates it, presumably on the basis of empirical data which this Court does not possess.

Comments

1. **Substantial Utility.** Justice Story famously wrote in 1817, “[t]he law . . . does not look to the degree of utility.” *Bedford v. Hunt*, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817). Similarly, the 19th-century treatise author, William Robinson, wrote, “[w]hen actual utility exists, its degree is unimportant. However, slight the advantage which the public have received from the inventor, it offers a sufficient reason for his compensation.” WILLIAM C. ROBINSON, 1 THE LAW OF PATENTS 464-65 (1890). These statements reflect a discomfort with having the court (or PTO), acting on behalf of the public interest, determine how useful an invention must be. But the substantial utility doctrine as set forth in *Brenner* seems to do just that. The *Brenner* Court also uses language that appears to coningle the policies of §§ 101 and 112. For instance, the Court employs phrases such as “basic quid pro quo” and “metes and bounds” of the claimed invention must be capable of “precise delineation.” These words smack of § 112’s enablement and definiteness requirements, respectively.
2. **Promoting the Useful Arts and Industry Norms.** Justice Harlan’s dissent envisioned a utility requirement that is much more consistent and

reflective of industry innovation norms. Recall, Harlan wrote: “What I find most troubling about the result reached by the Court is the impact it may have on chemical research. Chemistry is a highly interrelated field and a tangible benefit for society may be the outcome of a number of different discoveries, one discovery building upon the next.” In this regard, Justice Harlan’s position is arguably more consistent with the preamble of the Patent and Copyright clause of the Constitution. Judge Rich of the CCPA and then the Federal Circuit shared Justice Harlan’s view of § 101 utility. For instance, in *In re Kirk*, 376 F.2d 936 (CCPA 1967), Judge Rich, in a powerful dissent, wrote:

I believe . . . that usefulness, *to* chemists doing research on steroids, *as* intermediates to make other compounds they desire to make is sufficient [to satisfy the utility requirement]. I further believe that this is the law as to the meaning of “useful” in 35 U.S.C. § 101 as it was applied for decades and reaffirmed by the 1952 codification. . . . From a practical administrative standpoint, the best rule, which is what we had in substance until 1950, is that chemical compounds are per se “useful” within the meaning of 35 U.S.C. § 101. . . . [Such a rule] would have the salutary effects of . . . (5) increasing the incentives to produce and disclose new compounds, (6) encouraging the production and marketing of new compounds for experimental purposes which will develop new uses for them, thus advancing the art and advantaging the public.

In re Kirk, 376 F.2d at 946, 949, 957 (emphasis in original). In the context of the pharmaceutical industry, the Federal Circuit —in a manner that appears sensitive to industry practice—moved away somewhat from the substantial utility test by holding that the combination of *in vitro* and *in vivo* testing of structurally similar compounds complied with § 101’s utility requirement. See *Cross v. Iizuka*, 753 F.2d 1040, 1050 (Fed. Cir. 1985) (noting *in vitro* data is “[p]resumably . . . the accepted practice in the pharmaceutical industry. . . . *In vitro* testing, in general, is relatively less complex, less time consuming, and less expensive than *in vivo* testing. Moreover, *in vitro* results with respect to the particular pharmacological activity are generally predictive of *in vivo* test results, i.e., there is reasonable correlation there between”).

IN RE FISHER

421 F.3d 1365 (Fed. Cir. 2005)

MICHEL, Chief Judge.

Dane K. Fisher and Raghunath Lalgudi (collectively “Fisher”) appeal from the decision of the U.S. Patent and Trademark Office (“PTO”) Board of Patent Appeals and Interferences (“Board”) affirming the examiner’s final rejection of the only pending claim of application Serial No. 09/619,643 (the “’643 application”), entitled “Nucleic Acid Molecules and Other Molecules Associated with Plants,” as unpatentable for lack of utility under 35 U.S.C. § 101. Because we conclude that substantial evidence supports the Board’s findings that the claimed invention lacks a specific and substantial utility, we affirm.

I. BACKGROUND

A. Molecular Genetics and ESTs

The claimed invention relates to five purified nucleic acid sequences that encode proteins and protein fragments in maize plants. The claimed sequences are commonly referred to as “expressed sequence tags” or “ESTs.” Before delving into the specifics of this case, it is important to understand more about the basic principles of molecular genetics and the role of ESTs.

Genes are located on chromosomes in the nucleus of a cell and are made of deoxyribonucleic acid (“DNA”). DNA is composed of two strands of nucleotides in double helix formation. The nucleotides contain one of four bases, adenine (“A”), guanine (“G”), cytosine (“C”), and thymine (“T”), that are linked by hydrogen bonds to form complementary base pairs (*i.e.*, A-T and G-C).

When a gene is expressed in a cell, the relevant double-stranded DNA sequence is transcribed into a single strand of messenger ribonucleic acid (“mRNA”). Messenger RNA contains three of the same bases as DNA (A, G, and C), but contains uracil (“U”) instead of thymine. mRNA is released from the nucleus of a cell and used by ribosomes found in the cytoplasm to produce proteins.

Complementary DNA (“cDNA”) is produced synthetically by reverse transcribing mRNA. cDNA, like naturally occurring DNA, is composed of nucleotides containing the four nitrogenous bases, A, T, G, and C. Scientists routinely compile cDNA into libraries to study the kinds of genes expressed in a certain tissue at a particular point in time. One of the goals of this research is to learn what genes and downstream proteins are expressed in a cell so as to regulate gene expression and control protein synthesis.²

An EST is a short nucleotide sequence that represents a fragment of a cDNA clone. It is typically generated by isolating a cDNA clone and sequencing a small number of nucleotides located at the end of one of the two cDNA strands. When an EST is introduced into a sample containing a mixture of DNA, the EST may hybridize with a portion of DNA. Such binding shows that the gene corresponding to the EST was being expressed at the time of mRNA extraction.

Claim 1 of the ’643 application recites:

A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

The ESTs set forth in SEQ ID NO: 1 through SEQ ID NO: 5 are obtained from cDNA library LIB3115, which was generated from pooled leaf tissue harvested from maize plants (RX601, Asgrow Seed Company, Des Moines, Iowa, U.S.A.) grown in the fields at Asgrow research stations. SEQ ID NO: 1 through SEQ ID NO: 5 consist of 429, 423, 365, 411, and 331 nucleotides, respectively. When Fisher filed the ’643 application, he claimed ESTs corresponding to genes expressed from the maize pooled leaf tissue at the time of

2. We have discussed the basic principles of molecular genetics more extensively in prior cases. *See, e.g., In re Deuel*, 51 F.3d 1552, 1554-56 (Fed. Cir. 1995); *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1207-08 (Fed. Cir. 1991); *In re O’Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988).

anthesis. Nevertheless, Fisher did not know the precise structure or function of either the genes or the proteins encoded for by those genes.

The '643 application generally discloses that the five claimed ESTs may be used in a variety of ways, including: (1) serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression; (3) providing a source for primers for use in the polymerase chain reaction ("PCR") process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.

B. Final Rejection

In a final rejection, dated September 6, 2001, the examiner rejected claim 1 for lack of utility under § 101. The examiner found that the claimed ESTs were not supported by a specific and substantial utility. She concluded that the disclosed uses were not specific to the claimed ESTs, but instead were generally applicable to any EST. For example, the examiner noted that any EST may serve as a molecular tag to isolate genetic regions. She also concluded that the claimed ESTs lacked a substantial utility because there was no known use for the proteins produced as final products resulting from processes involving the claimed ESTs. The examiner stated: "Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities."

On July 19, 2000, Fisher filed a notice of appeal with the Board.

C. Board Proceedings

The Board considered each of Fisher's seven potential uses but noted that Fisher focused its appeal on only two: (1) use for the identification of polymorphisms; and (2) use as probes or as a source for primers. As to the first, the Board found that the application failed to explain why the claimed ESTs would be useful in detecting polymorphisms in maize plants. The Board reasoned that "[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage." Thus, the Board concluded that Fisher's asserted uses for the claimed ESTs tended to the "insubstantial use" end of the spectrum between a substantial and an insubstantial utility.

The Board also concluded that using the claimed ESTs to isolate nucleic acid molecules of other plants and organisms, which themselves had no known utility, is not a substantial utility. Specifically, the Board noted that Fisher argued that the "claimed ESTs may be useful in searching for promoters that are only active in leaves at the time of anthesis." The Board found, however, that the application failed to show that the claimed ESTs would be expressed only during anthesis or that they would be capable of isolating a promoter active in maize leaves at the time of anthesis.

Additionally, the Board addressed the remaining asserted utilities, highlighting in particular the use of the claimed ESTs to monitor gene ex-

pression by measuring the level of mRNA through microarray technology and to serve as molecular markers. The Board found that using the claimed ESTs in screens does not provide a specific benefit because the application fails to provide any teaching regarding how to use the data relating to gene expression. The Board analogized the facts to those in *Brenner v. Manson*, 383 U.S. 519 (1966), in which an applicant claimed a process of making a compound having no known use. In that case, the Supreme Court affirmed the rejection of the application on § 101 grounds. Here, the Board reasoned: “Just as the process in *Brenner* lacked utility because the specification did not disclose how to use the end-product, the products claimed here lack utility, because even if used in gene expression assays, the specification does not disclose how to use SEQ ID NO: 1-5 specific gene expression data.” The Board offered a similar rationale for the use of the claimed ESTs as molecular markers. Accordingly, the Board affirmed the examiner’s rejection of the ’643 application for lack of utility under § 101. The Board also affirmed the examiner’s rejection of the ’643 application for lack of enablement under § 112, first paragraph, since the enablement rejection was made as a corollary to the utility rejection.

II. DISCUSSION

Whether an application discloses a utility for a claimed invention is a question of fact. We consequently review the Board’s determination that the ’643 application failed to satisfy the utility requirement of § 101 for substantial evidence.

A. Utility

1.

Fisher asserts that the Board unilaterally applied a heightened standard for utility in the case of ESTs, conditioning patentability upon “some undefined ‘spectrum’ of knowledge concerning the corresponding gene function.” Fisher contends that the standard is not so high and that Congress intended the language of § 101 to be given broad construction. In particular, Fisher contends that § 101 requires only that the claimed invention “not be frivolous, or injurious to the well-being, good policy, or good morals of society,” essentially adopting Justice Story’s view of a useful invention from *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (No. 8568) (C.C.D. Mass. 1817). Under the correct application of the law, Fisher argues, the record shows that the claimed ESTs provide seven specific and substantial uses, regardless whether the functions of the genes corresponding to the claimed ESTs are known. Fisher claims that the Board’s attempt to equate the claimed ESTs with the chemical compositions in *Brenner* was misplaced and that several decisions in the field of pharmaceuticals, namely, *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985), *Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980), and *In re Jolles*, 628 F.2d 1322 (C.C.P.A. 1980), are analogous and support finding utility of the claimed ESTs. Fisher likewise argues that the general commercial success of ESTs in the marketplace confirms the utility of the claimed ESTs. Hence, Fisher avers that the Board’s decision was not supported by substantial evidence and should be reversed.

The government agrees with Fisher that the utility threshold is not high, but disagrees with Fisher’s allegation that the Board applied a heightened

utility standard. The government contends that a patent applicant need disclose only a single specific and substantial utility pursuant to *Brenner*, the very standard articulated in the PTO's "Utility Examination Guidelines" ("Utility Guidelines") and followed here when examining the '643 application. It argues that Fisher failed to meet that standard because Fisher's alleged uses are so general as to be meaningless. What is more, the government asserts that the same generic uses could apply not only to the five claimed ESTs but also to any EST derived from any organism. It thus argues that the seven utilities alleged by Fisher are merely starting points for further research, not the end point of any research effort. It further disputes the importance of the commercial success of ESTs in the marketplace, pointing out that Fisher's evidence involved only databases, clone sets, and microarrays, not the five claimed ESTs. Therefore, the government contends that we should affirm the Board's decision.

Several academic institutions and biotechnology and pharmaceutical companies write as amici curiae in support of the government. Like the government, they assert that Fisher's claimed uses are nothing more than a "laundry list" of research plans, each general and speculative, none providing a specific and substantial benefit in currently available form. The amici also advocate that the claimed ESTs are the objects of further research aimed at identifying what genes of unknown function are expressed during anthesis and what proteins of unknown function are encoded for by those genes. Until the corresponding genes and proteins have a known function, the amici argue, the claimed ESTs lack utility under § 101 and are not patentable.

We agree with both the government and the amici that none of Fisher's seven asserted uses meets the utility requirement of § 101. Section 101 provides: "Whoever invents . . . any new and *useful* . . . composition of matter . . . may obtain a patent therefor. . . ." (Emphasis added). In *Brenner*, the Supreme Court explained what is required to establish the usefulness of a new invention, noting at the outset that "a simple, everyday word ["useful," as found in § 101] can be pregnant with ambiguity when applied to the facts of life." 383 U.S. at 529. Contrary to Fisher's argument that § 101 only requires an invention that is not "frivolous, injurious to the well-being, good policy, or good morals of society," the Supreme Court appeared to reject Justice Story's de minimis view of utility. *Id.* at 532-33. The Supreme Court observed that Justice Story's definition "sheds little light on our subject," on the one hand framing the relevant inquiry as "whether the invention in question is 'frivolous and insignificant'" if narrowly read, while on the other hand "allowing the patenting of any invention not positively harmful to society" if more broadly read. *Id.* at 533. In its place, the Supreme Court announced a more rigorous test, stating:

The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial utility*. Unless and until a process is refined and developed to this point—where *specific benefit exists in currently available form*—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Brenner, 383 U.S. at 534-35 (emphases added). Following *Brenner*, our predecessor court, the Court of Customs and Patent Appeals, and this court have

required a claimed invention to have a specific and substantial utility to satisfy § 101. *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (Fed. Cir. 1996) (“Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.”).

The Supreme Court has not defined what the terms “specific” and “substantial” mean per se. Nevertheless, together with the Court of Customs and Patent Appeals, we have offered guidance as to the uses which would meet the utility standard of § 101. From this, we can discern the kind of disclosure an application must contain to establish a specific and substantial utility for the claimed invention.

Courts have used the labels “practical utility” and “real world” utility interchangeably in determining whether an invention offers a “substantial” utility. Indeed, the Court of Customs and Patent Appeals stated that “[p]ractical utility” is a shorthand way of attributing ‘real-world’ value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public*.” *Nelson*, 626 F.2d at 856 (emphasis added).⁴ It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the “substantial” utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.

Turning to the “specific” utility requirement, an application must disclose a use which is not so vague as to be meaningless. Indeed, one of our predecessor courts has observed “that the nebulous expressions ‘biological activity’ or ‘biological properties’ appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression ‘useful for technical and pharmaceutical purposes’ unsuccessfully relied upon by the appellant in *In re Diedrich*.” *In re Kirk*, 376 F.2d 936, 941 (1967). Thus, in addition to providing a “substantial” utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public.

In 2001, partially in response to questions about the patentability of ESTs, the PTO issued Utility Guidelines governing its internal practice for determining whether a claimed invention satisfies § 101. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). The PTO incorporated these guidelines into the Manual of Patent Examining Procedure (“MPEP”). *See* U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure § 2107 (8th ed.2001, rev. May 2004). The MPEP and Guidelines “are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute.” *Enzo Biochem v. Gen-Probe*, 323 F.3d 956, 964 (Fed. Cir. 2002). According to the Utility Guidelines, a specific utility is particular to the subject matter claimed and would not be applicable to a broad class of invention. Manual of Patent Examining Procedure § 2107.01. The Utility Guidelines also explain that a substantial utility defines a “real world” use. In particular,

4. In *Cross*, this court considered the phrase “practical utility” to be synonymous with the phrase “substantial utility.” 753 F.2d at 1047, n. 13.

“[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use are not substantial utilities.” *Id.* Further, the Utility Guidelines discuss “research tools,” a term often given to inventions used to conduct research. The PTO particularly cautions that

[a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. [The PTO] must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.

Id. The PTO’s standards for assessing whether a claimed invention has a specific and substantial utility comport with this court’s interpretation of the utility requirement of § 101.

Turning to the parties’ arguments, Fisher first raises a legal issue, charging that the Board applied a heightened standard for utility in the case of ESTs. Fisher apparently bases this argument on statements made by the Board in connection with its discussion of whether the claimed ESTs can be used to identify a polymorphism. In that context, the Board stated:

Somewhere between having no knowledge (the present circumstances) and having complete knowledge of the gene and its role in the plant’s development lies the line between ‘utility’ and ‘substantial utility.’ We need not draw the line or further define it in this case because the facts in this case represent the lowest end of the *spectrum*, i.e., an insubstantial use.

Board Decision, slip op. at 15 (emphasis added). Fisher reads the word “spectrum” out of context, claiming that the word somehow implies the application of a higher standard for utility than required by § 101. We conclude, however, that the Board did not apply an incorrect legal standard. In its decision, the Board made reference to a “spectrum” to differentiate between a substantial utility, which satisfies the utility requirement of § 101, and an insubstantial utility, which fails to satisfy § 101. The Board plainly did not announce or apply a new test for assessing the utility of ESTs. It simply followed the Utility Guidelines and MPEP, which mandate the specific and substantial utility test set forth in *Brenner*. Indeed, we note that Example 9 of the PTO’s “Revised Interim Utility Guidelines Training Materials” is applicable to the facts here. See U.S. Pat. & Trademark Off., Revised Interim Utility Guidelines Training Materials 50-53 (1999), available at www.uspto.gov/web/menu/utility.pdf. In that example, a cDNA fragment disclosed as being useful as a probe to obtain the full length gene corresponding to a cDNA fragment was deemed to lack a specific and substantial utility. Additionally, the MPEP particularly explains that a claim directed to a polynucleotide disclosed to be useful as a “gene probe” or “chromosome marker,” as is the case here, fails to satisfy the specific utility requirement unless a specific DNA target is also disclosed. Manual of Patent Examining Procedure § 2107.01.

Regarding the seven uses asserted by Fisher, we observe that each claimed EST uniquely corresponds to the single gene from which it was transcribed (“underlying gene”). As of the filing date of the ’643 application, Fisher admits that the underlying genes have no known functions. Fisher, nevertheless, claims that this fact is irrelevant because the seven asserted uses are not related to the functions of the underlying genes. We are not convinced by this con-

tention. Essentially, the claimed ESTs act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. The overall goal of such experimentation is presumably to understand the maize genome—the functions of the underlying genes, the identity of the encoded proteins, the role those proteins play during anthesis, whether polymorphisms exist, the identity of promoters that trigger protein expression, whether protein expression may be controlled, etc. Accordingly, the claimed ESTs are, in words of the Supreme Court, mere “object[s] of use-testing,” to wit, objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end. *Brenner*, 383 U.S. at 535.

Fisher compares the claimed ESTs to certain other patentable research tools, such as a microscope. Although this comparison may, on first blush, be appealing in that both a microscope and one of the claimed ESTs can be used to generate scientific data about a sample having unknown properties, Fisher’s analogy is flawed. As the government points out, a microscope has the specific benefit of optically magnifying an object to immediately reveal its structure. One of the claimed ESTs, by contrast, can only be used to detect the presence of genetic material having the same structure as the EST itself. It is unable to provide any information about the overall structure let alone the function of the underlying gene. Accordingly, while a microscope can offer an immediate, real world benefit in a variety of applications, the same cannot be said for the claimed ESTs. Fisher’s proposed analogy is thus inapt. Hence, we conclude that Fisher’s asserted uses are insufficient to meet the standard for a “substantial” utility under § 101.

Moreover, all of Fisher’s asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, *could* possibly achieve, but none for which they have been used in the real world. Focusing on the two uses emphasized by Fisher at oral argument, Fisher maintains that the claimed ESTs could be used to identify polymorphisms or to isolate promoters. Nevertheless, in the face of a utility rejection, Fisher has not presented any evidence, as the Board well noted, showing that the claimed ESTs have been used in either way. That is, Fisher does not present either a single polymorphism or a single promoter, assuming at least one of each exists, actually identified by using the claimed ESTs. Further, Fisher has not shown that a polymorphism or promoter so identified would have a “specific and substantial” use. The Board, in fact, correctly recognized this very deficiency and cited it as one of the reasons for upholding the examiner’s final rejection.

With respect to the remaining asserted uses, there is no disclosure in the specification showing that any of the claimed ESTs were used as a molecular marker on a map of the maize genome. There also is no disclosure establishing that any of the claimed ESTs were used or, for that matter, could be used to control or provide information about gene expression. Significantly, despite the fact that maize leaves produce over two thousand different proteins during anthesis, Fisher failed to show that one of the claimed ESTs translates into a portion of one of those proteins. Fisher likewise did not provide any evidence showing that the claimed ESTs were used to locate genetic molecules in other plants and organisms. What is more, Fisher has not proffered any evidence showing that any such generic molecules would

themselves have a specific and substantial utility. Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a "substantial" utility under § 101.

Furthermore, Fisher's seven asserted uses are plainly not "specific." Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. That is, any EST transcribed from any gene in the maize genome may be a molecular marker or a source for primers. Likewise, any EST transcribed from any gene in the maize genome may be used to measure the level of mRNA in a tissue sample, identify the presence or absence of a polymorphism, isolate promoters, control protein expression, or locate genetic molecules of other plants and organisms. Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.

We agree with the Board that the facts here are similar to those in *Brenner*. There, as noted above, the applicant claimed a process for preparing compounds of unknown use. Similarly, Fisher filed an application claiming five particular ESTs which are capable of hybridizing with underlying genes of unknown function found in the maize genome. The *Brenner* court held that the claimed process lacked a utility because it could be used only to produce a compound of unknown use. The *Brenner* court stated: "We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product." 383 U.S. at 535. Applying that same logic here, we conclude that the claimed ESTs, which do not correlate to an underlying gene of known function, fail to meet the standard for utility intended by Congress.

In addition to approving of the Board's reliance on *Brenner*, we observe that the facts here are even more analogous to those presented in *Kirk*, 376 F.2d 936, and *In re Joly*, 376 F.2d 906 (1967), two cases decided by our predecessor court shortly after *Brenner*. In *Kirk*, the applicant sought to patent new steroidal compounds disclosed as having two possible utilities. First, the applicant alleged that the claimed compounds were useful for their "biological activity" because "one skilled in the art would know how to use the compounds . . . to take advantage of their presently-existing biological activity." *Kirk*, 376 F.2d at 939. The court rejected this claimed utility on the ground that it was not sufficiently "specific," but was instead "nebulous." *Id.* at 941.

Second, the applicant asserted that the claimed compounds could be used by skilled chemists as intermediates in the preparation of final steroidal compounds of unknown use. Relying on *Brenner*, the court reasoned:

It seems clear that, if a process for producing a product of only conjectural use is not itself "useful" within § 101, it cannot be said that the starting materials for such a process—*i.e.*, the presently claimed intermediates—are "useful." It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might

be, the subject of research to determine some *specific use*. Cf. *Reiners v. Mehlretter*, 43 C.C.P.A. 1019, 236 F.2d 418, 421 [(C.C.P.A. 1956)] where compounds employed as intermediates to produce other directly useful compounds were found to be themselves useful.

Id. at 945-46 (emphasis added). Therefore, the court affirmed the Board's rejection of the claimed compounds for lack of utility.

The facts in *Joly* are nearly identical to the facts in *Kirk*. The *Joly* applicant filed an application claiming compounds useful as intermediates in preparing steroids that were themselves not shown or known to be useful, but that were similar in chemical structure to steroids of known pharmacological usefulness. The court adopted the reasoning of the *Kirk* court in its entirety and affirmed the Board's decision rejecting the claimed intermediates for failing to comply with § 101. *Joly*, 376 F.2d at 908-09.

Just as the claimed compounds in *Kirk* and *Joly* were useful only as intermediates in the synthesis of other compounds of unknown use, the claimed ESTs can only be used as research intermediates in the identification of underlying protein-encoding genes of unknown function. The rationale of *Kirk* and *Joly* thus applies here. In the words of the *Kirk* court:

We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound *in terms of possible use so general as to be meaningless* and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

376 F.2d at 942 (emphasis added).

That the *Kirk* and *Joly* decisions involved chemical compounds, while the present case involves biological entities, does not distinguish these decisions. The rationale presented therein, having been drawn from principles set forth by the Supreme Court in *Brenner*, applies with equal force in the fields of chemistry and biology as well as in any scientific discipline. In *Brenner*, the Supreme Court was primarily concerned with creating an unwarranted monopoly to the detriment of the public:

Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. . . . This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy.

Brenner, 383 U.S. at 535-36. Here, granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility. Thus, while Fisher's claimed ESTs may add a noteworthy contribution to biotechnology research, our precedent dictates that the '643 application does not meet the utility requirement of § 101 because Fisher does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.

* * *

3.

As a final matter, we observe that the government and its amici express concern that allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the "useful Arts" and "Science." See U.S. Const. art. I, § 8, cl. 8. The government and its amici point out that allowing EST claims like Fisher's would give rise to multiple patents, likely owned by several different companies, relating to the same underlying gene and expressed protein. Such a situation, the government and amici predict, would result in an unnecessarily convoluted licensing environment for those interested in researching that gene and/or protein.

The concerns of the government and amici, which may or may not be valid, are not ones that should be considered in deciding whether the application for the claimed ESTs meets the utility requirement of § 101. The same may be said for the resource and managerial problems that the PTO potentially would face if applicants present the PTO with an onslaught of patent applications directed to particular ESTs. Congress did not intend for these practical implications to affect the determination of whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. They are public policy considerations which are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law. Under Title 35, an applicant is entitled to a patent if his invention is new, useful, non-obvious, and his application adequately describes the claimed invention, teaches others how to make and use the claimed invention, and discloses the best mode for practicing the claimed invention. What is more, when Congress enacted § 101, it indicated that "anything under the sun that is made by man" constitutes potential subject matter for a patent. S. Rep. No. 82-1979, at 7 (1952), U.S. Code Cong. & Admin. News at 2394, 2399. Policy reasons aside, because we conclude that the utility requirement of § 101 is not met, we hold that Fisher is not entitled to a patent for the five claimed ESTs.

* * *

RADER, Circuit Judge, dissenting.

This court today determines that expressed sequence tags (ESTs) do not satisfy 35 U.S.C. § 101 unless there is a known use for the genes from which each EST is transcribed. While I agree that an invention must demonstrate

utility to satisfy § 101, these claimed ESTs have such a utility, at least as research tools in isolating and studying other molecules. Therefore, I respectfully dissent.

Several, if not all, of Fisher's asserted utilities claim that ESTs function to study other molecules. In simple terms, ESTs are research tools. Admittedly ESTs have use only in a research setting. However, the value and utility of research tools generally is beyond question, even though limited to a laboratory setting. Thus, if the claimed ESTs qualify as research tools, then they have a "specific" and "substantial" utility sufficient for § 101. If these ESTs do not enhance research, then *Brenner v. Manson* controls and erects a § 101 bar for lack of utility. For the following reasons, these claimed ESTs are more akin to patentable research tools than to the unpatentable methods in *Brenner*.

In *Brenner*, the Court confronted a growing conflict between this court's predecessor, the Court of Customs and Patent Appeals (CCPA), and the Patent Office over the patentability of methods of producing compounds with no known use. This conflict began with *In re Nelson*, the first in a series of cases wherein the CCPA reversed several Patent Office utility rejections. *Brenner* put an end to these cases because, in the 1960s, the Court could not distinguish between denying patents to compounds with no known use and denying patents to methods of producing those useless compounds. The Court commented:

We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.

Id. at 535. This court's predecessor later extended *Brenner* to bar patents on compounds as intermediates in the preparation of other compounds having no known use. See *In re Kirk*.

This case is very different. Unlike the methods and compounds in *Brenner* and *Kirk*, Fisher's claimed ESTs *are* beneficial to society. As an example, these research tools "may help scientists to isolate the particular underlying protein-encoding genes . . . [with the] overall goal of such experimentation . . . presumably [being] to understand the maize genome[.]" *Majority Opinion*, at 1373. They also can serve as a probe introduced into a sample tissue to confirm "that the gene corresponding to the EST was being expressed in the sample tissue at the time of mRNA extraction." *Id.*, at 1367.

These research tools are similar to a microscope; both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure. Both supply information about a molecular structure. Both advance research and bring scientists closer to unlocking the secrets of the corn genome to provide better food production for the hungry world. If a microscope has § 101 utility, so too do these ESTs.

The Board and this court acknowledge that the ESTs perform a function, that they have a utility, but proceed quickly to a value judgment that the utility would not produce enough valuable information. The Board instead complains that the information these ESTs supply is too "insubstantial" to merit protection. Yet this conclusion denies the very nature of scientific advance. Science always advances in small incremental steps. While acknowledging the

patentability of research tools generally (and microscopes as one example thereof), this court concludes with little scientific foundation that these ESTs do not qualify as research tools because they do not “offer an immediate, real world benefit” because further research is required to understand the underlying gene. This court further faults the EST research for lacking any “assurance that anything useful will be discovered in the end.” These criticisms would foreclose much scientific research and many vital research tools. Often scientists embark on research with no assurance of success and knowing that even success will demand “significant additional research.”

Nonetheless, this court, oblivious to the challenges of complex research, discounts these ESTs because it concludes (without scientific evidence) that they do not supply enough information. This court reasons that a research tool has a “specific” and “substantial” utility *only* if the studied object is readily understandable using the claimed tool — that no further research is required. Surely this cannot be the law. Otherwise, only the final step of a lengthy incremental research inquiry gets protection.

Even with a microscope, significant additional research is often required to ascertain the particular function of a “revealed” structure. To illustrate, a cancerous growth, magnified with a patented microscope, can be identified and distinguished from other healthy cells by a properly trained doctor or researcher. But even today, the scientific community still does not fully grasp the reasons that cancerous growths increase in mass and spread throughout the body, or the nature of compounds that interact with them, or the interactions of environmental or genetic conditions that contribute to developing cancer. Significant additional research is required to answer these questions. Even with answers to these questions, the cure for cancer will remain in the distance. Yet the microscope still has “utility” under § 101. Why? Because it takes the researcher one step closer to answering these questions. Each step, even if small in isolation, is nonetheless a benefit to society sufficient to give a viable research tool “utility” under § 101. In fact, experiments that fail still serve to eliminate some possibilities and provide information to the research process.

The United States Patent Office, above all, should recognize the incremental nature of scientific endeavor. Yet, in the interest of easing its administrative load, the Patent Office will eliminate some research tools as providing “insubstantial” advances. How does the Patent Office know which “insubstantial” research step will contribute to a substantial breakthrough in genomic study? Quite simply, it does not.

* * *

In truth, I have some sympathy with the Patent Office’s dilemma. The Office needs some tool to reject inventions that may advance the “useful arts” but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement to reject these research tools as contributing “insubstantially” to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103. Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions.

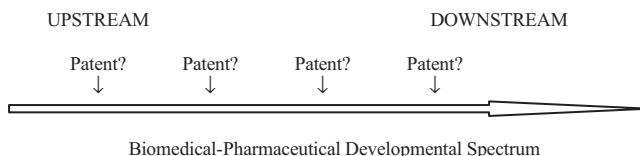
* * *

Comments

1. ***Substantial and Specific Utility Defined.*** A patent applicant must show both substantial and specific utility to satisfy § 101. The *Fisher* court initially noted that the Supreme Court has not defined substantial and specific utility. Beginning with substantial utility, the court noted that “practical utility” and “real world utility” have been used interchangeably with substantial utility, but they all require the claimed invention to provide “some immediate benefit to the public.” The PTO’s utility guidelines state “[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a ‘real world’ context of use are not substantial utilities.” U.S. PTO, REVISED INTERIM UTILITY EXAMINATION GUIDELINES TRAINING MATERIALS, at 6. See <http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf>. This approach is consistent with *Brenner*.

The *Fisher* court also defined “specific utility” to mean that “an application must disclose a use which is not so vague as to be meaningless.” That is, the claimed invention must provide the public with “a well-defined and particular benefit.” In the biological realm, “nebulous expressions” such as “biological activity” or “biological properties” will not suffice. The 2001 PTO Utility Guidelines define specific utility as “utility that is specific to the subject matter claimed,” in contrast to “a general utility that would be applicable to the broad class of the invention.” *Id.* at 4.

2. ***The Utility Requirement and Genomics: The Upstream-Downstream Debate.*** There is little doubt that patents play an extremely important role in the biotechnology industry. To the extent there is controversy relating to patenting biotechnological inventions, it pertains to when (not if) patents should intervene. It is helpful to think of biomedical research on a developmental spectrum when thinking about the utility requirement, specifically, and the role of patent law, generally. Most commentators would agree that patents play an important role in downstream products (and processes), so-called small molecule drugs that are dominant in the pharmaceutical industry. But consensus dissipates somewhat as you move further upstream in the developmental spectrum, particularly into the realm of research tools that have foundational applicability, yet are far removed from the downstream product. Examples of research tools include polymerase chain reaction (PCR), used to replicate DNA; Express Sequence Tags (ESTs as in *Fisher*); DNA sequencing technology, Single Nucleotide Polymorphisms (SNPs), and even DNA sequences (*i.e.*, genes). (Perhaps the most well known research tool is the Cohen-Boyer technology relating to recombinant DNA.)



The concern with patenting upstream is either a single patent owner will have broad patent rights or there will be numerous patent holders. The former may exercise his rights strategically as a hold-out or may not be willing to engage in self-induced competition if he also a developer, in both instances impeding innovation or downstream development. With many patent holders, the concern is one of thickets or an “anticommons,” meaning that downstream developers will face insurmountable transactions costs when they seek to obtain permission to use upstream patented research. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, in *SCIENCE* 1 May 1998, vol. 280, pp. 698-701 at <http://www.sciencemag.org/cgi/content/full/280/5364/698>; Arti K. Rai, *Genome Patents: A Case Study in Patenting Research Tools*, 77 *ACADEMIC MEDICINE* 1368-72 (Dec. 2002); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 *NW. U. L. REV.* 77-152 (1999).

In contrast, some commentators assert that upstream research is usually a product of biotechnology companies, many of which are small and in need of capital. Patenting upstream research may provide an important economic tool to recoup R&D costs or attract investment from downstream players so that development can continue. See F.M. Scherer, *The Economics of Human Gene Patents*, 77 *ACADEMIC MEDICINE* 1348 (2002). Other commentators have questioned the anticommons scenario on empirical grounds. See David E. Adelman, *The Fallacy of the Commons*, 20 *BERKELEY TECH. L.J.* 985 (2005); David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in The Biotech Patent Debate*, 85 *TEX. L. REV.* 1677 (2007). See also John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in *PATENTS IN THE KNOWLEDGE-BASED ECONOMY* 285-340 (National Academies Press 2003):

[W]e report the results of 70 interviews with personnel at biotechnology and pharmaceutical firms and universities in considering the effects of research tool patents on industrial or academic biomedical research. . . . [W]e consider whether biomedical innovation has suffered because of either an anticommons or restrictions on the use of upstream discoveries in subsequent research. Notwithstanding the possibility of such impediments to biomedical innovation, there is still ample reason to suggest that patenting benefits biomedical innovation, especially via its considerable impact on R & D incentives or via its role in supporting an active market for technology. . . . To prefigure our result, we find little evidence of routine breakdowns in negotiations over rights, although research tool patents are observed to impose a range of social costs and there is some restriction of access.

Id. at 287-89. See also REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 134 (National Research Council) (Steven A. Merrill & Anne-Marie Mazza eds., 2006) (concluding that while “there are reasons to be concerned about the future,” for present purposes “the number of projects abandoned or delayed as a result of technology access difficulties is reported to be small, as is the number of occasions in which investigators revise their protocols to avoid intellectual property complications or pay high costs to obtain access to intellectual property”).

Note on Design Patents

A design patent protects the ornamental features (*e.g.*, shape or configuration) as embodied in or applied to a utilitarian or functional article. The design must be new, original, and ornamental. *See* 35 U.S.C. §§ 171-173. A design patent application has only one claim, which refers to the drawings. Design patents differ from utility patents in that the latter protects the functional features of the claimed article, the way it is used and how it works whereas a design patent simply covers the way in which the article looks. A single article can be subject to both a utility and design patent. For instance, the PTO recently issued design patent number 500,000 in December, 2004 on a design of an automobile body. (Certainly, the automobile itself has several features eligible for utility patent protection.) Note on the cover page below that the letter “D” precedes the patent number to indicate the patent is a design patent. The claim of the design patent reads: “An ornamental design for an automobile body, as shown and described.”

(12) **United States Design Patent**
Dyson et al.

(10) **Patent No.:** **US D500,000 S**
(45) **Date of Patent:** **** Dec. 21, 2004**

(54) **AUTOMOBILE BODY**

(75) Inventors: **Andrew P Dyson**, West Bloomfield, MI (US); **Joseph S Dehner**, Bloomfield, MI (US); **David C McKinnon**, Bloomfield, MI (US); **Glenn W Abbott**, West Bloomfield, MI (US)

(73) Assignee: **DaimlerChrysler Corporation**, Auburn Hills, MI (US)

(**) Term: **14 Years**

(21) Appl. No.: **29/201,094**

(22) Filed: **Mar. 10, 2004**

(51) **LOC (7) Cl.** **12-08**

(52) **U.S. Cl.** **D12/92**

(58) **Field of Search** D12/90–92, 86;
D21/424, 433; 296/185

(56) **References Cited**

U.S. PATENT DOCUMENTS

D408,328	S	*	4/1999	Ayoub et al.	D12/92
D465,436	S	*	11/2002	Dehner et al.	D12/92
D476,601	S		7/2003	Stoddard et al.	D12/92
D477,253	S	*	7/2003	Minami et al.	D12/92
D483,696	S	*	12/2003	Howell et al.	D12/92

* cited by examiner

Primary Examiner—Melody N. Brown
(74) *Attorney, Agent, or Firm*—Ralph E. Smith

(57) **CLAIM**

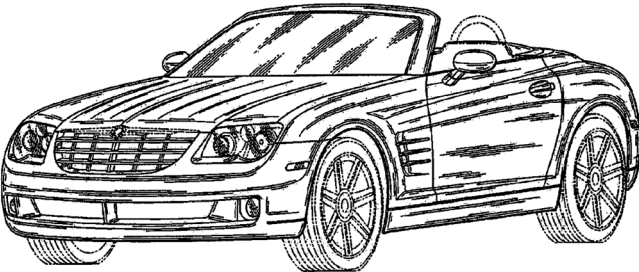
The ornamental design for an automobile body, as shown and described.

DESCRIPTION

FIG. 1 is a front perspective view of an automobile body showing our new design;
FIG. 2 is a side view thereof;
FIG. 3 is a rear perspective view thereof;
FIG. 4 is a front view thereof;
FIG. 5 is a rear view thereof;
FIG. 6 is a front perspective view of an automobile body showing a second embodiment of our new design;
FIG. 7 is a side view of FIG. 6;
FIG. 8 is a rear perspective view of FIG. 6;
FIG. 9 is a front view of FIG. 6; and,
FIG. 10 is a rear view of FIG. 6.

It will be understood that the dashed lines presented in the drawings are for illustration only, and do not form a part of the claimed design.

1 Claim, 8 Drawing Sheets



There is a two-part test for determining design patent infringement: (1) construction of the patent claim, and (2) comparison of the construed claim to the accused product. Construing the scope of a design patent claim encompasses “its visual appearance as a whole.” *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1577 (Fed. Cir. 1995). In construing a design patent claim, the scope of the claimed design encompasses “its visual appearance as a whole,” and in particular “the visual impression it creates.” See *Durling v. Spectrum Furniture Co.*, 101 F.3d 100, 104-05 (Fed. Cir. 1996). The comparison of the construed claim to the accused product involves two separate tests that must both be satisfied. First is the “ordinary observer” test, and second, the “point of novelty” test. See *Unidynamics Corp. v. Automatic Prods. Int’l, Ltd.*, 157 F.3d 1311, 1323 (Fed. Cir. 1998). Regarding the “ordinary observer” test, the Supreme Court stated:

[I]f, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other, the first one patented is infringed by the other.

81 U.S. (14 Wall.) 511, 528 (1871). The “point of novelty” test demands proof that the “accused design appropriates the novelty which distinguishes the patented design from the prior art.” *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1444 (Fed. Cir. 1984).

The Federal Circuit noted that application of the “point of novelty” and “ordinary observer” tests “sometimes lead to the same result.” See *Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 628 n.16 (Fed. Cir. 1984). The points of novelty test was at issue in *Lawman Armor v. Winner Int’l*, 449 F.3d 1192 (Fed. Cir. 2006). In *Lawman*, Lawman owned a patent on the design of the well-known steering wheel locking device called “The Club.” The district court held there was no infringement because, according to the court, all eight specific points of novelty could be located in a combination of prior art references. The Federal Circuit affirmed, and rejected Lawman’s argument that there has to be a suggestion or motivation to combine prior art references under the points of novelty test:

What Lawman’s contention comes down to is that the ’621 patent contains a ninth “point of novelty,” namely, the combination in a single design of the eight non-novel “points of novelty” it embodies. This argument is inconsistent with, and would seriously undermine, the rationale of the “points of novelty” test. “The purpose of the ‘points of novelty’ approach . . . is to focus on those aspects of a design which render the design different from prior art designs.” *Winner Int’l Corp. v. Wolo Mfg. Corp.*, 905 F.2d 375, 376 (Fed. Cir. 1990). “New” designs frequently involve only relatively small changes in the shape, size, placement, or color of elements of old designs. It is those changes in and departures from the old designs that constitute the “points of novelty” in the patented new design.

If the combination of old elements shown in the prior art is itself sufficient to constitute a “point of novelty” of a new design, it would be the rare design that would not have a point of novelty. The practical effect of Lawman’s theory would be virtually to eliminate the significance of the “points of novelty” test in determining infringement of design patents, and to provide patent protection for designs that in fact involve no significant changes from the prior art. *Id.* (“To consider the overall appearance of a design without regard to prior art would eviscerate the purpose of the ‘point of novelty’ approach, which is to focus on

those aspects of a design which render the design different from prior art designs.”).

Id. at 1385-86. In an opinion dissenting from the denial to rehear *Lawman* en banc, Judge Newman warned that the panel decision’s “view of design patent law is contrary to the weight of Federal Circuit precedent and . . . will have a seriously adverse effect on design patent law.” Judge Newman continued, “[t]he panel has reaffirmed its holding that a design patent is not valid if it is a combination of known design elements, even when the combination is novel and distinctive.” Indeed, “[t]he *amicus curiae* point out that many, if not most, design patents are novel combinations of known design elements, and that recognition of a design’s overall appearance can constitute a point of novelty, in the usage that has evolved in design patent law.” *Lawman Armor Corp. v. Winner Int’l, LLC*, 449 F.3d 1192, 1194 (Fed. Cir. 2006).

Filings of design patents have increased substantially over the past 20 years. In 1980, for instance, 7,830 applications were filed with 3,949 issuing. And in 2003, 22,602 were filed with 16,574 issuing. See www.uspto.gov. This increase reflects the commercial value of many designs. Indeed, the Federal Circuit recently upheld a \$813,000 verdict in favor of a design patent holder. See *Junker v. Eddings*, 396 F.3d 1359 (Fed. Cir. 2005).

CHAPTER

4

Novelty and Priority

INTRODUCTION

This chapter is devoted to the concepts of novelty and priority. The novelty requirement—embodied in § 102(a), (e), and (g)(2)—guards the public domain, precluding a patent from issuing on claimed subject matter that is not new. Subsection (a) relates to third-party knowledge, use, publication, and patenting activity prior to the applicant’s date of invention. Under § 102(e), the focus is on third-party patent disclosures filed prior to the applicant’s date of invention. And § 102(g)(2) pertains to third-party inventive activity prior to the applicant’s date of invention. Under all three subsections, the issue is *not* which party is entitled to a patent; rather, the issue is whether some third party knew or disclosed the applicant’s claimed invention before the applicant himself invented, thereby defeating novelty. Sections A and B are devoted to novelty.

Section 102(g)(1) is the priority provision, which is invoked when two or more parties are claiming the same invention. Thus, unlike the novelty provisions where only one party is seeking patent protection on a given invention, each party involved in a priority contest is asserting he invented first, and is therefore asking the PTO or the court to award priority of invention to him. The process by which priority is determined is called an *interference*, an administrative proceeding within the PTO. Section C explores the issue of priority.

STATUTE: Conditions for patentability; novelty and loss of right to patent

35 U.S.C. §§ 102(a), (e) & (g)(2)

A. NOVELTY

The novelty requirement asks whether the applicant’s invention is new. Think of novelty as focusing on just one applicant and asking whether some third person, who is not seeking a patent, previously knew, disclosed or invented what the applicant is seeking to patent. If an invention isn’t new, it is said to be *anticipated* by the prior art. Novelty differs from statutory bars (the subject of Chapter 5) in two important ways. First, statutory bars focus on activity of both the inventor and third parties, and second, the critical date is one year before the application was filed. Novelty focuses on activity before the date of

invention and is only concerned with activity of third parties prior to the date of invention. (Proving date of invention is discussed in detail in Section C.)

1. Novelty's Doctrinal Framework

The *Atlas* case explores the doctrinal framework for proving anticipation (or lack of novelty). Proving anticipation requires the party challenging the patent's validity to show that each limitation of the claimed invention is disclosed—either expressly or inherently—in a single prior art reference.

ATLAS POWDER COMPANY v. IRECO INCORPORATED

190 F.3d 1342 (Fed. Cir. 1999)

RADER, Circuit Judge.

The United States District Court for the District of Wyoming determined that U.S. Patent No. 4,111,727 (the Clay patent) and its reissue, U.S. Patent No. RE 33,788 (the reissue patent) were invalid. Atlas Powder Company (Atlas), a licensee under those patents, sued IRECO Incorporated (IRECO) for infringement of the Clay patent. Following two bench trials, the district court concluded that both the original Clay patent and the reissue patent were invalid as anticipated by either U.S. Patent No. 3,161,551 (Egley) or U.K. Patent No. 1,306,546 (Butterworth). Because the district court correctly interpreted the claims and applied the law of anticipation, this court affirms the finding of invalidity.

I.

The Clay patent and its reissue both claim explosive compositions. To detonate, explosives require both fuel and oxidizers. The oxidizer rapidly reacts with the fuel to produce expanding gases and heat — an explosion. Composite explosives mix various sources of fuel and oxygen. The most widely used and economical composite explosive is ammonium nitrate and fuel oil (ANFO). ANFO explosives mix about 94% by weight of ammonium nitrate (AN), the oxidizer, with 6% by weight of fuel oil (FO). The AN may include porous prills, dense prills, Stengel flakes, or crystalline AN. ANFO explosives have two primary disadvantages. First, wet conditions dissolve the AN and make the explosive unusable in damp settings. Second, ANFO is a relatively weak explosive because interstitial air occupies considerable space in the mixture, thereby decreasing the amount of explosive material per unit of volume.

To address these shortcomings, explosive experts developed water-in-oil emulsions. These emulsions dissolved the oxidizer into water and then dispersed the solution in oil. Because oil surrounds the oxidizer, it is resistant to moisture, thus solving one of the problems with ANFO. Emulsions also increased the explosive's bulk strength by increasing the density of explosive material in the mixture. Emulsions, however, also have a disadvantage. Emulsions will not detonate unless sensitized. Sensitivity of a blasting composition refers to the ease of igniting its explosion. Experts generally sensitize emulsions by using gassing agents or adding microballoons throughout the mixture. The gassing agents or microballoons provide tiny gas or air bubbles throughout the mixture. Upon detonation, the gas pockets compress and heat

up, thereby igniting the fuel around them. In other words, the tiny gas or air bubbles act as “hot spots” to propagate the explosion.

The Clay patent and its reissue both claim composite explosives made from the combination of an ANFO blasting composition and an unsensitized water-in-oil emulsion. Both patents claim essentially the same blasting composition. Claim one of the reissue patent recites:

1. A blasting composition consisting essentially of 10 to 40% by weight of a greasy water-in-oil emulsion and 60 to 90% of a substantially undissolved particulate solid oxidizer salt constituent, wherein the emulsion comprises about 3 to 15% by weight of water, about 2 to 15% of oil, 70 to 90% of powerful oxidizer salt comprising ammonium nitrate which may include other powerful oxidizer salts, wherein the solid constituent comprises ammonium nitrate and *in which sufficient aeration is entrapped to enhance sensitivity to a substantial degree*, and wherein the emulsion component is emulsified by inclusion of 0.1 to 5% by weight, based on the total composition, of an [oil-in-water] water-in-oil emulsifier to hold the aqueous content in the disperse or internal phase.

(Emphasis added.)

When this lawsuit began, Atlas was the exclusive licensee under the Clay patent in the continental U.S. and Hawaii. Atlas commenced this lawsuit against IRECO in 1986, alleging infringement of the Clay patent. During the course of litigation, Dr. Robert Clay, the inventor, filed a reissue petition with the United States Patent and Trademark Office (PTO). Atlas then moved to stay the litigation pending resolution of the reissue application. The district court denied that motion and conducted a first bench trial on the issues of validity and infringement of the Clay patent in October 1986. Dr. Clay then requested suspension of prosecution of the reissue application by the PTO in February 1987. After waiting several years for a decision from the district court, Dr. Clay requested that the PTO reinstate the reissue proceedings in 1990. In January 1992, the Clay reissue patent issued upon surrender of the original patent. Later that year, the district court rendered its findings and judgment regarding the validity and infringement of the Clay patent.

In its 1992 judgment, the district court found claims 1, 2, 3, 10, 12, 13, and 14 of the Clay patent invalid as anticipated by either one of two prior art references, Egly or Butterworth. Egly and Butterworth each disclose blasting compositions containing a water-in-oil emulsion and ANFO with ingredients identical to those of the Clay patents in overlapping amounts. The following chart illustrates the overlap between the explosive compositions disclosed in the prior art patents and the Clay reissue patent:

Composition Contents	Clay	Egly	Butterworth
Water-in-oil Emulsion	10-40%	20-67%	30-50%
Solid Ammonium Nitrate	60-90%	33-80%	50-70%
Emulsion Contents			
Ammonium Nitrate	70-90%	50-70%	65-85%
Water	about 3-15%	about 15-about 35%	7-27%
Fuel Oil	about 2-15%	about 5-about 20%	2-27%
Emulsifier	0.1-5%	about 1-5%	0.5-15%

The only element of the Clay patent claims which is arguably not present in the prior art compositions is “sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree.” The trial court determined that “sufficient aeration” was an inherent element in the prior art blasting compositions within the overlapping ranges. The district court also found that none of the accused products infringed any of the asserted claims. The 1992 judgment was not final, however, and specifically reserved a decision on the effect of the reissue patent for phase two of the case.

On September 22, 1993, the district court granted Hanex Products Inc.’s (Hanex) motion to intervene in the lawsuit. Hanex owns the two patents and had licensed them to Atlas. Hanex asserted the same claim of patent infringement against IRECO that Atlas had asserted, but also initiated a declaratory judgment action against ICI Explosives USA, Inc. (ICI), Atlas’ successor-in-interest, seeking the sole right to control the litigation. In July 1994, the district court granted declaratory relief in favor of Hanex, against ICI, giving Hanex the sole right to control and direct the litigation on the two patents.

After the reissue patent issued, the district court conducted a second bench trial, in January 1996, on the issues of phase two. Specifically, the district court considered whether reissue affected its 1992 judgment. On September 25, 1998, the district court rendered its final judgment finding claims 1, 2, 3, 10, 12, 13, and 14 of the Clay reissue patent invalid as anticipated and finding that IRECO had not infringed any of the asserted claims. Despite the PTO’s consideration of the Egly and Butterworth references during prosecution of the reissue, the district court concluded that IRECO had overcome the Clay reissue patent’s presumption of validity under 35 U.S.C. § 282 (1994) by clear and convincing evidence. The district court noted that IRECO presented a great deal of testimonial and documentary evidence on inherent disclosures of the prior art that was not before the PTO in the reissue proceeding. Hanex appealed to this court from the 1998 final judgment.

II.

Anticipation is a question of fact, including whether or not an element is inherent in the prior art. Therefore, this court reviews a finding of anticipation under the clearly erroneous standard.

“To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d at 1477. Anticipation of a patent claim requires a finding that the claim at issue “reads on” a prior art reference. *See Titanium Metals Corp. v. Banner*, 778 F.2d 775, 781 (Fed. Cir. 1985). In other words, if granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art. *See id.* at 781. Specifically, when a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim. *See id.* at 780-82 (“It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if one of them is in the prior art.”). In chemical compounds, a single prior art species within the patent’s claimed genus reads on the generic claim and anticipates.

As noted previously, both Egly and Butterworth disclose blasting compositions with ingredients identical to those of the Clay patent and its reissue in overlapping amounts. The only element which is arguably missing from the prior art is the requirement that “sufficient aeration [be] entrapped to enhance sensitivity to a substantial degree.” To decide the issue of anticipation, therefore, the district court examined whether “sufficient aeration . . . to enhance sensitivity” was inherently part of the prior art compositions. That decision, in turn, required the trial court to interpret the claim term “sufficient aeration.” By looking at the express language of the claims and the patent’s written description, the district court concluded that the claim term “sufficient aeration” included both interstitial air (between oxidizer particles) and porous air (within the pores of oxidizer particles).

The first task of this court on appeal is to construe independently the disputed claim term. This question requires this court to determine whether the claim term “sufficient aeration” includes porous air, as the trial court determined. The claim term “sufficient aeration” does not limit the air content of the composition to interstitial air. Rather, the broad term “aeration” contains no qualitative limits on the kind of air exposure, only the quantitative limit that the air exposure be “sufficient” to enhance sensitivity. If the inventor intended “sufficient aeration” to carry qualitative limits, he also did not express that intention in the patent’s written description. The specification gives no explicit definition of the phrase “sufficient aeration . . . to enhance sensitivity,” which appears in the patent for the first time in the claims.

It is, of course, possible that the inventor did not include qualitative limits on the term “sufficient aeration” in the specification because those of ordinary skill in the art understand that only interstitial air enhances sensitivity and satisfies the claim’s language. *See Autogiro Co. of Am. v. U.S.*, 181 Ct. Cl. 55, 384 F.2d 391, 397, 155 USPQ 697 (Ct. Cl. 1967) (“Claims cannot be clear and unambiguous on their face.”). The trial record, however, shows that those of ordinary skill in this art at the time the patent application was filed knew that both interstitial and porous air enhance sensitivity. Dr. Clay himself, the inventor of the patents in suit, testified that air from any source would contribute to the explosion of a heavy ANFO composition and, particularly, air trapped within the pores of porous prilled AN. Therefore, this court detects no error in the district court’s conclusion that “sufficient aeration . . . to enhance sensitivity” is understood by those of ordinary skill in the art to include both interstitial and porous air. The district court appropriately construed the claims at issue to include aeration from both sources.

III.

Based on its correct interpretation of “sufficient aeration,” the district court heard evidence on whether both interstitial and porous air were present and enhanced sensitivity in the prior art explosive compositions. Based on the evidence, the district court concluded that IRECO had shown the inherency of the disputed claim element in the prior art and overcome “the presumption of validity under 35 U.S.C. § 282 by providing clear and convincing evidence of invalidity.” This court must determine whether the district court committed clear error by determining that the evidence clearly and convincingly established that “sufficient aeration . . . to enhance sensitivity” was inherent in either Egly or Butterworth.

To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. *See id.* Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. *See Titanium Metals*, 778 F.2d at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties.").

This court's decision in *Titanium Metals* illustrates these principles. In *Titanium Metals*, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals*, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id.* at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

The trial record contains exhaustive evidence regarding the inherency of both interstitial and porous air in the Egly and Butterworth compositions within the overlapping ranges. The testimony from expert witnesses for both parties established that whether sufficient air is present in the explosive composition to facilitate detonation is a function of the ratio of the emulsion to the solid constituent. Dr. Clay testified that "if you mix porous prills, for example, with 30% typical water-in-oil emulsions, you're going to have air in there and it will detonate." Another of Atlas' experts testified that a mixture of 30% of either an Egly or a Butterworth emulsion, mixed with 70% standard fertilizer grade porous AN would have interstitial air, assuming nothing was done to disturb the size distribution of the AN prills. The other experts agreed that the emulsions described in both Egly and Butterworth would inevitably and inherently have interstitial air remaining in the mixture up to a ratio of approximately 40% emulsion to 60% solid constituent. The expert testimony supports the district court's conclusion that "sufficient aeration" is inherent in both Egly and Butterworth.

The district court also relied on evidence from several tests which showed that "sufficient aeration . . . to enhance sensitivity" was inherently present

within the overlapping ranges of the Clay patents and Egly and Butterworth. In tests conducted with porous prilled AN combined with FO, stable detonations were obtained in every 8" diameter bore hole test where the percentage of emulsion ranged from 30% to 42.5%. Butterworth specifically discloses the use of porous prilled AN. Butterworth, p. 3, ll. 35-50. These tests, therefore, support the finding that "[t]he emulsions described by Butterworth, combined with the ratios of ANFO disclosed by Butterworth, would inevitably and inherently have interstitial air remaining up to approximately 40% emulsion." The district court also found that the solid AN disclosed in Egly would have included porous prills. These tests, therefore, further support the court's finding that "emulsions described in the Egly Patent, combined with either AN or ANFO, would inevitably and inherently have interstitial air remaining in the mixture up to approximately 40% emulsion to 60% solid constituent." This court discerns no clear error in the district court's conclusion that "sufficient aeration" was inherent in each anticipating prior art reference.

Because "sufficient aeration" was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of Dr. Clay's alleged invention—that air may act as the sole sensitizer of the explosive composition. An inherent structure, composition, or function is not necessarily known. Once it is recognized that interstitial and porous air were inherent elements of the prior art compositions, the assertion that air may act as a sole sensitizer amounts to no more than a claim to the discovery of an inherent property of the prior art, not the addition of a novel element. Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation. In addition, there was evidence that Butterworth did recognize the functioning of interstitial and porous air in sensitizing the composition. Butterworth recognizes the need for a gaseous sensitizer. It teaches that the "sensitizer may be a gaseous sensitizer present in the composition in the form of gas bubbles or discrete particles containing an entrapped gas such as air." Although this typically suggests use of a gassing agent or microballoons, Butterworth expressly recognizes that in certain ranges (i.e., 50% to 70% by weight of ANFO) the mixture of porous prilled AN and FO alone provides the necessary sensitization. The district court found that Butterworth thus inherently appreciates that interstitial and porous air may serve as the necessary sensitizer. This court discerns no clear error in that finding.

In reaching this judgment, this court notes that Egly teaches away from air entrapment. Specifically, Egly teaches that it is desirable to "fill all spaces in between each particle to give added density." This statement in Egly, however, does not defeat the district court's finding of anticipation for several reasons. First, Egly's teaching does not in any way discredit the trial court's alternative reliance on Butterworth for invalidation of the Clay patent and its reissue. More important, the statement in Egly is, in fact, only a showing that Egly did not recognize the function of the inherently present interstitial air. As noted previously, an insufficient scientific understanding does not defeat a showing of inherency. In fact, even in Egly itself, the only way taught for removing interstitial air is the addition of more emulsion. Egly, however, teaches the use of a broad range—between 20% and 67% by weight—of water-in-oil emulsion. While Egly compositions containing amounts approaching 67% by

weight of water-in-oil emulsions may have little or no entrapped air, the evidence established that at emulsion levels below 40%, Egly compositions “inevitably and inherently” trap sufficient amounts of air to enhance sensitivity. This evidence included both substantial amounts of expert testimony and data showing extensive testing of Egly compositions.

Finally, although the record showed that special mixing techniques—such as grinding and screening the AN particles—remove interstitial air from the blasting compositions, Egly did not teach or suggest any such techniques. Thus, although Egly may have suggested removal of air, it nonetheless inherently contained interstitial aeration sufficient to enhance sensitivity when comprised of elements within the Clay patent ranges. Consequently, this court discerns no clear error in the district court’s conclusion that Egly compositions within the range of the Clay patent claims inherently contain sufficient air to enhance sensitivity.

Based upon all the evidence, substantial amounts of which were not before the PTO in its reissue examination, the district court concluded that IRECO had proven

clearly and convincingly that, unless extraordinary measures are taken to grind and screen ammonium nitrate, the existence of “interstitial air,” or sufficient aeration to sustain a stable detonation, is a function of the ratios of emulsion to solid constituent. Specifically, at ratios of 30% emulsion and 70% solid constituent, which are common to the Clay Patent, the Egly Patent, and the Butterworth Patent, there is inherently sufficient aeration to sustain a stable detonation, barring extraordinary efforts to grind and screen the ammonium nitrate used in the solid constituent.

This court discerns no clear error in the district court’s factual determination that the prior art inherently possesses sufficient aeration to enhance sensitivity to a substantial degree within the overlapping ranges. Nor does this court discern clear error in the district court’s finding of anticipation based on either Egly or Butterworth. To uphold the Clay patent and its reissue would preclude the public from practicing the prior art.

Comments

1. ***Identity of Invention and Anticipatory Enablement.*** A finding of anticipation (either based on knowledge or a publication) requires each and every claim limitation to be disclosed in a single reference (identity of invention), and the reference must enable the claimed invention so as to place the invention in the possession of a person having ordinary skill in the art (anticipatory enablement). A reference does not have to explain every detail of the claimed invention because the reference is “considered together with the knowledge of one of ordinary skill in the pertinent art.” *In re Samour*, 571 F.2d 559, 562 (CCPA 1978). The single reference requirement highlights an important distinction between the novelty and non-obviousness requirements. As you will see in Chapter 6, combining references is permissible when judging obviousness.
2. ***Inherency.*** Anticipation must be proven by showing that each limitation of the claimed invention is present, either expressly or under principles of

inherency. While express disclosure is straightforward enough, the meaning of inherency is not readily apparent. The Federal Circuit has held that a claim limitation is inherently anticipated if the limitation is necessarily present in or inevitably flows from the reference. See *Toro Co. v. John Deere & Co.*, 355 F.3d 1313, 1320 (Fed. Cir. 2004); *Continental Can Co., USA v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (“If . . . [the prior art] the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function.”). Inherency does not require that a person of ordinary skill in the art appreciate or recognize the inherent disclosure at the time of invention. See *Schering Corporation v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 471 F.3d 1363, 1368 (Fed. Cir. 2006) (“The general principle that a newly-discovered property of the prior art cannot support a patent on that same art is not avoided if the patentee explicitly claims that property. . . . ‘[I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure.’”). Inherency comes into play when “the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.” *Continental Can*, 948 F.2d at 1269. See also *Atlas Powder* (the principal case) (stating “one of the principles underlying the doctrine of inherent anticipation is to ensure that ‘[t]he public remains free to make, use or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate’”).

An illustrative inherency case is *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005). In this case, SmithKline owned the ’723 U.S. patent that claimed “crystalline paroxetine hydrochloride hemihydrate (PHC hemihydrate),” which was the active ingredient in SmithKline’s antidepressant drug, Paxil. Shortly after Paxil hit the market, Apotex, a generic drug manufacturer, initiated regulatory proceedings seeking FDA approval to market its own PHC antidepressant. Apotex asserted that its product would not infringe the ’723 patent because Apotex’s active ingredient was PHC anhydrate, not PHC hemihydrate. SmithKline sued Apotex under the theory PHC anhydrate tablets necessarily contain, by a manufacturing conversion process, at least trace amounts of PHC hemihydrate. Apotex responded by arguing that the ’723 patent was inherently anticipated by the ’196 patent, which expressly disclosed PHC anhydrate. The ’196 patent did not expressly disclose PHC hemihydrate — the active ingredient claimed in the ’723 patent that was not discovered until five years after the ’196 patent was filed. The district court held that the ’723 patent was not inherently anticipated because Apotex “did not prove by clear and convincing evidence that it was impossible to make pure PHC anhydrate.” *Id.* at 1342. The Federal Circuit found the district court’s standard “too exacting.” Instead, the court stated Apotex need only prove that the prior art disclosure “‘is sufficient to show that the natural result flowing from the operation as taught [in the prior art] would result in the claimed product.’” *Id.* at 1343. Applying this test, the court found that the ’196 patent anticipates claim 1 of the ’723 patent because the ’196 patent

inherently disclosed PHC hemihydrate; that is, “producing PHC anhydrate according to the ’196 patent inevitably results in the production of at least trace amounts of anticipating PHC hemihydrate.” *Id.* Thus, although not expressly disclosed, the ’196 reference enabled a person of ordinary skill in the art to make PHC hemihydrate; indeed, one could say that PHC hemihydrate inevitably resulted from practicing the ’196 patent.

2. “Known or Used” Under § 102(a)

This section is devoted to the words “known” and “used” in § 102(a), which are not as straightforward as one may initially think. For instance, “known or used” by whom? And what exactly does it mean the invention was “known or used”? The *Gayler* and *Rosaire* cases and Comments that follow explore the nuances of this language in the context of patent law’s policy objectives.

GAYLER v. WILDER

51 U.S. (10 How.) 477 (1850)

Chief Justice TANEY delivered the opinion of the court.

The [assignee, Wilder,] brought an action against Gayler and Brown, for an alleged infringement of a patent right for the use of plaster of Paris in the construction of fire-proof chests. In the declaration, it was averred that one Daniel Fitzgerald was the original and first inventor of a new and useful improvement in fire-proof chests or safes, and that letters patent were granted him therefor, bearing date the 1st day of June, 1843.

* * *

It appears that James Conner, who carried on the business of a stereotype founder in the city of New York, made a safe for his own use between the years 1829 and 1832, for the protection of his papers against fire; and continued to use it until 1838, when it passed into other hands. It was kept in his counting-room and known to the persons engaged in the foundry; and after it passed out of his hands, he used others of a different construction.

It does not appear what became of this safe afterwards. And there is nothing in the testimony from which it can be inferred that its mode of construction was known to the person into whose possession it fell, or that any value was attached to it as a place of security for papers against fire; or that it was ever used for that purpose.

Upon these facts the court instructed the jury, “that if Connor had not made his discovery public, but had used it simply for his own private purpose, and it had been finally forgotten or abandoned, such a discovery and use would be no obstacle to the taking out of a patent by Fitzgerald or those claiming under him, if he be an original, though not the first, inventor or discoverer.”

The instruction assumes that the jury might find from the evidence that Conner’s safe was substantially the same with that of Fitzgerald, and also prior in time. And if the fact was so, the question then was whether the patentee was “the original and first inventor or discoverer”, within the meaning of the act of Congress.

The act of 1836, ch. 357, § 6, authorizes a patent where the party has discovered or invented a new and useful improvement, “not known or used by others before his discovery or invention.” And the 15th section provides that, if it appears on the trial of an action brought for the infringement of a patent that the patentee “was not the original and first inventor or discoverer of the thing patented”, the verdict shall be for the defendant.

Upon a literal construction of these particular words, the patentee in this case certainly was not the original and first inventor or discoverer, if the Conner safe was the same with his, and preceded his discovery. But we do not think that this construction would carry into effect the intention of the legislature. It is not by detached words and phrases that a statute ought to be expounded. The whole act must be taken together, and a fair interpretation given to it, neither extending nor restricting it beyond the legitimate import of its language, and its obvious policy and object. And in the 15th section, after making the provision above mentioned, there is a further provision, that, if it shall appear that the patentee at the time of his application for the patent believed himself to be the first inventor, the patent shall not be void on account of the invention or discovery having been known or used in any foreign country, it not appearing that it had been before patented or described in any printed publication.

In the case thus provided for, the party who invents is not strictly speaking the first and original inventor. The law assumes that the improvement may have been known and used before his discovery. Yet his patent is valid if he discovered it by the efforts of his own genius, and believed himself to be the original inventor. The clause in question qualifies the words before used, and shows that by knowledge and use the legislature meant knowledge and use existing in a manner accessible to the public. If the foreign invention had been printed or patented, it was already given to the world and open to the people of this country, as well as of others, upon reasonable inquiry. They would therefore derive no advantage from the invention here. It would confer no benefit upon the community, and the inventor therefore is not considered to be entitled to the reward. But if the foreign discovery is not patented, nor described in any printed publication, it might be known and used in remote places for ages, and the people of this country be unable to profit by it. The means of obtaining knowledge would not be within their reach; and, as far as their interest is concerned, it would be the same thing as if the improvement had never been discovered. It is the inventor here that brings it to them, and places it in their possession. And as he does this by the effort of his own genius, the law regards him as the first and original inventor, and protects his patent, although the improvement had in fact been invented before, and used by others.

So, too, as to the lost arts. It is well known that centuries ago discoveries were made in certain arts the fruits of which have come down to us, but the means by which the work was accomplished are at this day unknown. The knowledge has been lost for ages. Yet it would hardly be doubted, if any one now discovered an art thus lost, and it was a useful improvement, that, upon a fair construction of the act of Congress, he would be entitled to a patent. Yet he would not literally be the first and original inventor. But he would be the

first to confer on the public the benefit of the invention. He would discover what is unknown, and communicate knowledge which the public had not the means of obtaining without his invention.

Upon the same principle and upon the same rule of construction, we think that Fitzgerald must be regarded as the first and original inventor of the safe in question. The case as to this point admits, that, although Conner's safe had been kept and used for years, yet no test had been applied to it, and its capacity for resisting heat was not known; there was no evidence to show that any particular value was attached to it after it passed from his possession, or that it was ever afterwards used as a place of security for papers; and it appeared that he himself did not attempt to make another like the one he is supposed to have invented, but used a different one. And upon this state of the evidence the court put it to the jury to say, whether this safe had been finally forgotten or abandoned before Fitzgerald's invention, and whether he was the original inventor of the safe for which he obtained the patent; directing them, if they found these two facts, that their verdict must be for the plaintiff. We think there is no error in this instruction. For if the Conner safe had passed away from the memory of Conner himself, and of those who had seen it, and the safe itself had disappeared, the knowledge of the improvement was as completely lost as if it had never been discovered. The public could derive no benefit from it until it was discovered by another inventor. And if Fitzgerald made his discovery by his own efforts, without any knowledge of Conner's, he invented an improvement that was then new, and at that time unknown; and it was not the less new and unknown because Conner's safe was recalled to his memory by the success of Fitzgerald's.

We do not understand the Circuit Court to have said that the omission of Conner to try the value of his safe by proper tests would deprive it of its priority; nor his omission to bring it into public use. He might have omitted both, and also abandoned its use, and been ignorant of the extent of its value; yet, if it was the same with Fitzgerald's, the latter would not upon such grounds be entitled to a patent, provided Conner's safe and its mode of construction were still in the memory of Conner before they were recalled by Fitzgerald's patent.

The circumstances above mentioned, referred to in the opinion of the Circuit Court, appeared to have been introduced as evidence tending to prove that the Conner safe might have been finally forgotten, and upon which this hypothetical instruction was given. Whether this evidence was sufficient for that purpose or not, was a question for the jury, and the court left it to them. And if the jury found the fact to be so, and that Fitzgerald again discovered it, we regard him as standing upon the same ground with the discoverer of a lost art, or an unpatented and unpublished foreign invention, and like him entitled to a patent. For there was no existing and living knowledge of this improvement, or of its former use, at the time he made the discovery. And whatever benefit any individual may derive from it in the safety of his papers, he owes entirely to the genius and exertions of Fitzgerald.

Upon the whole, therefore, we think there is no error in the opinion of the Circuit Court, and the judgment is therefore affirmed.

ROSAIRE v. BAROID SALES DIVISION

218 F.2d 72 (5th Cir.1955)

TUTTLE, Circuit Judge.

In this suit for patent infringement there is presented to us for determination the correctness of the judgment of the trial court, based on findings of fact and conclusions of law, holding that the two patents involved in the litigation were invalid and void and that furthermore there had been no infringement by defendant.

The Rosaire and Horvitz patents relate to methods of prospecting for oil or other hydrocarbons. The inventions are based upon the assumption that gases have emanated from deposits of hydrocarbons which have been trapped in the earth and that these emanations have modified the surrounding rock. The methods claimed involve the steps of taking a number of samples of soil from formations which are not themselves productive of hydrocarbons, either over a horizontal area or vertically down a well bore, treating each sample, as by grinding and heating in a closed vessel, to cause entrained or absorbed hydrocarbons therein to evolve as a gas, quantitatively measuring the amount of hydrocarbon gas so evolved from each sample, and correlating the measurements with the locations from which the samples were taken.

Plaintiff claims that in 1936 he and Horvitz invented this new method of prospecting for oil. In due course the two patents in suit, Nos. 2,192,525 and 2,324,085, were issued thereon. Horvitz assigned his interest to Rosaire. Appellant alleged that appellee Baroid began infringing in 1947; that he learned of this in 1949 and asked Baroid to take a license, but no license agreement was worked out, and this suit followed, seeking an injunction and an accounting.

In view of the fact that the trial court's judgment that the patents were invalid, would of course dispose of the matter if correct, we turn our attention to this issue. Appellee's contention is that the judgment of the trial court in this respect should be supported on two principal grounds. The first is that the prior art, some of which was not before the patent office, anticipated the two patents; the second is that work carried on by one Teplitz for the Gulf Oil Corporation invalidated both patents by reason of the relevant provisions of the patent laws which state that an invention is not patentable if it "was known or used by others in this country" before the patentee's invention thereof, 35 U.S.C.A. § 102(a). Appellee contends that Teplitz and his coworkers knew and extensively used in the field the same alleged inventions before any date asserted by Rosaire and Horvitz.

On this point appellant himself in his brief admits that "Teplitz conceived of the idea of extracting and quantitatively measuring entrained or absorbed gas from the samples of rock, rather than relying upon the free gas in the samples. We do not deny that Teplitz conceived of the methods of the patents in suit." And further appellant makes the following admission: "We admit that the Teplitz-Gulf work was done before Rosaire and Horvitz conceived of the inventions. We will show, however, that Gulf did not apply for patent until 1939, did not publish Teplitz's ideas, and did not otherwise give the public the benefit of the experimental work."

In support of their respective positions, both appellant and appellee stress the language in our opinion in the case of *Pennington v. National Supply Co.*,

where, speaking through Judge Holmes, we said: "Appellant insists that the court erred in considering the prior use of the Texas machine, because that machine was abandoned by the Texas Company and was not successful until modified and rebuilt. As to this, it does not appear that the Texas machine was a failure, since it drilled three wells for the Texas Company, which was more than was usually accomplished by the rotary drilling machines then in use."

"An unsuccessful experiment which is later abandoned does not negative novelty in a new and successful device". *T. H. Symington Co. v. National Malleable Castings Co.*, 250 U.S. 383. Nevertheless, the existence and operation of a machine, abandoned after its completion and sufficient use to demonstrate its practicability, is evidence that the same ideas incorporated in a later development along the same line do not amount to invention. If the prior machine does not anticipate, it would not have done so if it had been neither unsuccessful nor abandoned. Novelty is ascribed to new things, without regard to the successful and continued use of old things. Correlatively, it is denied to old things, without regard to the circumstances which caused their earlier applications to be unsatisfactory or their use to be abandoned.

The question as to whether the work of Teplitz was "an unsuccessful experiment", as claimed by appellant, or was a successful trial of the method in question and a reduction of that method to actual practice, as contended by appellee, is, of course, a question of fact. On this point the trial court made the following finding of fact: "I find as a fact, by clear and substantial proof beyond a reasonable doubt, that Abraham J. Teplitz and his coworkers with Gulf Oil Corporation and its Research Department during 1935 and early 1936, before any date claimed by Rosaire, spent more than a year in the oil fields and adjacent territory around Palestine, Texas, taking and analyzing samples both over an area and down drill holes, exactly as called for in the claims of the patents which Rosaire and Horvitz subsequently applied for and which are here in suit. This Teplitz work was a successful and adequate field trial of the prospecting method involved and a reduction to practice of that method. The work was performed in the field under ordinary conditions without any deliberate attempt at concealment or effort to exclude the public and without any instructions of secrecy to the employees performing the work."

As we view it, if the court's findings of fact are correct then under the statute as construed by the courts, we must affirm the finding of the trial court that appellee's patents were invalid.

A close analysis of the evidence on which the parties rely to resolve this question clearly demonstrates that there was sufficient evidence to sustain the finding of the trial court that there was more here than an unsuccessful or incomplete experiment. It is clear that the work was not carried forward, but that appears to be a result of two things: (1) that the geographical area did not lend itself properly to the test, and (2) that the "entire gas prospecting program was therefore suspended in September of 1936, in order that the accumulated information might be thoroughly reviewed." It will be noted that the program was not suspended to test the worth of the method but to examine the data that was produced by use of the method involved. The above quotation came from one of the recommendations at the end of Teplitz's report, and was introduced on behalf of the appellant himself. Expert testi-

mony presented by witnesses Rogers, Eckhardt and Weaver supported appellee's contention.

With respect to the argument advanced by appellant that the lack of publication of Teplitz's work deprived an alleged infringer of the defense of prior use, we find no case which constrains us to hold that where such work was done openly and in the ordinary course of the activities of the employer, a large producing company in the oil industry, the statute is to be so modified by construction as to require some affirmative act to bring the work to the attention of the public at large.

While there is authority for the proposition that one of the basic principles underlying the patent laws is the enrichment of the art, and that a patent is given to encourage disclosure of inventions, no case we have found requires a holding that, under the circumstances that attended the work of Teplitz, the fact of public knowledge must be shown before it can be urged to invalidate a subsequent patent. The case of *Corona Cord Tire Co. v. Dovan Chemical Corporation*, *supra*, is authority for the opposing view, that taken by the court below. In that case the Supreme Court said: "In 1916, while with the Norwalk Company, Kratz prepared D.P.G. and demonstrated its utility as a rubber accelerator by making test slabs of vulcanized or cured rubber with its use. Every time that he produced such a slab he recorded his test in cards which he left with the Norwalk Company and kept a duplicate of his own. . . . This work was known to, and was participated in, by his associate in the Norwalk Company, his immediate superior and the chief chemist of the company, Dr. Russell, who fully confirms Kratz's records and statement." *Corona Cord Tire*, 276 U.S. 358, 378, 379.

The court further states in the *Corona* case at page 382 of 276 U.S.: "But, even if we ignore this evidence of Kratz's actual use of D.P.G. in these rubber inner tubes which were sold, what he did at Norwalk, supported by the evidence of Dr. Russell, his chief, and by the indubitable records that are not challenged, leaves no doubt in our minds that he did discover in 1916 the strength of D.P.G. as an accelerator as compared with the then known accelerators, and that he then demonstrated it by a reduction of it to practice in production of cured or vulcanized rubber. This constitutes priority in this case."

The judgment of the trial court is affirmed.

Comments

1. **"Known or Used" by Whom?** The words "known or used" in § 102(a) refer to third-party knowledge and use. As Justice Story wrote in *Pennock*, "known or used . . . cannot mean that the thing invented was not known or used . . . by the inventor himself, for that would prohibit him from the only means to obtain a patent." *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 18 (1829). In other words, an inventor cannot anticipate himself. And Congress used the disjunctive "or" when describing knowledge and use in § 102(a), which means that knowledge alone can defeat novelty. Recall the *Gayler* court said Connor could have defeated novelty provided the safe's "mode of construction were still in the memory of Conner" before Fitzgerald applied for a patent. In other words, novelty could be defeated in *Gayler* even if

Connor abandoned the invention or never used it. This point raises an important distinction between §§ 102(a) and (g), the latter requiring the invention not be abandoned to serve as prior art. See Comment 3 after the principal case of *Thomson v. Quixote*, below.

2. **“Known or Used” Where?** To serve as prior art, knowledge and use must be in the United States. Section 102(a) distinguishes knowledge and use from patents and printed publications, which can act as prior art if available in the United States or a foreign country. Prior to 1836, knowledge and use anywhere in the world defeated patent rights. But a geographic distinction was inserted in the 1836 Act because with the re-introduction of an examination system, it became clear that it would be infeasible for examiners to search or appreciate foreign-based knowledge and use. See Mario Biagioli, *Patent Republic: Representing Inventions, Constructing Rights and Authors* (forthcoming in *Social Research* 2007) (arguing that in 1836 “[n]ovelty . . . was redefined to conform to the less expansive notion of prior art that had to be introduced to make the examiners’ job reasonable and to create politically defensible expectations about what the Patent Office could and could not do. Such an institutional decision, however, resulted from the consequences of the introduction of specification requirements. What examiners could and could not do was what the specifications (as material inscriptions) allowed them to do. They could check a text against another text they could find in their library, but could not travel the world looking for machines”). In *Gayler*, the Court, in a slightly different context (namely, discussing information accessible to the public), stated:

If the foreign invention had been printed or patented, it was already given to the world and open to the people of this country, as well as of others, upon reasonable inquiry. They would therefore derive no advantage from the invention here. It would confer no benefit upon the community, and the inventor therefore is not considered to be entitled to the reward. But if the foreign discovery is not patented, nor described in any printed publication, it might be known and used in remote places for ages, and the people of this country be unable to profit by it. The means of obtaining knowledge would not be within their reach.

3. **How Public Must the Knowledge and Use Be?** It does not take much to satisfy the publicity requirement of § 102(a). Recall the work of Teplitz in *Rosaire*, which from a practical standpoint, was inaccessible to the public. So perhaps the publicity requirement of § 102(a) must be understood as the absence of secrecy. In *Gayler*, the court sided with Fitzgerald because it was he who disclosed the invention to the public, or as the court stated, “[i]t is the inventor here that brings it to them.” Yet Justice Taney’s favorable statements about Fitzgerald are tempered by the court’s recognition that if “Conner’s safe and its mode of construction were still in the memory of Conner,” Fitzgerald would be denied a patent even if Conner abandoned the invention and was “ignorant of the extent of its value.” It was only because of the near total lack of evidence of prior knowledge of the safe that Fitzgerald’s patent rights remained in tact. In the eyes of patent law, Conner and other prior users did not contribute enough to the public to serve as prior art.

But what did Teplitz's work or what would a more detailed memory by Conner bring to the public? It was Rosaire, Horvitz, and Fitzgerald that took the affirmative step of applying for a patent, and, by satisfying § 112's requirements, disclosed their respective inventions to the public, at least in a more extensive manner than those who came prior. As Judge Hand wrote of the *Gayler* holding, "what had not in fact enriched the art, should not count as prior art." *Gillman v. Stern*, 114 F.2d 28, 31 (2d Cir. 1940). See also Justice Grier's forceful statement in *Adams v. Jones*, 1 F. Cas. 126 (1859). In ruling on behalf of the patentee, he stated that "[i]t is only when some person, by labor and perseverance, has been successful in perfecting some valuable manufacture, by ingenious improvements, and labor-saving devices, that their patents are sought to be annulled by digging up some useless, musty, forgotten contrivances of unsuccessful experiments." Do the courts—in *Egbert*, *Gayler*, and *Rosaire*—take a minimalist approach because it is easier to apply, and therefore, imbues more certainty for inventors and attorneys? Or is it because Francis Barnes, James Conner (almost), and "one Teplitz" actually disclosed something to the public?

Another interesting case is *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368 (Fed. Cir. 1998). In *Woodland*, the '440 patent, owned by Woodland Trust, related to a method and apparatus for protecting a plot of foliage plants from freezing, by establishing an insulating covering of ice over ground level watering. The patent was filed on July 1, 1983 and issued on August 16, 1988. Flowertree asserted the '440 patent was invalid under § 102(a) because the invention was known and used prior to 1983 by Joseph Burke and William Hawkins, who owned Flowertree. Four witnesses, including the son of William Hawkins, testified that the claimed invention was known (and is still known) and in use in the 1960s and 1970s in Flowertree's Florida nurseries, but the use was discontinued in the late 1970s. The court did not find this evidence persuasive because it failed to prove that knowledge and use of the claimed invention was publicly accessible prior to Woodland Trust's date of invention. In particular, the court cited the lack of physical evidence of prior knowledge, the relationship of the witnesses, and the extensive passing of time (20 years) between the asserted prior uses and trial. *Id.* at 1373.

COMPARATIVE PERSPECTIVE

Defining Prior Art and Geographical Limitations

Section 102(a)—for reasons discussed in Comment 2, above—precludes a patent from issuing on an invention if it was "known or used *in this country*." This geographic constraint is at odds with the European Patent Convention (Article 54(2)) and the Japan Patent Law (Section 29 (1)), both of which treat public knowledge and use anywhere as prior art. A noteworthy reason why this disparity is relevant relates to something called "bioprospecting," a process whereby companies (e.g., pharmaceutical) in developed countries learn of, for example, indigenous flora—used locally for medicinal purposes—or traditional knowledge (TK) from developing countries and thereafter obtain patent protection

on the active ingredient contained in the flora or on information learned from the TK. Prominent examples include the need tree, turmeric, and basmati rice patent controversies. For more discussion on this issue, see Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679 (2003); Craig Allen Nard, *In Defense of Geographic Disparity*, 88 MINN. L. REV. 221 (2003); Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection*, 6 IND. J. GLOBAL LEGAL STUD. 11 (1998) and sources cited therein.

3. Novelty-Defeating Patent Disclosures Under § 102(e)

Section 102(e) embodies another novelty provision, but is limited to patent disclosures filed prior to the invention date. The typical scenario—as in *Alexander Milburn*—involves an inventor whose patent application is rejected (or invalidated) based on the disclosure (*i.e.*, specification) of a third party’s earlier-filed patent application. Importantly, the prior disclosure of the third-party application can serve as a prior art reference only if the application ultimately issues. Section 102(e) does not pertain to a situation where two or more parties claim the same invention. This scenario is the province of § 102(g)(1), which is explored in Section C.

ALEXANDER MILBURN CO. v. DAVIS-BOURNONVILLE CO.

270 U.S. 390 (1926)

Justice HOLMES delivered the opinion of the Court.

This is a suit for the infringement of the plaintiff’s patent for an improvement in welding and cutting apparatus alleged to have been the invention of one Whitford. The suit embraced other matters but this is the only one material here. The defense is that Whitford was not the first inventor of the thing patented, and the answer gives notice that to prove the invalidity of the patent evidence will be offered that one Clifford invented the thing, his patent being referred to and identified. The application for the plaintiff’s patent was filed on March 4, 1911, and the patent was issued on June 4, 1912.

There was no evidence carrying Whitford’s invention further back. Clifford’s application was filed on January 31, 1911, before Whitford’s, and his patent was issued on February 6, 1912. It is not disputed that this application gave a complete and adequate description of the thing patented to Whitford, but it did not claim it. The District Court gave the plaintiff a decree, holding that while Clifford might have added this claim to his application, yet as he did not, he was not a prior inventor. The decree was affirmed by the Circuit Court of Appeals.

The patent law authorizes a person who has invented an improvement like the present, “not known or used by others in this country, before his inven-

tion," etc., to obtain a patent for it. Rev. Sts. § 4886, amended by Act March 3, 1897. Among the defences to a suit for infringement the fourth specified by the statute is that the patentee "was not the original and first inventor or discoverer of any material and substantial part of the thing patented." Rev. Sts. § 4920, amended by Act March 3, 1897, c. 391, § 2, 29 Stat. 692 (Comp. St. § 9466). Taking these words in their natural sense as they would be read by the common man, obviously one is not the first inventor if, as was the case here, somebody else has made a complete and adequate description of the thing claimed before the earliest moment to which the alleged inventor can carry his invention back. But the words cannot be taken quite so simply. In view of the gain to the public that the patent laws mean to secure we assume for purposes of decision that it would have been no bar to Whitford's patent if Clifford had written out his prior description and kept it in his portfolio uncommunicated to anyone. More than that, since the decision in the case of the Cornplanter Patent, 23 Wall. 181, it is said, at all events for many years, the Patent Office has made no search among abandoned patent applications, and by the words of the statute a previous foreign invention does not invalidate a patent granted here if it has not been patented or described in a printed publication. These analogies prevailed in the minds of the courts below.

On the other hand publication in a periodical is a bar. This as it seems to us is more than an arbitrary enactment, and illustrates, as does the rule concerning previous public use, the principle that, subject to the exceptions mentioned, one really must be the first inventor in order to be entitled to a patent. We understand the Circuit Court of Appeals to admit that if Whitford had not applied for his patent until after the issue to Clifford, the disclosure by the latter would have had the same effect as the publication of the same words in a periodical, although not made the basis of a claim. The invention is made public property as much in the one case as in the other. But if this be true, as we think that it is, it seems to us that a sound distinction cannot be taken between that case and a patent applied for before but not granted until after a second patent is sought. The delays of the patent office ought not to cut down the effect of what has been done. The description shows that Whitford was not the first inventor. Clifford had done all that he could do to make his description public. He had taken steps that would make it public as soon as the Patent Office did its work, although, of course, amendments might be required of him before the end could be reached. We see no reason in the words or policy of the law for allowing Whitford to profit by the delay and make himself out to be the first inventor when he was not so in fact, when Clifford had shown knowledge inconsistent with the allowance of Whitford's claim, *Webster Loom Co. v. Higgins*, 105 U.S. 580, and when otherwise the publication of his patent would abandon the thing described to the public unless it already was old, *McClain v. Ortmyer*, 141 U.S. 419, 424.

The question is not whether Clifford showed himself by the description to be the first inventor. By putting it in that form it is comparatively easy to take the next step and say that he is not an inventor in the sense of the statute unless he makes a claim. The question is whether Clifford's disclosure made it impossible for Whitford to claim the invention at a later date. The disclosure would have had the same effect as at present if Clifford had added to his

description a statement that he did not claim the thing described because he abandoned it or because he believed it to be old. It is not necessary to show who did invent the thing in order to show that Whitford did not.

It is said that without a claim the thing described is not reduced to practice. But this seems to us to rest on a false theory helped out by the fiction that by a claim it is reduced to practice. A new application and a claim may be based on the original description within two years, and the original priority established notwithstanding intervening claims. *Chapman v. Wintroath*, 252 U.S. 126, 137. A description that would bar a patent if printed in a periodical or in an issued patent is equally effective in an application so far as reduction to practice goes.

As to the analogies relied upon below, the disregard of abandoned patent applications however explained cannot be taken to establish a principle beyond the rule as actually applied. As an empirical rule it no doubt is convenient if not necessary to the Patent Office, and we are not disposed to disturb it, although we infer that originally the practice of the Office was different. The policy of the statute as to foreign inventions obviously stands on its own footing and cannot be applied to domestic affairs. The fundamental rule we repeat is that the patentee must be the first inventor. The qualifications in aid of a wish to encourage improvements or to avoid laborious investigations do not prevent the rule from applying here.

Comments

1. **§ 102(e)(1): *Published Patent Applications as Prior Art.*** Section 102(e)(1) states that a patent shall issue unless the applicant's invention was described in "an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent." This revision to § 102(e) was part of the American Inventors Protection Act of 1999, which required applications filed on or after November 29, 2000 to be published "18 months after the earliest filing date." (An exception to this rule is when the applicant does not plan on filing outside the United States.) The effective prior art date of a published patent application is its filing date, even though the application was published 18 months thereafter.

2. **§ 102(e)(2): *Milburn Codified and Then Some.*** Section 102(e)(2) states that:

a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The first part of this section is a codification of *Milburn* and limits prior art to *United States* patent applications that *issue* as patents. But the remaining part of the section allows—under certain conditions—for international patent applications (*i.e.*, non-U.S.) to serve as prior art. The conditions are that the applicant must designate the United States as a

country in which it seeks protection and the application eventually be translated into English. If these conditions are met the effective prior art date of the international patent application—filed pursuant to the Patent Cooperation Treaty (PCT)—will be its international filing date. The significance of this language in § 102(e)(2) is that a PCT application can serve as prior art even though the applicant never files in the United States. (Recall, the condition is that the applicant only *designate* the U.S.)

The criticism, most often voiced, about § 102(e) prior art is that the prior art application is held in secret (by law) either until it is published—as in (e)(1)—or until it issues as a patent, as in the first clause of (e)(2). Justice Holmes’s *Milburn* opinion provided an answer to this criticism. He wrote, “delays in the Patent Office ought not to cut down the effect of what has been done.” What has been done? The prior applicant disclosed the invention before the subsequent applicant’s date of invention. But for the delays in the patent office the prior applicant’s application would issue the day it was filed, in which case its prior art effect under § 102(a) would be unquestioned. Is this reasoning persuasive? A billion dollar prior art search would not turn up the prior applicant’s application.

3. ***Patent Disclosure as Prior Art.*** Under section 102(e), a patent application is prior art for what it discloses, not for what it claims. If two or more applications claim the same subject matter then the relevant statutory section is 102(g)(1). The issue now is not one of prior art, but who is entitled to the patent. As Justice Holmes wrote in *Alexander Milburn*, “[i]t is not necessary to show who did invent the thing in order to show that Whitford did not.” 270 U.S. at 401.

4. Novelty-Defeating Inventive Activity Under § 102(g)(2)

The last novelty provision relates to prior-inventive activity. Under § 102(g)(2), a patent will not issue if the claimed invention was already “invented” in the United States. Unlike § 102(e), the prior art in this section is not a patent application, but rather inventive activity. The inventive activity must meet two conditions before it can be used as prior art. First, the activity must occur in the United States, and second, it must be continuously used (not abandoned). The continuity-of-use requirement highlights an important distinction between §§ 102(a) and (g)(2), provisions that otherwise look very similar. Another important difference is that § 102(g)(2) does not have a publicity requirement as does § 102(a). Thus, a trade secret can serve as 102(g)(2) prior art. The Comments following *Thomson* explore the relationship of these two provisions in more detail.

THOMSON, S.A. v. QUIXOTE CORP.

166 F.3d 1172 (Fed. Cir. 1999)

RICH, Circuit Judge.

Thomson, S.A. (“Thomson”) appeals from the June 24, 1997 order of the United States District Court for the District of Delaware in an action for patent

infringement. The court sustained the jury verdict that U.S. Patent Nos. 4,868,808, 5,182,743, 4,961,183, and 5,175,725 are invalid for lack of novelty under 35 U.S.C. § 102(g). We affirm.

BACKGROUND

Plaintiff-Appellant Thomson is the assignee of the patents in suit, which are directed to optical information-storage devices, such as compact discs (“CDs”). Thomson makes and markets machines that “read” or “play” CDs, and grants licenses under the patents in suit to companies which produce CDs. Defendants-Appellees, Quixote Corp. and Disc Manufacturing, Inc. (collectively, “Quixote”) make CDs.

Thomson sued Quixote for patent infringement. The parties agreed to base the outcome of the trial on three representative claims: claims 1 and 13 of U.S. Patent No. 4,868,808, and claim 1 of U.S. Patent No. 5,182,743.

At trial, the parties stipulated that Thomson’s invention date for the patents in suit is August 25, 1972. Quixote’s defense included evidence purporting to show that the representative claims are anticipated by an unpatented laser videodisc developed before August 1972 by a non-party, MCA Discovision, Inc. (“MCA”). After trial, the jury found in special verdicts that all of the representative claims were literally infringed, but that those claims are invalid due to lack of novelty (*i.e.*, anticipated) under 35 U.S.C. § 102(g).

Thomson submitted a motion requesting that the district court either set aside the jury’s verdict of invalidity and enter Judgment as a Matter of Law (“JMOL”) holding the patents not invalid, or grant a new trial on the lack of novelty issue.

In its opinion denying Thomson’s motion, the district court described evidence in the record supporting the jury’s finding of anticipation for each of the limitations that Thomson asserted had not been proven to be present in the MCA videodisc. The court noted that the evidence supporting the anticipation finding came from one or more sources: the live testimony of two people who had worked on the MCA laser videodisc project; an expert’s report and portions of his deposition testimony, both of which were read into the record; the expert’s exhibits; and certain MCA documents that the expert had reviewed. The court concluded that substantial evidence supports the jury’s finding that Quixote had shown, by clear and convincing evidence, that every limitation in the representative claims was anticipated by the MCA device.

Thomson appeals the district court’s denial of its motion for JMOL.

ANALYSIS

* * *

Thomson’s core argument in support of reversing the district court’s denial of its motion for JMOL is based on its assertions that (1) the jury verdict rests upon mere testimonial evidence by the two non-party MCA employees who worked on the videodisc project, and (2) this evidence is insufficient as a matter of law to support a holding of invalidity under subsection 102(g), because such testimonial evidence by inventors of their prior invention requires corroboration. Even if we accept Thomson’s first assertion, and fur-

ther assume that the MCA employees were acting as inventors in the laser videodisc project, Thomson's argument fails because this case does not present circumstances in which there is a need for corroboration, as herein-after explained.

We begin with the language of 35 U.S.C. § 102(g):

A person shall be entitled to a patent unless. . . .

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to practice, from a time prior to conception by the other.

We have interpreted the first sentence of subsection 102(g) to permit qualifying art to invalidate a patent claim even if the same art may not qualify as prior art under other subsections of § 102.³ Art is not qualified under subsection 102(g) unless, viewed under a rule of reason, the totality of the evidence that the art satisfies the requirements of subsection 102(g) is clear and convincing. We have also often held, in both interference and infringement lawsuits, that an inventor's testimony alone respecting the facts surrounding a claim of derivation or priority of invention cannot satisfy the clear and convincing standard without corroboration. Although courts have reviewed infringement suits in which the defendant had attempted to prove subsection 102(g)-type anticipation by a non-party inventor at trial, neither the Supreme Court nor we have directly held whether the corroboration rule must be applied to testimony by non-party inventors that is directed to establishing their invention as anticipating the claims at issue.

The cases that discuss skepticism of uncorroborated inventor testimony directed to establishing priority over an opponent's patent claim involve situations where the inventor is self-interested in the outcome of the trial and is thereby tempted to "remember" facts favorable to his or her case. *See, e.g., Barbed-Wire*, 143 U.S. at 284-85 (indicating that testifying non-party inventors' patents would increase in value if patent claims at issue were invalidated); *Price v. Symsek*, 988 F.2d at 1194 (showing that testifying inventor's interfering patent claims would be invalidated if he could not establish priority; and holding that board extended corroboration rule beyond reasonable bounds).

3. The interpretation of subsection 102(g) to provide a prior art basis for invalidating a patent claim in infringement litigation was not intended by the drafters of the 1952 Patent Act. As the second sentence in the subsection indicates, 102(g) was written merely to provide a statutory basis for determining priority of invention in the context of interference proceedings before what was then the United States Patent Office. *See* P.J. Federico, *Commentary on the New Patent Act* at 19, in 35 U.S.C.A. (1954 ed., discontinued in subsequent volumes) (reprinted in 75 J. Pat. Trademark Off. Soc'y 161, 180 (1993)). Nevertheless, the first sentence is clear and, as the cases show, has been taken to have independent significance as a basis for prior art outside of the interference context.

This result makes sense. The first to invent who has invested time and labor in making and using the invention—but who might have opted not to apply for a patent—will not be liable for infringing another's patent on that same invention, while the public will have benefited because the invention was not abandoned, suppressed or concealed.

The clear and convincing standard of proof required to establish priority, along with the numerous methods in the Federal Rules of Civil Procedure and Evidence by which a party may test, challenge, impeach, and rebut oral testimony, normally protects patentees from erroneous findings of invalidity. Thus, the corroboration rule is needed only to counterbalance the self-interest of a testifying inventor against the patentee. We therefore hold that corroboration is required only when the testifying inventor is asserting a claim of derivation or priority of his or her invention and is a named party, an employee of or assignor to a named party, or otherwise is in a position where he or she stands to directly and substantially gain by his or her invention being found to have priority over the patent claims at issue.

In the current case, the purported inventors who testified were non-parties and their testimony concerned an unpatented prior invention. Although Thomson argues that the corroboration rule is justified here because both testifying witnesses were involved in businesses that supplied goods and services to Quixote, this does not rise to the level of self-interest required to justify triggering application of the corroboration rule. In fact, Thomson's only reference to the record showing this potential source of bias is a transcript of Thomson's cross examination of one of the witnesses, which means that the jury had the necessary facts to assess the credibility of the witnesses.

We therefore conclude that the district court was correct in holding that substantial evidence supports the jury's finding that Quixote showed, by clear and convincing evidence, that every limitation in the representative claims was anticipated, and that the district court was correct in denying Thomson's motion for JMOL.

* * *

Comments

1. **Original Intent of § 102(g).** Using § 102(g) as a prior art provision was a dubious proposition prior to *Thomson*. This is reflected in a speech given by then attorney Giles Rich, in which he said that “[t]he purpose of paragraph (g) is to codify the law on determining priority” and “preserve[] in the statutes a basis for interferences.” Giles S. Rich, Speech to the New York Patent Law Association (Nov. 6, 1951). See also P.J. Federico, *Commentary on the New Patent Act* at 19, 35 U.S.C. §§ 1 et seq. (1954 ed., discontinued in subsequent volumes) (reprinted in 75 J. PAT. TRADEMARK OFF. SOC’Y 161, 180 (1993)) (stating section (g) “relates to prior inventorship”). Federico’s commentary is one of the most cited secondary sources by the Federal Circuit.

With § 102(g)’s origins in mind, the court in *Thomson* stated in footnote 3, “[n]evertheless, the first sentence [of § 102(g)] is clear and . . . has been taken to have independent significance as a basis for prior art outside of the interference context.” This statement is significant because of its author—Judge Giles Rich, who had a deep understanding of patent law and the history of the 1952 Patent Act. Since *Thomson*, § 102(g) has been

split into two subsections, one for interferences (§ 102(g)(1)) and one for prior art (§ 102(g)(2)).

2. ***Distinguishing Between § 102(g)(1) and (2).*** When an application is made for a patent claiming the same subject matter as another application or an issued patent, § 102(g)(1) governs, and an interference may be declared by the Patent & Trademark Office. An interference is a procedural mechanism to determine who is the first inventor (*i.e.*, who has priority of invention). Priority is discussed in section C, *infra*. Section 102(g)(2) provides a novelty-based statutory foundation for so-called “secret” prior art. Under this section, a patent will not issue if the claimed invention “was made in this country by another inventor who had not abandoned, suppressed, or concealed it” before the patent applicant’s date of invention. Unlike § 102(g)(1), § 102(g)(2) contemplates a scenario whereby the first inventor has opted *not* to pursue a patent, but is making or using the claimed invention. See *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 384 (1928) (noting that first inventor who decides not to pursue a patent may still use his inventive activity as prior art).
3. ***The Relationship Between § 102(a) and § 102(g).*** What is the relationship between § 102(a) and (g)? It appears that (g) eviscerates (a) because the former incorporates public and “secret” knowledge and use. But there are important distinctions. For instance, while § 102(a) has a publicity requirement, it does not require continued use like § 102(g); that is, under § 102(g), the invention must not be abandoned, suppressed or concealed. Recall in *Rosaire* that Teplitz’s use served as prior art under § 102(a) because, while the work was ultimately suspended, it nonetheless was “successful” and “done openly and in the ordinary course of the activities of the employer.” And in *Gayler*, remember the court wrote:

We do not understand the Circuit Court to have said that the omission of Conner to try the value of his safe by proper tests would deprive it of its priority; nor his omission to bring it into public use. He might have omitted both, and also abandoned its use, and been ignorant of the extent of its value; yet, if it was the same with Fitzgerald’s, the latter would not upon such grounds be entitled to a patent, provided Conner’s safe and its mode of construction were still in the memory of Conner before they were recalled by Fitzgerald’s patent.

In other words, as long as Connor had knowledge of the invention, novelty may be defeated even if he abandoned or never used the invention. MCA’s inventive activity in *Thomson* qualified for § 102(g) prior art, but could not satisfy § 102(a)’s requirements. As the *Thomson* court wrote, “[w]e have interpreted . . . 102(g) to permit qualifying art to invalidate a patent claim even if the same art may not qualify as prior art under other subsections of § 102.” See *International Glass Co. v. United States*, 408 F.2d 395, 402 (Ct. Cl. 1969) (discussing differences between § 102(a) and § 102(g)).

4. ***Why Isn’t § 102(g) Activity Considered Concealment?*** Prior art under § 102(g)(2) is thought of as “secret” because it is very difficult to uncover, particularly process-related inventions. But at what point does the secrecy of the prior use become so great as to constitute concealment under § 102(g)? Does it matter if the first inventor commercially exploits the secret invention

(*e.g.*, a secret process from which products are sold). The circumstances and rationale have yet to be fully developed by the courts and have been treated somewhat inconsistently. But there are certain distinctions that can be discerned from the case law. For instance, in *Gillman v. Stern*, 114 F.2d 28 (2nd Cir. 1940), Judge Learned Hand wrote of non-informing public uses and secret uses, and somewhat reluctantly embraced the notion that non-informing public uses, unlike secret uses, can serve as prior art. *Id.* Judge Hand was apparently dissatisfied with this distinction, but felt constrained by the statute. He wrote of non-informing public use and secret use:

It is true that in each case the fund of common knowledge is not enriched, and that might indeed have been good reason originally for throwing out each as anticipations. But when the statute made any 'public use' fatal to a patent, and when thereafter the court held that it was equally fatal, whether or not the patentee had consented to it, there was no escape from holding — contrary to the underlying theory of the law — that it was irrelevant whether the use informed the public so that they could profit by it.

Id. at 31. Judge Hand held that the prior use in *Gillman* was not anticipatory prior art because the prior user, Haas was a third party (not the inventor), who, “kept his machine absolutely secret from the outside world.”

The non-informing public use/secret use distinction was applied by the Seventh Circuit in *Dunlop Holdings, Ltd. v. Ram Golf Corp.*, 524 F.2d 33 (7th Cir. 1975). Dunlop held a patent on a highly durable golf ball as a result of the covering, which was made of a synthetic material called “Surlyn” that possessed improved cut-resistant properties. Prior to Dunlop’s invention date, Butch Wagner began experimenting with Surlyn-covered golf balls, which led to his developing a formula that adjusted the weight and texture of the golf ball cover. Although Wagner was careful to keep his formula secret, he sold thousands of golf balls covered with Surlyn. The accused infringer, Ram, asserted that Dunlop’s patent was invalid in the light of Wagner’s prior inventive activity. The court, in an opinion by then Judge Stevens, held that Wagner’s inventive activity was a non-informing public use, and therefore, invalidating prior art. Judge Stevens distinguished *Gillman* by noting that “Haas had used the machine in his own factory under tight security” and although “the output from the machine had been sold, the public had not been given access to the machine itself.” *Id.* at 36. (The court also distinguished *Palmer v. Dubzik*, 481 F.2d 1377 (CCPA 1973), on the basis that *Palmer*, like *Gillman*, involved a machine and “the benefits of using the machine were not made available to anyone except the inventor.” *Dunlop*, 524 F.2d at 37.) In contrast, “the evidence clearly demonstrates that Wagner endeavored to market his golf balls as promptly and effectively as possible. . . . Therefore, at best, the evidence establishes a non-informing public use of the subject matter of the invention.” *Dunlop*, 524 F.2d at 36. The court concluded by offering an explanation as to why Wagner’s non-informing public use forecloses a finding of concealment. The court explained that even though Wagner’s use does not disclose his discovery to the public, he nonetheless gave “the public the benefit of the invention” by introducing the discovery into the marketplace, a fact that militates against a finding of suppression “in an economic sense.” *Id.* at 37.

Building upon the marketplace rationale, the court stated that despite a lack of express disclosure “when the article itself is freely accessible to the public at large, it is fair to presume that its secret will be uncovered by potential competitors long before the time when a patent would have expired if the inventor had made a timely application and disclosure to the Patent Office.” *Id.* In a footnote to this point, the court stressed that it is likely that competitor would soon reverse engineer the golf ball covering revealing its “secret ingredient.”

Thus, the fact that the prior use is practiced as a trade secret does not necessarily lead to a finding of suppression or concealment under § 102(g)(2). See *Friction Division Products Inc. v. E.I. du Pont de Nemours & Co.*, 658 F. Supp. 998, 1013-14 (D. Del.1987) (relying heavily on *Dunlop Holdings* and finding trade secret processes prior art and stating “[p]ublic use of the invention, without disclosing the details of it, is sufficient to negate any intention to abandon, suppress or conceal”); *Pall Corp. v. Micron Separations, Inc.* 792 F.2d 1298, 1306 (D. Mass. 1992) (“The law does not require any disclosure of the actual invention to the public nor any commercial use for an invention to qualify as prior art.”). The focus has been on whether the prior user engaged in a non-informing public use or a secret use. In *Dunlop*, then Judge Stevens provided a rationale for the distinction between non-informing public uses and secret uses. First, by emphasizing the importance of introducing the product into the market, the court invoked patent law’s Constitutional purpose of promoting the progress of the useful arts. Of course, an express disclosure would be more consistent with Article I, Section 8, Clause 8. And second, Judge Stevens stressed that by introducing the product Wagner provided an impetus for competition and improvement activity. Is this second rationale consistent with patent law’s incentive structure? Does it inadequately recognize the contribution of Dunlop, the second inventor in the tradition of Daniel Fitzgerald in *Gayler v. Wilder* — someone who made an express disclosure to society?

5. **Prior User Rights.** In footnote 3 of *Thomson*, the court acknowledged the historical ambiguity surrounding § 102(g)’s prior art status, and concluded that allowing § 102(g) prior art “makes sense” because “[t]he first to invent who has invested time and labor in making and using the invention—but who might have opted not to apply for a patent—will not be liable for infringing another’s patent on that same invention, while the public will have benefited because the invention was not abandoned, suppressed or concealed.” This footnote portrayed a zero-sum game. If the court decided not to use § 102(g) for prior art purposes, the first inventor becomes an infringer and the patent’s validity is maintained. But, as the court held, employing § 102(g) allowed the first inventor to escape infringement, but the patent was rendered invalid. Each result is arguably unsatisfactory. In the first scenario, the first inventor is benefiting society by practicing the invention and should not be punished for failing to obtain a patent. In fact, then Judge Stevens in *Dunlop Holdings* took note of this unfairness, which was a factor in the court’s finding that Wagner, the prior user, did not suppress or conceal the invention. According to the court, “the inventor is under no duty to apply for a patent; he is free to contribute his idea to the public, either voluntarily by an express disclosure, or involuntarily by a noninforming public use. In either case, although he may forfeit his

entitlement to monopoly protection, it would be unjust to hold that such an election should impair his right to continue diligent efforts to market the product of his own invention.” *Dunlop Holdings*, 524 F.2d 37. *See also Checkpoint Systems, Inc. v. United States International Trade Commission*, 54 F.2d at 762 (no duty to apply for patent). In the second scenario, the patentee is also benefiting society by disclosing the invention to the public and should not be punished based on secret prior art.

To address this winner take all situation, some have proposed the United States should adopt prior-user rights—a doctrine embraced by the European patent system as well as others. The idea behind this right is that the prior user will be permitted to continue using his invention, but his activity cannot be used as prior art against a later inventor who decided to obtain patent rights. Both parties win in this scenario. The patentee is forced into a competitive situation because he was not the first to invent, but his patent remains valid against the prior use. The prior user is not an infringer, but is typically “locked in” to its current commercial use, meaning that he cannot greatly expand commercial operations, not sell his prior user right unless the prior user sells his entire company. The patent law of the United Kingdom provides a European example. There, a prior use defense is available only if the prior activity is done in the U.K. and in good faith. Moreover, the “defense is available where the defendant had done the acts or made ‘serious and effective preparations’ before the priority date of the patent to do an act which would be infringing if it was carried out after the grant of the patent.” LIONEL BENTLY & BRAD SHERMAN, *INTELLECTUAL PROPERTY* 508-09 (2001). While licensees are prevented from invoking a prior user defense, the right may be assigned to one who acquires “that part of the business in the course of which the act was done or the preparations were made.” *Id.*

Prior user rights are also seen as an important component of a first-to-file patent system, one that awards patent rights to the party who was the first to file a patent application even though he may not be the first to invent. Giving the first inventor a prior user right is a way to ameliorate any perceived inequities. *See* Mark A. Lemley & Colleen V. Chien, *Are the U.S. Patent Priority Rules Really Necessary?* 54 *HASTINGS L.J.* 1299 (2003) (finding that in over 40% of interferences and court cases, the party who was last to file was the first to invent). Consider some of the potential disadvantages to a prior user defense. Would the prior user be less inclined to seek patent protection (thus disclosing the invention), knowing it can seek refuge as a prior user? Relatedly, would the second inventor also be disinclined to file for patent protection because the prior user would be beyond his legal grasp? In other words, is the prior user defense simply compulsory licensing by another name? Would a prior user defense disproportionately favor larger entities at the expense of smaller concerns and individuals?

In 1999, the American Inventors Protection Act (AIPA) produced the “First Inventor Defense Act of 1999,” which is a watered-down version of prior user rights. Under § 273,

It shall be a defense to an action for infringement under section 271 of this title with respect to any subject matter that would otherwise infringe one or more claims for a *method* in the patent being asserted against a person, if such person

had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent.

35 U.S.C. § 273(b)(1) (emphasis added). Note that the defense is limited to method patents, but § 273(a)(3) limits the defense even more by defining “method” as “a method of doing or conducting business.” The reason for limiting the defense to business method patents relates to the controversy surrounding the *State Street Bank* decision that expressly allowed for the patenting of business methods.

For purposes of § 102(g) prior art, § 273(b)(6) allows that the first inventor defense “may be asserted only by the person who performed the acts necessary to establish the defense” and this defense “cannot be licensed or assigned or transferred to another person.” Moreover, § 273(b)(9) states a “patent shall not be deemed to be invalid under section 102 or 103 of this title solely because a defense is raised or established under this section.” Thus, a first inventor defense does not lead to the invalidation of the patent-in-suit.

5. Foreign-Based Activity as Prior Art Under §§ 102(e) and (g)

Patent law is a global affair. Multinational companies typically seek patent protection in several countries, and have R&D facilities throughout the world. When filing outside the United States, various international treaties come into play. Under the Paris Convention of 1883, for instance, a party who files for patent protection in a Paris Convention member country, say Spain, can receive the benefit of the Spanish filing date when he subsequently files—within 12 months—in another member country.* For example, Eaton Corp. files a patent application in Spain claiming ABC on May 2, 2007. If Eaton files other applications (claiming the same subject matter) in other member states within 12 months, each application will be accorded the Spanish filing date, as if they were all filed on May 2, 2007. *See* 35 U.S.C. § 119. Thus, the Paris Convention provides a significant procedural advantage for applicants with a global patent strategy.

This common scenario is uncontroversial, but only applies when one is *obtaining* patent rights. What is the prior art effect of Eaton’s filing in Spain? That is, under § 102(e), can Eaton’s patent *application* in Spain, as described above, serve as a prior art as of May 2, 2007 against a U.S. patent application filed thereafter? Is *Milburn* applicable? What about inventive activity abroad? Does the reasoning in *Thomson* apply? This section and the *Hilmer* cases address these questions.

* The full title of the treaty is the “Paris Convention for the Protection of Industrial Property,” signed in Paris on March 20, 1883. The treaty entered into force in 1884 with 14 member states. As of 2007, there were 171 member states.

IN RE HILMER (HILMER I)**359 F.2d 859 (CCPA 1966)**

RICH, Judge.

The sole issue is whether a majority of the Patent Office Board of Appeals erred in overturning a consistent administrative practice and interpretation of the law of nearly forty years standing by giving a United States patent effect as prior art as of a foreign filing date to which the *patentee* of the reference was entitled under 35 U.S.C. § 119.

Because it held that a U.S. patent, cited as a prior art reference under 35 U.S.C. § 102(e) and § 103, is effective as of its foreign “convention” filing date, relying on 35 U.S.C. § 119, the board affirmed the rejection of claims 10, 16, and 17 of application serial No. 750,887, filed July 25, 1958, for certain sulfonyl ureas.

This opinion develops the issue, considers the precedents, and explains why, on the basis of legislative history, we hold that section 119 does not modify the express provision of section 102(e) that a reference patent is effective as of the date the application for it was “filed in the United States.”

The two “references” relied on are: Habicht 2,962,530 Nov. 29, 1960 (filed in the United States January 23, 1958, found to be entitled to priority as of the date of filing in Switzerland on January 24, 1957) and Wagner et al. 2,975,212 March 14, 1961 (filed in the United States May 1, 1957).

The rejection here is the aftermath of an interference (No. 90,218) between appellants and Habicht, a *priority* dispute in which Habicht was the winning party on a single count. He won because appellants conceded priority of the invention *of the count* to him. The earliest date asserted by appellants for their invention is their German filing date, July 31, 1957, which, we note, is a few months later than Habicht’s priority date of January 24, 1957.

After termination of the interference and the return of this application to the examiner for further *ex parte* prosecution,* the examiner rejected the appealed claims on Habicht, as a primary reference, in view of Wagner *et al.*, as a secondary reference, holding the claimed compounds to be “unpatentable over the primary reference in view of the secondary reference which renders them obvious to one of ordinary skill in the art.”

Appellants appealed to the board contending that “The Habicht disclosure cannot be utilized as anticipatory art.” They said, “The rejection has utilized . . . the disclosure of the winning party as a basis for the rejection. The appellants insist that this is contrary to the patent statutes.” Explaining this they said:

. . . the appellants’ German application was filed subsequent to the Swiss filing date (of Habicht) *but prior to the U.S. filing date of the Habicht application*. The appellants now maintain that the Habicht disclosure *cannot* be utilized as anticipatory in view of 35 U.S.C. 119 which is entitled “Benefit of Earlier Filing Date in Foreign Countries: Right of Priority.” This section defines the rights of foreign applicants and more specifically defines those rights with respect to dates to which they are entitled if this same privilege is awarded to citizens of the

* [After losing the interference, Hilmer returned to the PTO claiming a *variation* of the invention that was subject to the interference proceeding with Habicht — Ed.]

United States. There is no question (but) that Section 119 only deals with “right of priority.” The section does not provide for the use of a U.S. patent as an anticipatory reference as of its foreign filing date. . . .

* * *

The second restriction in the board’s fourth statement of the issue is that “the reference patent is found to be entitled to the date of a prior foreign application under 35 USC 119. . . .” To some degree this loads the question. There is in it an implicit assumption that if the patent is “entitled to the date of a prior foreign application,” it is entitled to it, and that is that. But one must examine closely into what is meant by the word “entitled.” In essence, that is the problem in this appeal and we wish to point to it at the outset to dispel any mistaken assumptions. A patent may be “entitled” to a foreign filing date for some purposes and not for others, just as a patent may be “used” in two ways. A patent owner uses his patent as a legal right to exclude others, granted to him under 35 U.S.C. § 154. Others, wholly unrelated to the patentee, use a patent, not as a legal right, but simply as evidence of prior invention or prior art, *i.e.*, as a “reference.” This is not an exercise of the patent right. This is how the Patent Office is “using” the Habicht patent. These are totally different things, governed by different law, founded on different theories, and developed through different histories.

* * *

We can now summarize the issue and simultaneously state the board’s decision. Continuing the above quotation, the board said:

The Examiner insists, however, that the effective date of the Habicht patent is January 24, 1957, the date of an application filed in Switzerland which is claimed by Habicht under 35 USC 119. Appellants have not overcome this earlier date of Habicht. The issue is hence presented of whether the foreign priority date of a United States patent can be used as the effective filing date of the patent *when it is used as a reference*. (and this is the second statement of the issue by the board.) Our conclusion is that the priority date governs.

This is the decision alleged to be in error. We think it was error.

* * *

Turning from the general to the specific, we will now consider our specific reasons for construing the applicable statutes as they have for so long been construed, contrary to the recent innovation of the Patent Office.

OPINION

* * *

The board’s construction is based on the idea that the language of the statute is plain, that it means what it says, and that what it says is that the application filed abroad is to have the same *effect* as though it were filed here—for *all purposes*. We can reverse the statement to say that the actual U.S. application is to have the same effect as though it were filed in the U.S. on the day when the foreign application was filed, the whole thing being a question of effective date. We take it either way because it makes no difference here.

Before getting into history, we note first that there is in the very words of the statute a refutation of this literalism. It says “shall have the same effect”

and it then says “but” for several situations it shall not have the same effect, namely, it does not enjoy the foreign date with respect to any of the patent-defeating provisions based on publication or patenting anywhere in the world or public use or being on sale in this country *more than one year before the date of actual filing in this country*.

As to the other statute involved, we point out that the words of section 102(e), which the board “simply” reads together with section 119, also seem plain. Perhaps they mean precisely what they say in specifying, as an express patent-defeating provision, an application by another describing the invention but only as of the date it is “filed *in the United States*.”

The great logical flaw we see in the board’s reasoning is in its premise (or is it an *a priori* conclusion?) that “these two provisions must be read together.” Doing so, it says 119 in effect destroys the plain meaning of 102(e) but the board will not indulge the reverse construction in which the plain words of 102(e) limit the apparent meaning of 119. We see no reason for reading these two provisions together and the board has stated none. We believe, with the dissenting board member, that 119 and 102(e) deal with unrelated concepts and further that the historical origins of the two sections show neither was intended to affect the other, wherefore they should not be read together in violation of the most basic rule of statutory construction, the “master rule,” of carrying out the legislative intent. Additionally, we have a long and consistent administrative practice in applying an interpretation contrary to the new view of the board, confirmed by legislation ratification in 1952. . . .

Section 119

* * *

This priority right was a protection to one who was trying to *obtain* patents in foreign countries, the protection being against patent-defeating provisions of national laws based on events intervening between the time of filing at home and filing abroad. . . .

* * *

We need not guess what Congress has since believed to be the meaning of the disputed words in section 119, for it has spoken clearly. Section 1 of the bill, the report says, was to extend “the so-called period of priority,” which then existed under R.S. 4887. On p. 3 the report says:

In this connection, it may be observed that the portion of the statute which provides that the filing of a foreign application — shall have the same force and effect as the same application would have if filed in this country on the date on which the application for patent for the same invention, discovery, or design was first filed in such foreign country — is intended to mean “shall have the same force and effect,” etc., insofar as applicant’s right to a patent is concerned. This statutory provision has no bearing upon the right of another party to a patent except in the case of an interference where the two parties are claiming the same patentable invention. U.S. Code Congressional Service 1946, p. 1493.

We emphasize none of those words because we wish to emphasize them all. We cannot readily imagine a clearer, more definitive statement as to the

legislature's own view of the words "same effect," which now appear in section 119. This statement flatly contradicts the board's views. The board does not mention it.

* * *

For the foregoing reasons, we are clearly of the opinion that section 119 is not to be read as anything more than it was originally intended to be by its drafters, the Commission appointed under the 1898 Act of Congress, namely, a revision of our statutes to provide for a right of priority in conformity with the International Convention, for the benefit of United States citizens, by creating the necessary reciprocity with foreign members of the then Paris Union.

* * *

Section 102(e)

We have quoted this section above and pointed out that it is a patent-defeating section, by contrast with section 119 which gives affirmative "priority" rights *to applicants* notwithstanding it is drafted in terms of "An application." The priority right is to save the applicant (or his application if one prefers to say it that way) *from patent-defeating provisions* such as 102(e); and of course it has the same effect in guarding the validity of the patent when issued.

Section 102(e), on the other hand, is one of the provisions which defeats applicants and invalidates patents and is closely related in fact and in history to the requirement of section 102(a) which prohibits a patent if

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, *before the invention* thereof by the applicant for patent, . . .

* * *

We will not undertake to trace the ancestry of 102(e) back of its immediate parentage but clearly it had ancestors or it would never have come to the Supreme Court. We will regard its actual birth as the case of *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (March 8, 1926), which we shall call *Milburn*. It is often called the *Davis-Bournonville* case. It was an infringement suit on a patent to Whitford and the defense, under R.S. 4920, was that he was not the first inventor. . . .

We need not go into the reasoning of the *Milburn* case, which has its weaknesses, because all that matters is the rule of law it established: That a complete description of an invention in a U.S. patent application, filed before the date of invention of another, if it matures into a patent, may be used to show that that other was not the first inventor. This was a patent-defeating, judge-made rule and now is section 102(e). The rule has been expanded somewhat subsequent to 1926 so that the reference patent may be used as of its U.S. filing date as a general prior art reference. . . .

What has always been pointed out in attacks on the *Milburn* rule, or in attempts to limit it, is that it uses, as prior knowledge, information which was secret at the time *as of which* it is used—the contents of U.S. patent applications which are preserved in secrecy, generally speaking, 35 U.S.C. 122. This

is true, and we think there is some validity to the argument that that which is secret should be in a different category from knowledge which is public. Nevertheless we have the rule. However, we are not disposed to extend that rule, which applies to the date of filing applications *in the United States*, the actual filing date when the disclosure is on deposit in the U.S. Patent Office and on its way, in due course, to publication in an issued patent.

The board's new view, as expressed in this case . . . has the practical potential effect of pushing back the date of the unpublished, secret disclosures, which ultimately have effect as prior art references in the form of U.S. patents, by the full one-year priority period of section 119. We think the *Milburn* rule, as codified in section 102(e), goes far enough in that direction. We see no valid reason to go further, certainly no compelling reason.

* * *

Section 104

This brings us to another related section of the statute. We noted above that section 102(a) refers to knowledge of an invention *in this country* as a patent-defeating provision. This had been interpreted, long before the 1952 codification, to mean public knowledge. . . .

* * *

The "elsewhere" is section 104 which has also superseded section 9 of the 1946 Boykin act, above discussed. Before quoting it, we will mention another patent-defeating provision, 102(g) which says a patent may not be obtained on an invention if "before the applicant's invention thereof the invention was made *in this country* by another who had not abandoned, suppressed, or concealed it." The first sentence of section 104 reads:

§ 104, Inventions made abroad.

Inventions made abroad and in the courts, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country, except as provided in section 119 of this title.

The second sentence is an exception not relevant here.

It seems clear to us that the prohibitions of 104, the limitations in sections 102(a) and 102(g) to "in this country," and the specifying in 102(e) of an application filed "in the United States" clearly demonstrates a policy in our patent statutes to the effect that knowledge and acts in a foreign country are not to defeat the rights of applicants for patents, except as applicants may become involved in *priority* disputes. We think it follows that section 119 must be interpreted as giving only a positive right or benefit to an applicant who has first filed abroad to *protect him* against possible intervening patent-defeating events in *obtaining* a patent. Heretofore it has always been so interpreted with the minor exceptions, of little value as precedents, herein-after discussed. So construed, it has no effect on the effective date of a U.S. patent as a reference under section 102(e).

* * *

The simple observable fact, therefore, is that the effect of section 102(e) is to make a U.S. patent *available* as a reference, as of its U.S. filing date, and that thereafter the rejection of an application, or the holding of invalidity in the case of a patent, is *predicated on* some other section of the statute containing a patent-defeating provision to which the reference applies. Much confused thinking could be avoided by realizing that rejections are based on statutory provisions, not on references, and that the references merely supply the evidence of lack of novelty, obviousness, loss of right or whatever may be the ground of rejection of the board's decision.

Section 120

At oral argument the Patent Office Solicitor argued by “analogy” from 35 U.S.C. § 120 (a section which he said gives one U.S. application the benefit of an earlier U.S. application under specified circumstances *for all purposes*) that section 119 should similarly give to a patent, used as a reference under section 102(e), effect as of an earlier *foreign* filing date.

* * *

We find no substance in this argument because: (1) as above pointed out, our statute law makes a clear distinction between acts abroad and acts here except for patents and printed publications. Section 120, following policy in sections 102(a), (e) and (g) and 104, contains the limitation to applications “filed in the United States,” excluding foreign applications from its scope. (2) Use of the same expression is mere happenstance and no reason to transfer the meaning and effect of section 120 as to U.S. filing dates to section 119 with respect to foreign filing dates. Section 120 was not drafted until 49 years after the predecessor of section 119 was in the statute.

* * *

The decision of the board is reversed and the case is remanded for further proceedings consistent herewith.

IN RE HILMER (HILMER II)

424 F.2d 1108 (CCPA 1970)

RICH, Acting Chief Judge.

This is a sequel to our opinion in *In re Hilmer* (herein “*Hilmer I*”), familiarity with which is assumed.

* * *

In *Hilmer I*, the question we decided was whether the Habicht patent was effective as a prior art reference under 35 U.S.C. § 102(e) as of the Swiss filing date. We held that it was not and that it was “prior art” under 102(e) only as of the U.S. filing date, which date Hilmer could overcome by being entitled to rely on the filing date of his German application to show his date of invention. This disposed of a rejection predicated on the disclosure of the Habicht patent, as a primary reference, coupled with a secondary prior art patent to Wagner *et al.*, No. 2,975,212, issued March 14, 1961, filed May 1, 1957 (herein “Wagner”).

* * *

The board's conclusion was that the subject matter of claim 1, the compound claimed, is prior art against Hilmer. As to the basis on which it can be considered to be, or treated as, prior art, the board divided. Two members stated that the statutory basis is 35 U.S.C. § 102(g) combined with § 119 and read in the light of § 104.

Note must be taken of the fact that the rejection here is under 103 for obviousness wherefore it is clear that the subject matter of the appealed claims is different from the subject matter of Habicht's claim 1, allegedly, however, only in an obvious way by reason of the further disclosures of Wagner. Were the appealed claims to the *same* subject matter, it seems clear that Hilmer, because he conceded *priority* to Habicht, would not be entitled to them and Hilmer appears to have admitted as much throughout this appeal. But, it is contended, the situation is different when the claims on appeal are to different subject matter. We confess to some difficulty in determining just what appellants' view is but it seems to come down to this:

Appellants are entitled to the benefit of their German filing date and this antedates Habicht's U.S. filing date, which is the earliest date as of which Habicht's claim 1 invention can be "prior art." The words appellants use, referring to Habicht's U.S. filing date, are, "the only possible date that can be considered for anticipation purposes." Appellants appear to use the term "anticipation" in the broad sense to mean "prior."

We turn now to the reasoning by which the board majority arrived at the conclusion that the compound of Habicht claim 1 is in the prior art—*i.e.*, ahead of Hilmer's German filing date—and usable with the Wagner patent to support a section 103 obviousness rejection. We note at the outset that the board majority in no way relied on what occurred in the interference, on the concession of priority, or on any estoppel growing out of the interference.

Before examining the board majority's statutory theory, we will recall the fact that in *Hilmer I* we dealt with another statutory theory that by combining § 102(e) and § 119 a U.S. patent had an effective date as a prior art reference for all it discloses as of its foreign convention filing date. We reversed that holding and remanded. We now are presented with another theory that by combining § 102(g) with § 119 at least the claimed subject matter of a U.S. patent is prior art as of the convention filing date. The crux of the matter lies in § 102(g), which we must have before us.

* * *

The board majority's rationalization begins thus:

Section 102(g) of the statute refers to the prior invention of another as a basis for refusing a patent. Inasmuch as the subject matter of the claim of the Habicht patent is patented to another, it must be recognized as an invention of another, and being the invention of another, some date of invention must be ascribed to it. When nothing else is available, the date of filing the application [in the United States] is by law taken as the date of invention since the invention obviously must have been made on or before the day the application for a patent for it was filed.

But this much, assuming its correctness, would not sustain the rejection because appellants are entitled to a date of invention which is earlier than the

day the Habicht application was filed in the United States, the date obviously referred to in the above quotation. To sustain the rejection it was necessary for the board to accord an earlier date to Habicht's invention, the only such date available being the date Habicht filed his application in *Switzerland*. This, however, is not in compliance with the provision of 102(g) that the invention be "made" (or at the very least *be*) "in this country." The board majority attempted to vault this hurdle as follows:

While Section 102(g) refers to the prior invention as made "in this country," this limitation is removed as to application filing date by Section 119 of the statute which provides that an application for a patent for an invention shall have the same effect as though filed in this country on the date a prior application was filed in a foreign country, under the conditions prescribed. That this is the effect of Section 119 is also evident from Section 104. . . . The Habicht invention is . . . entitled to the filing date of the application in Switzerland as its date of invention in this country. Hence, we conclude on the basis of Section 102(g) and Section 119 that the claimed subject matter of the Habicht patent is available for use against the present application (as patent-defeating prior art) as of the date of the application filed in Switzerland.

We disagree with this line of reasoning.

In *Hilmer I* we explained at length why we could not accept similar reasoning about § 119 which was there alleged to remove or qualify the limitation in § 102(e) to the date when an application was filed "in the United States." For the same reasons we hold, contrary to the *ipse dixit* of the board, that § 119 does not remove the limitation of § 102(g) found in the phrase "in this country."

We disagree with the board that such an effect "is also evident from Section 104." Section 104 merely states that, except as provided by § 119, an applicant or patentee may not establish a date of invention "by reference to knowledge or use thereof, or other activity" in a foreign country. Thus § 119 and § 104 relate, respectively, only to what an applicant or patentee may and may not do to protect himself against patent-defeating events occurring between his invention date and his U.S. filing date. Moreover, we discussed § 104 and § 102(a), (e), and (g) in *Hilmer I* and there showed that they indicate an intention on the part of Congress that knowledge and acts in a foreign country are not to defeat the rights of an applicant for a patent, except as the applicant may become involved in a priority dispute with another applicant entitled to § 119 benefits. The present appeal does not involve a priority dispute. We repeat what we said at the end of that discussion in *Hilmer I*:

We think it follows that section 119 must be interpreted as giving only a positive right or benefit to an applicant who has first filed abroad to protect *him* against possible intervening patent-defeating events in obtaining a patent.

That Habicht, as an applicant, was entitled to the benefit of his Swiss filing date does not mean that his invention acquires that same date under § 102(g) as patent-defeating prior art, in direct contravention of the "in this country" limitation of the section.

* * *

As we understand the meaning of the term “priority,” it refers either (a) to the issue which exists in the interference proceedings, namely, which of two or more rival inventors *attempting to patent the same invention* shall be deemed prior or first in law and *entitled to the patent* or (b) preservation of an effective filing date during a period such as the “convention” year as against acts which would otherwise bar the grant of a patent, for the protection *of an applicant* against loss of right *to a patent*. Nothing we have seen tends to indicate that this matter of “priority” has ever been intended to modify the long-standing provisions of our statutes as to what shall be deemed “prior art” under § 103.

* * *

Comments

1. **Hilmer I and the Milburn Rule.** The *Hilmer* decisions make a clear distinction between obtaining patent rights and defeating patent rights. Despite the “same effect” language of § 119, the *Hilmer I* decision stands for the proposition that a foreign filing date (unlike a domestic filing date) cannot be used as a foreign-application prior art date in determining the patentability of later inventions by others. Given the policy of *Milburn*, what is the difference between Habicht filing his application in Switzerland or the U.S.? Certainly patent offices outside the United States have inefficiencies and experience delays; or as Justice Holmes put it, “[t]he delays of the patent office ought not to cut down the effect of what has been done.” The answer may simply be a matter of statutory construction in that § 102(e)(2) requires the earlier application be filed in United States. And the court expressed skepticism of the *Milburn* rule because of the secret nature of the earlier-filed application. Moreover, what is particularly troublesome from Habicht’s perspective is that his U.S. patent is—as a result of the *Hilmer* decisions—competing with a very close (too close) substitute in the form of what is arguably Hilmer’s obvious variation.
2. **Hilmer II and Foreign-Based Inventive Activity.** According to *Hilmer II*, inventive activity *outside* the United States cannot be used as prior art to defeat patent rights under § 102(g)(2). In *Hilmer II*, the court stated that Congress intended that “knowledge and acts in a foreign country are not to defeat the rights of an applicant for a patent, except as the applicant may become involved in a priority dispute with another applicant.” Thus, as discussed in the Comments following the *Mahurkar* case in Section C, foreign-based inventive activity can only be used in the context of a priority dispute (interference) when two or more parties are vying for the patent. As in *Hilmer I*, the *Hilmer II* court was very skeptical of so-called “secret prior” art. It is one thing to allow inventive acts in the United States to qualify as prior art to defeat patent rights; but it is an entirely different matter to permit acts outside the U.S. to defeat patents, acts that are arguably more difficult to find or appreciate. This geographical distinction is analogous to the geographical distinction in § 102(a). In that section, it is thought that knowledge and use are more difficult to find or locate than patents and publications.

The concern with *Hilmer II*, however, is that it is arguably inconsistent with international obligations. The United States is a signatory member of both the Paris Convention and the Trade Related Aspects of Intellectual Property Rights (TRIPS). Of note, Article 27(1) of TRIPS sets forth the non-discrimination principle and states that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention.” Article 4 of TRIPS states that “With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.” Article 4 of the Paris Convention’s priority provision entitles a U.S. patent applicant to a filing date of up to 12 months earlier than its U.S. filing date. Given these articles, one can ask whether the *Hilmer* decisions are consistent with TRIPS and the Paris Convention? Some commentators are skeptical. See Toshiko Takenaka, *Rethinking the United States First-to-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 HOUS. L. REV. 621, 659 (2002) (“The *Hilmer* doctrine . . . has been extensively criticized by foreign legal commentators for violating the priority right provision under the Paris Convention, as well as the non-discrimination policy provision regarding the place of invention under the TRIPS Agreement”).

B. “PRINTED PUBLICATION”

The phrase “printed publication” appears in both § 102(a) and (b), and its meaning is the same for both. At one level, a printed publication is easy to identify. For instance, a scholarly article published in the journal *Nature* or a book published by Oxford University Press. But what about unpublished materials such as a Ph.D. thesis indexed in a university library or a slide presentation at a professional conference? Are these “printed publications” in the eyes of patent law? The focus of the inquiry, as discussed in *In re Klopfenstein*, is on public accessibility and dissemination.

IN RE KLOPFENSTEIN

380 F.3d 1345 (Fed. Cir. 2004)

PROST, Circuit Judge.

Carol Klopfenstein and John Brent appeal a decision from the Patent and Trademark Office’s Board of Patent Appeals and Interferences (“Board”) upholding the denial of their patent application. The Board upheld the Patent and Trademark Office’s (“PTO’s”) initial denial of their application on the ground that the invention described in the patent application had already been described in a printed publication more than one year before the date of the patent application. We affirm.

Background

A.

The appellants applied for a patent on October 30, 2000. Their patent application, Patent Application Serial No. 09/699,950 (“the ’950 application”), discloses methods of preparing foods comprising extruded soy cotyledon fiber (“SCF”). The ’950 application asserts that feeding mammals foods containing extruded SCF may help lower their serum cholesterol levels while raising HDL cholesterol levels. The fact that extrusion reduces cholesterol levels was already known by those of ordinary skill in the art that worked with SCF. What was not known at the time was that double extrusion increases this effect and yielded even stronger results.

In October 1998, the appellants, along with colleague M. Liu, presented a printed slide presentation (“Liu” or “the Liu reference”) entitled “Enhancement of Cholesterol-Lowering Activity of Dietary Fibers By Extrusion Processing” at a meeting of the American Association of Cereal Chemists (“AACC”). The fourteen-slide presentation was printed and pasted onto poster boards. The printed slide presentation was displayed continuously for two and a half days at the AACC meeting.

In November of that same year, the same slide presentation was put on display for less than a day at an Agriculture Experiment Station (“AES”) at Kansas State University.

Both parties agree that the Liu reference presented to the AACC and at the AES in 1998 disclosed every limitation of the invention disclosed in the ’950 patent application. Furthermore, at neither presentation was there a disclaimer or notice to the intended audience prohibiting note-taking or copying of the presentation. Finally, no copies of the presentation were disseminated either at the AACC meeting or at the AES, and the presentation was never catalogued or indexed in any library or database.

B.

On October 24, 2001, nearly one year after its filing, the ’950 patent application was rejected by the PTO examiner. The examiner found all of the application’s claims anticipated by the Liu reference or obvious in view of Liu and other references. Shortly thereafter, the appellants amended the claims of the ’950 patent and described the circumstances under which the Liu reference had been displayed to the AACC and at the AES. The appellants argued that the Liu reference was not a “printed publication” because no copies were distributed and because there was no evidence that the reference was photographed. The examiner rejected these arguments and issued a final office action on April 10, 2002 rejecting the claims of the ’950 application. The appellants then appealed to the Board.

Before the Board, the appellants again advanced their argument that the lack of distribution and lack of evidence of copying precluded the Liu reference from being considered a “printed publication.” The appellants further contended that the Liu reference was also not a “printed publication” because it was not catalogued or indexed in any library or database. The Board rejected the appellants’ arguments and affirmed the decision of the PTO examiner, finding the Liu reference to be a “printed publication.” The Board affirmed on the grounds that the full invention of the ’950 application was made publicly

accessible to those of ordinary skill in the art by the Liu reference and that this introduction into the public domain of disclosed material via printed display represented a “printed publication” under 35 U.S.C. § 102(b).

Discussion

A.

The only question in this appeal is whether the Liu reference constitutes a “printed publication” for the purposes of 35 U.S.C. § 102(b). As there are no factual disputes between the parties in this appeal, the legal issue of whether the Liu reference is a “printed publication” will be reviewed de novo.

B.

The appellants argue on appeal that the key to establishing whether or not a reference constitutes a “printed publication” lies in determining whether or not it had been disseminated by the distribution of reproductions or copies and/or indexed in a library or database. They assert that because the Liu reference was not distributed and indexed, it cannot count as a “printed publication” for the purposes of 35 U.S.C. § 102(b). To support their argument, they rely on several precedents from this court and our predecessor court on “printed publications.” They argue that *In re Cronyn*, *In re Hall*, *Massachusetts Institute of Technology v. AB Fortia*, (“MIT”), and *In re Wyer*, among other cases, all support the view that distribution and/or indexing is required for something to be considered a “printed publication.”²

We find the appellants’ argument unconvincing and disagree with their characterization of our controlling precedent. Even if the cases cited by the appellants relied on inquiries into distribution and indexing to reach their holdings, they do not limit this court to finding something to be a “printed publication” *only* when there is distribution and/or indexing. Indeed, the key inquiry is whether or not a reference has been made “publicly accessible.” As we have previously stated,

The statutory phrase “printed publication” has been interpreted to mean that before the critical date the reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to the legal determination whether a prior art reference was “published.”

In re Cronyn, 890 F.2d at 1160.³ For example, a public billboard targeted to those of ordinary skill in the art that describes all of the limitations of an invention and that is on display for the public for months may be neither “distributed” nor “indexed”—but it most surely is “sufficiently accessible to the public interested in the art” and therefore, under controlling precedent, a “printed publication.” Thus, the appellants’ argument that “distribution and/

2. Appellants acknowledge that our precedent considers the term “printed publication” to be a unitary concept that may not correspond exactly to what the term “printed publication” meant when it was introduced into the patent statutes in 1836. *In re Wyer*, 655 F.2d at 226. Indeed, the question to be resolved in a “printed publication” inquiry is the extent of the reference’s “accessibility to at least the pertinent part of the public, of a perceptible description of the invention, in whatever form it may have been recorded.” *Id.*

3. While the *Cronyn* court held “dissemination” to be necessary to finding something to be a “printed publication”, the court there used the word “disseminate” in its literal sense, i.e. “make widespread” or “to foster general knowledge of.” *Webster’s Third New International Dictionary* 656

or indexing” are the key components to a “printed publication” inquiry fails to properly reflect what our precedent stands for.

Furthermore, the cases that the appellants rely on can be clearly distinguished from this case. *Cronyn* involved college students’ presentations of their undergraduate theses to a defense committee made up of four faculty members. Their theses were later catalogued in an index in the college’s main library. The index was made up of thousands of individual cards that contained only a student’s name and the title of his or her thesis. The index was searchable by student name and the actual theses themselves were neither included in the index nor made publicly accessible. We held that because the theses were only presented to a handful of faculty members and “had not been cataloged [sic] or indexed in a meaningful way,” they were not sufficiently publicly accessible for the purposes of 35 U.S.C. § 102(b). *In re Cronyn*, 890 F.2d at 1161.

In *Hall*, this court determined that a thesis filed and indexed in a university library did count as a “printed publication.” The *Hall* court arrived at its holding after taking into account that copies of the indexed thesis itself were made freely available to the general public by the university more than one year before the filing of the relevant patent application in that case. But the court in *Hall* did not rest its holding merely on the indexing of the thesis in question. Instead, it used indexing as a factor in determining “public accessibility.” As the court asserted:

The [“printed publication”] bar is grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone. . . . Because there are many ways in which a reference may be disseminated to the interested public, “public accessibility” has been called the touchstone in determining whether a reference constitutes a “printed publication” bar under 35 U.S.C. § 102(b).

In re Hall, 781 F.2d at 898-99.

In *MIT*, a paper delivered orally to the First International Cell Culture Congress was considered a “printed publication.” In that case, as many as 500 persons having ordinary skill in the art heard the presentation, and at least six copies of the paper were distributed. The key to the court’s finding was that actual copies of the presentation were distributed. The court did not consider the issue of indexing. The *MIT* court determined the paper in question to be a “printed publication” but did not limit future determinations of the applicability of the “printed publication” bar to instances in which copies of a reference were actually offered for distribution. *MIT*, 774 F.2d at 1108-10.⁴

Finally, the *Wyer* court determined that an Australian patent application kept on microfilm at the Australian Patent Office was “sufficiently accessible to the public and to persons skilled in the pertinent art to qualify as a ‘printed

(1993). The court did not use the word in the narrower sense the appellants have employed it, which requires distribution of reproductions or photocopies.

4. With regard to scientific presentations, it is important to note that an entirely oral presentation at a scientific conference that includes neither slides nor copies of the presentation is without question not a “printed publication” for the purposes of 35 U.S.C. § 102(b). Furthermore, a presentation that includes a transient display of slides is likewise not necessarily a “printed publication.” See, e.g., *Regents of the Univ. of Cal. v. Howmedica, Inc.*, 530 F. Supp. 846, 860 (D.N.J.1981). While *Howmedica* is not binding on this court, it stands for the important

publication.’” *In re Wyer*, 655 F.2d at 226. The court so found even though it did not determine whether or not there was “actual viewing or dissemination” of the patent application. *Id.* It was sufficient for the court’s purposes that the records of the application were kept so that they could be accessible to the public. *Id.*⁵ According to the *Wyer* court, the entire purpose of the “printed publication” bar was to “prevent withdrawal” of disclosures “already in the possession of the public” by the issuance of a patent. *Id.*

Thus, throughout our case law, public accessibility has been the criterion by which a prior art reference will be judged for the purposes of § 102(b). Oftentimes courts have found it helpful to rely on distribution and indexing as proxies for public accessibility. But when they have done so, it has not been to the exclusion of all other measures of public accessibility. In other words, distribution and indexing are not the only factors to be considered in a § 102(b) “printed publication” inquiry.

C.

In this case, the Liu reference was displayed to the public approximately two years before the ’950 application filing date. The reference was shown to a wide variety of viewers, a large subsection of whom possessed ordinary skill in the art of cereal chemistry and agriculture. Furthermore, the reference was prominently displayed for approximately three cumulative days at AACC and the AES at Kansas State University. The reference was shown with no stated expectation that the information would not be copied or reproduced by those viewing it. Finally, no copies of the Liu display were distributed to the public and the display was not later indexed in any database, catalog or library.

Given that the Liu reference was never distributed to the public and was never indexed, we must consider several factors relevant to the facts of this case before determining whether or not it was sufficiently publicly accessible in order to be considered a “printed publication” under § 102(b). These factors aid in resolving whether or not a temporarily displayed reference that was neither distributed nor indexed was nonetheless made sufficiently publicly accessible to count as a “printed publication” under § 102(b). The factors relevant to the facts of this case are: the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied. Only after considering and balancing these factors can we determine whether or not the Liu reference was sufficiently publicly accessible to be a “printed publication” under § 102(b).

The duration of the display is important in determining the opportunity of the public in capturing, processing and retaining the information conveyed by the reference. The more transient the display, the less likely it is to be considered a “printed publication.” *See, e.g. Howmedica*, 530 F. Supp. at 860 (holding that a presentation of lecture slides that was of limited duration was insufficient to make the slides “printed publications” under § 102(b)). Con-

proposition that the mere presentation of slides accompanying an oral presentation at a professional conference is not per se a “printed publication” for the purposes of § 102(b).

5. Unlike in *Cronyn*, it was the actual patent application—and not just an index card searchable by author name only—that was made publicly accessible.

versely, the longer a reference is displayed, the more likely it is to be considered a “printed publication.” In this case, the Liu reference was displayed for a total of approximately three days. It was shown at the AACC meeting for approximately two and a half days and at the AES at Kansas State University for less than one day.

The expertise of the intended audience can help determine how easily those who viewed it could retain the displayed material. As Judge Learned Hand explained in *Jockmus v. Leviton*, 28 F.2d 812, 813-14 (2d Cir. 1928), a reference, “however ephemeral its existence,” may be a “printed publication” if it “goes direct to those whose interests make them likely to observe and remember whatever it may contain that is new and useful.” In this case, the intended target audience at the AACC meeting was comprised of cereal chemists and others having ordinary skill in the art of the '950 patent application. The intended viewers at the AES most likely also possessed ordinary skill in the art.

Whether a party has a reasonable expectation that the information it displays to the public will not be copied aids our § 102(b) inquiry. Where professional and behavioral norms entitle a party to a reasonable expectation that the information displayed will not be copied, we are more reluctant to find something a “printed publication.” This reluctance helps preserve the incentive for inventors to participate in academic presentations or discussions. Where parties have taken steps to prevent the public from copying temporarily posted information, the opportunity for others to appropriate that information and assure its widespread public accessibility is reduced. These protective measures could include license agreements, non-disclosure agreements, anti-copying software or even a simple disclaimer informing members of the viewing public that no copying of the information will be allowed or countenanced. Protective measures are to be considered insofar as they create a reasonable expectation on the part of the inventor that the displayed information will not be copied. In this case, the appellants took no measures to protect the information they displayed—nor did the professional norms under which they were displaying their information entitle them to a reasonable expectation that their display would not be copied. There was no disclaimer discouraging copying, and any viewer was free to take notes from the Liu reference or even to photograph it outright.

Finally, the ease or simplicity with which a display could be copied gives further guidance to our § 102(b) inquiry. The more complex a display, the more difficult it will be for members of the public to effectively capture its information. The simpler a display is, the more likely members of the public could learn it by rote or take notes adequate enough for later reproduction. The Liu reference was made up of 14 separate slides. One slide was a title slide; one was an acknowledgement slide; and four others represented graphs and charts of experiment results. The other eight slides contained information presented in bullet point format, with no more than three bullet points to a slide. Further, no bullet point was longer than two concise sentences. Finally, as noted earlier, the fact that extrusion lowers cholesterol levels was already known by those who worked with SCF. The discovery disclosed in the Liu reference was that double extrusion increases this effect. As a result, most of the eight substantive slides only recited what had already been known in the

field, and only a few slides presented would have needed to have been copied by an observer to capture the novel information presented by the slides.

Upon reviewing the above factors, it becomes clear that the Liu reference was sufficiently publicly accessible to count as a “printed publication” for the purposes of 35 U.S.C. § 102(b). The reference itself was shown for an extended period of time to members of the public having ordinary skill in the art of the invention behind the ’950 patent application. Those members of the public were not precluded from taking notes or even photographs of the reference. And the reference itself was presented in such a way that copying of the information it contained would have been a relatively simple undertaking for those to whom it was exposed — particularly given the amount of time they had to copy the information and the lack of any restrictions on their copying of the information. For these reasons, we conclude that the Liu reference was made sufficiently publicly accessible to count as a “printed publication” under § 102(b).

Comments

1. **“Public Accessibility.”** Public accessibility is the key to determining whether a reference constitutes a printed publication. *See In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986) (referring to public accessibility as the “touchstone” for printed publication determinations). Accessibility focuses on the public interested in the art, so that by examining the reference, one could make the claimed invention without further research or experimentation. There is no requirement that particular members of the public actually receive the printed publication or the information be disseminated. *See In re Wyer*, 655 F.2d 221, 226 (CCPA 1981) (Australian patent application kept on microfilm at the Australian Patent Office was “sufficiently accessible to the public and to persons skilled in the pertinent art to qualify as a ‘printed publication’” even though court did not determine whether there was “actual viewing or dissemination” of the patent application). And the public accessibility requirement may be satisfied even though access is “restricted to a part of the public, so long as accessibility is sufficient ‘to raise a presumption that the public concerned with the art would know of’” the invention. *In re Bayer*, 568 F.2d 1357, 1361 (CCPA 1978).

In *In re Hall*, which was discussed in the principal case, the Federal Circuit held that a single doctoral thesis deposited and indexed in a German library was sufficiently accessible to be a “printed publication.” But the “indexing” system in *In re Cronyn*, 890 F.2d 1158 (Fed. Cir. 1989), was not sufficient. In *Cronyn*, the alleged printed publication were student theses filed in Reed College’s main library and in the library of the particular department in which the student’s work was done. The theses were listed on individual cards that displayed the student’s name and the title of the thesis. The cards were filed alphabetically by the author’s name, and the titles were sometimes descriptive. The Federal Circuit held the theses were not publicly accessible because, unlike *In re Hall*, the theses were not indexed, catalogued, or shelved in “a meaningful way.” The court continued: “Although the titles of the theses were listed on 3 out of 450 cards filed alphabetically by author in a shoebox in the chemistry department library, such “availability” was not

sufficient to make them reasonably accessible to the public. Here, the only research aid was the student's name, which, of course, bears no relationship to the subject of the student's thesis." *Id.* at 1161.

Accessibility was given a generous definition in *Bruckelmyer v. Ground Heaters*, 445 F.3d 1374 (Fed. Cir. 2006). The patentee owned two patents for a method of thawing frozen ground. Thawing was important to enable concrete to be poured. The patentee stipulated that if a Canadian patent *application* were deemed a printed publication, it would render the patentee's patents invalid. The application, as filed, contained drawings that were not included in the issued patent because they were deleted during prosecution; but the drawings were key to a finding of invalidity. The issue on appeal was whether the published application, which contained the drawings, was a printed publication under § 102(b). Relying on *Klopfenstein* and *Cronyn*, the patentee argued that the drawings were not printed publications because they were not publicly accessible, which, according to the patentee, requires the reference to "either (1) be published to those interested in the art for a sufficient amount of time to allow them to 'captur[e], process[] and retain[] the information conveyed by the reference, or (2) those interested must be able to locate the material in a meaningful way." *Id.* at 1377. The Federal Circuit disagreed because the patent application was laid open for inspection, which allowed persons of ordinary skill in the art exercising reasonable diligence to locate the application. The court relied on *In re Wyer*, 655 F.2d 221 (CCPA 1981), which involved an Australian patent application laid open for public inspection and an abstract of the application that was published by the Australian Patent Office more than two years before the filing date of the corresponding U.S. patent application. According to court in *Bruckelmyer*, "the existence of a published abstract that would have allowed one skilled in the art exercising reasonable diligence to locate the foreign patent application and the fact that the application was classified and indexed in the patent office, were central to the *Wyer* court's conclusion that the application was 'publicly accessible.'" *Bruckelmyer*, 445 F.3d at 1379. A petition for en banc review was denied, but prompted a dissent from Judge Newman. In focusing on the importance of public accessibility, she wrote:

It is undisputed that these cancelled drawings are not available in any database or any library, and that no index, no catalog, no abstract suggests their existence or their content. It is not contested that the only way to obtain these drawings (although their existence was unknown) is to personally go to the Canadian Patent Office in Hull, Quebec, and ask to examine the file wrapper (the prosecution history) of this particular patent.

453 F.3d 1352, 1353 (Fed. Cir. 2006) (Newman, J., dissenting from denial of petition to hear en banc). For a discussion of the implications of *Klopfenstein* on the academic community and scientists, see Sean B. Seymore, *The "Printed Publication" Bar After Klopfenstein: Has the Federal Circuit Changed the Way Professors Should Talk About Science?*, 40 AKRON L. REV. 493 (2007).

2. **What Does "Printed" Mean?** Technology, as it typically does, has outpaced the term "printed publication." Historically, dissemination relied on a

document being printed. But today, there is the Internet and digital technology. Judge Newman provides a helpful explanation of the terms “printed” and “publication” as used in §§ 102(a) and (b):

[I]n the case of “printed” publications, Congress no doubt reasoned that one would not go to the trouble of printing a given description of a thing unless it was desired to print a number of copies of it.

Printing alone, of course, would be insufficient to reasonably assure that the public would have access to the work, for the possibility always exists that the printed matter may be suppressed and might never reach the public. Then too, there are time lapses between the printing and the publishing of a given work, and the public is not to be charged with knowledge of a subject until such time as it is available to it. For this reason, it is required that the description not only be printed but be published as well.

But though the law has in mind the probability of public knowledge of the contents of the publication, the law does not go further and require that the probability must have become an actuality. In other words, once it has been established that the item has been both printed and published, it is not necessary to further show that any given number of people actually saw it or that any specific number of copies have been circulated. The law sets up a conclusive presumption to the effect that the public has knowledge of the publication when a single printed copy is proved to have been so published.

The earlier cases decided by the CCPA interpreted “printed” as Congress no doubt understood the term: multiple copies that were made in order to disseminate the information. The idea was that there must be some likelihood that the information would, at least in principle, be available to interested persons in the United States. We need not consider the role in section 102 of today’s searchable electronic data bases and other media, for in this case the subject matter entered no searchable library. The policy consideration for foreign prior art remains the same as when the statute was enacted—a requirement that the information be reasonably available in this country. The decisions developed the criterion that a “publication” must be “publicly accessible,” as in *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981), where the court defined “publicly accessible” as meaning “disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.”

Bruckelmyer v. Ground Heaters 453 F.3d 1352, 1354 (Fed. Cir. 2006) (Newman, J., dissenting from denial of petition to hear en banc).

COMPARATIVE PERSPECTIVE

Novelty and State of the Art Under the European Patent Convention

Article 54 of the European Patent Convention defines both novelty and prior art. Article 54(1) states that an “invention shall be considered new if it does not form part of the state of the art.” State of the art is defined as “everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.” Article 54(2) EPC. (Although information made available to the public on the *same* day of filing is not considered state of the art.) This conception of prior art is known as “absolute novelty,” which is considerably broader than the American conception

embodied in 35 U.S.C. § 102. Indeed, the examination guidelines of the European Patent Office state under Article 54 there “are no restrictions whatever as to the geographical location where or the language or manner in which the relevant information was made available to the public.” C-IV-5.1 European Patent Office Guidelines for Examination. The concept of absolute novelty was first adopted in Article 4 of the Strasbourg Convention of 1963. *See* The Strasbourg Convention of 1963: Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27 November 1963.

Thus, there are three important distinctions between Article 54 and § 102. First, the critical date under Article 54 is the date of filing of the European patent application, not the date of invention or one year from the date of filing. (Importantly, under the EPC the date of priority can act as the filing date for prior art purposes assuming the applicant complies with the priority procedures of Articles 87-89. *See* Article 89 EPC and C-IV-5.3 European Patent Office Guidelines for Examination.); second, there is no geographical restriction under Article 54 as there is under 35 U.S.C. § 102(a) and (b); and third, Article 54 does not permit a universal grace period that applies to all forms of public disclosures and uses, although there are limited exceptions. *See* the Comparative Perspective on Prejudicial Disclosures in Chapter 5.

1. Available to the Public and the Person Skilled in the Art

State of the art information can take many forms, including (1) **documentation**. A published document is deemed a part of the state of the art as of its publication date. *See* C-IV-7.3 European Patent Office Guidelines for Examination. A trade journal article is available when it is delivered to subscribers, not when it is sent to the journal. 1 EUROPEAN PATENT CONVENTION: A COMMENTARY 109 (M. Singer & D. Stauder eds., 2003); **oral recitation**. *See* D-V-3.21 European Patent Office Guidelines for Examination (“The state of the art is made available to the public by oral description when facts are unconditionally brought to the knowledge of members of the public in the course of a conversation or a lecture or by means of radio, television or sound reproduction equipment (tapes and records)”; **public use of a product or process**. *See* D-V-3.11 European Patent Office Guidelines for Examination (“Use may be constituted by producing, offering, marketing or otherwise exploiting a product, or by offering or marketing a process or its application or by applying the process. Marketing may be affected, for example, by sale or exchange. The state of the art may also be made available to the public in other ways, as for example by demonstrating an object or process in specialist training courses or on television.”); or **commercial sales**. Only a single use or sale will render the article used or sold available to the public under 54(2). *See* EPO Board of Appeals T0482/89 (stating that “in accordance with principles well-established in the case law of the majority of

Contracting States, that a single sale is sufficient to render the article sold available to the public within the meaning of Article 54(2) EPC, provided the buyer is not bound by an obligation to maintain secrecy”).

All that is required is that the information be made available to a single member of the public without a confidentiality requirement and that the information be enabling to a person skilled in the art. *See* European Patent Office Guidelines for Examination C-IV 5.2 (“Subject-matter can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given to the skilled person is sufficient to enable him, at the relevant date, to practise the technical teaching which is the subject of the disclosure, taking into account also the general knowledge at that time in the field to be expected of him.”). The person skilled in the art is not expressly mentioned in Article 54, but is regarded as “the decisive factor for the understanding of the technical teaching” not only for purposes of novelty, but also inventive step and adequacy of disclosure. *See* 1 EUROPEAN PATENT CONVENTION: A COMMENTARY 110 (M. Singer & D. Stauder eds., 2003). Unlike EPC Article 54, Articles 56 (Inventive Step) and 83 (Disclosure of Invention) expressly mention “person skilled in the art.”

2. Novelty

Information that forms part of the state of the art does not necessarily mean that information is novelty defeating. The information must anticipate the claimed invention. In the important *Mobil Oil III* case, the Enlarged EPO Board of Appeals stated:

Article 54(2) EPC defines the state of the art as comprising “everything made available to the public by means of a written or oral description, by use, or in any other way.” . . . The word “available” carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection. . . . A claimed invention lacks novelty unless it includes at least one essential technical feature which distinguishes it from the state of the art. When deciding upon the novelty of a claim, a basic initial consideration is therefore to construe the claim in order to determine its technical features.

Enlarged EPO Board of Appeals G 0002/88. The prior art must contain “a clear and unmistakable disclosure of the subject matter of the later invention” to defeat novelty. EPO Board of Appeals T 450/89. *See also* T0661/97 (“The Board concurs with the decision T 450/89 . . . that novelty should be affirmed if the prior art document does not comprise clear and unmistakable disclosure for the subject-matter of the later invention.”); T1261/01 (lack of novelty requires “clear and unambiguous disclosure in the prior art of all features of the claim”). The European Examination Guidelines state novelty is defeated if the claimed subject matter can be derived “directly and unambiguously” from the prior art. C-IV-7.2.

A little background on what constitutes a “technical feature” may be helpful. The EPC and its implementing regulations require that claims be drafted in terms of technical features of the invention. For instance,

Article 84 of the EPC requires that claims “define the matter for which protection is sought” and “be clear and concise and be supported by the description.” EPC Implementing Regulation 29 builds on Article 84, by requiring that claims “define the matter for which protection is sought in terms of the technical features of the invention.” A technical feature has been defined as “anything that is necessary to solve the technical problem under consideration.” ¹ EUROPEAN PATENT CONVENTION: A COMMENTARY 116 (M. Singer & D. Stauder eds., 2003). According to the EPO Board of Appeals,

It follows that the technical features of the invention are the physical features which are essential to it. When considering the two basic types of claim . . . the technical features of a claim to a physical entity [i.e., product or apparatus claim] are the physical parameters of the entity, and the technical features of a claim to an activity [i.e., process or method claim] are the physical steps which define such activity.

Enlarged EPO Board of Appeals G 0002/88.

When comparing the claimed invention’s technical features to the prior art, it is important to keep in mind that, as under American patent law, prior art references cannot be combined to defeat novelty, although combination is permissible when determining inventive step. *See* T1261/01 (noting “the lack-of-novelty objection fails because it relies on combining features taken from various parts” of the prior art). *See also* European Patent Office Guidelines for Examination C-IV-7.1 (“It should be noted that in considering novelty (as distinct from inventive step), it is not permissible to combine separate items of prior art together.”). And when a single reference discloses “scattered elements” that form part of different embodiments, the EPO Board of Appeals requires the reference to disclose a “specific combination” to be novelty-defeating. For instance, in *Grehal* the applicant invented a shear that incorporated a stirrup. The party opposing the patent application, Diener, cited as prior art a catalogue that disclosed the features of the claimed invention, although these prior art features were disclosed in two different embodiments. According to Diener, the prior art features “were described in one and the same technical context and in one and the same document (the catalogue),” and therefore, “when taken as a whole, this set of known features anticipated the invention.” The EPO disagreed:

[W]hen assessing novelty it was not enough only to consider the content of a single document: each entity described in the document also had to be

examined separately. It is not permissible to combine separate items belonging to different embodiments described in one and the same document merely because they are disclosed in that one document, unless of course such combination has been specifically suggested therein. In other words, when the content of a single prior art document (in this case, a catalogue disclosing various types of shear) is considered in isolation when contesting the novelty of a claim, the said content must not be treated as something in the nature of a reservoir from which it would be permissible to draw features pertaining to separate embodiments in order to create artificially a particular embodiment which would destroy novelty, unless the document itself suggests such a combination of features. In the present case, apart from the fact that it is open

to question whether a catalogue can be treated as a single document rather than as a selection of documents, the [prior art] shears are two completely separate items from the catalogue, shown on two different pages under different order numbers. They are therefore definitely two separate entities forming two independent bases for comparison which should be considered in isolation when assessing novelty, and it is not admissible to piece together artificially a more relevant state of the art from features belonging to one or both of these entities, even if they are both disclosed in one and the same document.

EPO Board of Appeals T 305/87. *Accord* T 166/01 (noting these “scattered elements” [disclosed in the prior art] are not disclosed as a specific combination, contrary to the requirements set out in . . . T 305/87 that a specific combination has to be pointed out by a prior art document for it to be novelty-destroying”). *See also* European Patent Office Guidelines for Examination C-IV-7.1 (“It is . . . not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested.”).

The state of the art does not need to reveal the claimed invention expressly. Rather, claimed subject matter that can be implicitly derived from the prior art will also defeat novelty. *See* European Patent Office Guidelines for Examination C-IV-7.2 (“A document takes away the novelty of any claimed subject-matter derivable directly and unambiguously from that document including any features implicit to a person skilled in the art in what is expressly mentioned in the document, *e.g.* a disclosure of the use of rubber in circumstances where clearly its elastic properties are used even if this is not explicitly stated takes away the novelty of the use of an elastic material.”) Implicit derivation should not be confused with inherency. An inherent feature under the EPC does not constitute state of the art. Enlarged EPO Board of Appeals G 0002/88. According to the Enlarged Board of Appeals:

[U]nder Article 54(2) EPC the question to be decided is what has been “made available” to the public: the question is not what may have been “inherent” in what was made available (by a prior written description, or in what has previously been used (prior use), for example). Under the EPC, a hidden or secret use, because it has not been made available to the public, is not a ground of objection to validity of a European patent. . . . Thus, the question of “inherency” does not arise as such under Article 54 EPC.

Id.

C. PRIORITY

The United States is a first-to-invent country, which means that the party who invented first is awarded the patent.¹ The first party to invent is said to have priority of invention over other inventors who are also seeking a patent on

1. Every other country in the industrialized world subscribes to a first-to-file system, which, as the name suggests, awards the patent to the first party who filed the patent application. *See* the

the same invention. This seemingly simple doctrine is governed by several complex rules that play out in an interference proceeding,² and oftentimes in federal court.

The question of priority is governed by § 102(g)(1) of the patent code, which reads in relevant part:

A person shall be entitled to a patent unless . . . during the course of an *interference* . . . , another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not *abandoned, suppressed, or concealed*. . . . In determining priority of invention under this subsection, there shall be considered not only the respective dates of *conception* and *reduction to practice* of the invention, but also the *reasonable diligence* of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Thus, there are numerous terms that must be defined and addressed: (1) abandoned, suppressed, or concealed; (2) conception; (3) reduction to practice; and (4) reasonable diligence.

But first the general rule for awarding priority: The first party (say Party A) to reduce to practice is the first to invent and, therefore, is awarded the patent, *unless* the party (say Party B) who was last to reduce to practice was also the first to conceive, in which case Party B is awarded priority if he can show that he exercised reasonable diligence from just prior to Party A's conception date until Party B's reduction to practice.

The principal cases below and comments that follow unpack this rule and define the various terms therein. The *Mahurkar* case explores the terms "conception" and "reduction to practice" in the context of proving date of invention. And the *Griffith* and *Fujikawa* cases explore "reasonable diligence" and "abandonment, suppression, and concealment."

1. Proving Date of Invention

The *Mahurkar* case explores how date of invention is proven. The important issues (and terms of art) of conception and reduction to practice are discussed.

Policy Perspective at the end of this chapter for a short discussion of the strengths and weaknesses of first-to-invent and first-to-file regimes.

2. An interference is an inter partes administrative proceeding (within the USPTO), that seeks to determine who should be awarded priority of invention. There are complex procedural rules that accompany interference practice. See 35 U.S.C. § 135 (2006); 37 C.F.R. § 41.200 et seq.; and Chapter 2300 of the MANUAL OF PATENT EXAMINATION PROCEDURE. The term "interference" can be gleaned from § 135(a) of the patent code, which reads:

Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared and the Director shall give notice of such declaration to the applicants, or applicant and patentee, as the case may be.

MAHURKAR v. C.R. BARD, INC.

79 F.3d 1572 (Fed. Cir. 1996)

RADER, Circuit Judge.

Dr. Sakharam D. Mahurkar sued C.R. Bard, Inc., Davol Inc., and Bard Access Systems, Inc. (Bard) for infringing U.S. Patent No. 4,808,155 (the '155 patent).

On appeal, the parties raised numerous issues to which this court gave full consideration. Because the district court correctly granted Dr. Mahurkar's motion on anticipation, this court affirms in part.

The '155 patent discloses a simple double-lumen catheter. A double-lumen catheter simultaneously removes and restores fluids to the human body during a transfusion. To accomplish this mission, this flexible surgical instrument uses two channels—one to withdraw fluids, another to inject fluids.

Dr. Mahurkar created the claimed invention to treat chronic dialysis patients whose veins usually will no longer tolerate acute catheters. Dr. Mahurkar's invention does not traumatize sensitive veins, yet still supports maximum blood flow with a minimum catheter cross section. After a chronic patient's veins have deteriorated from frequent transfusions, this catheter permits insertion into a major vein—percutaneous insertion—without expensive cut-down surgery.

Dr. Mahurkar filed an initial patent application on his invention on October 24, 1983. After two continuations, the United States Patent and Trademark Office (PTO) issued the '155 patent on February 28, 1989.

In May 1990, Dr. Mahurkar granted Bard a limited license under the '155 patent. This license limited Bard to non-hemodialysis applications. Dr. Mahurkar asserts that Bard made and sold infringing hemodialysis catheters in violation of that license. Specifically, Dr. Mahurkar claims that Bard's "Hickman I" and "Hickman II" hemodialysis catheters infringe the '155 patent.

Bard argues that the '155 patent is invalid under 35 U.S.C. § 102(a). In July 1983, Cook, Inc. published a nationwide catalog (the Cook catalog) disclosing a Cook Double Lumen Subclavian Hemodialysis Catheter. At the conclusion of the evidence at trial, Bard moved for judgment as a matter of law (JMOL) that the Cook catalog anticipated the '155 patent. Dr. Mahurkar cross-moved. The district court granted Dr. Mahurkar's motion for JMOL. According to the district court, no reasonable jury could find the Cook catalog anticipated claim 1 of the '155 patent.

* * *

At trial, Bard sought to show that the Cook catalog anticipated claim 1 of the '155 patent. The catalog's July 1983 publication date preceded the filing of the '155 patent by about three months. The parties disputed only the status of the Cook catalog as prior art under 35 U.S.C. § 102(a). By challenging the validity of the '155 patent, Bard bore the burden of persuasion by clear and convincing evidence on all issues relating to the status of the Cook catalog as prior art.

Section 102(a) of Title 35 defines one class of prior art. As a printed publication, the Cook catalog fits within some terms of 35 U.S.C. § 102(a). Section 102(a) also requires, however, that the catalog description appear before the invention.

In *ex parte* patent prosecution, an examiner may refer to a document published within one year before the filing date of a patent application as prior art. However, this label only applies until the inventor comes forward with evidence showing an earlier date of invention. Once the inventor shows an earlier date of invention, the document is no longer prior art under section 102(a).

Any suggestion that a document is prior art because it appears before the filing date of a patent ignores the requirements of section 102(a). Section 102(a) explicitly refers to invention dates, not filing dates. Thus, under section 102(a), a document is prior art only when published before the invention date. For the Cook catalog to constitute prior art, therefore, it must have been published before Dr. Mahurkar's invention date.

Resolution of this point turns on procedural rules regarding burdens of proof as well as several rules of law borrowed from the interference context. Bard offered into evidence at trial a document published about three months before the filing date of Dr. Mahurkar's patent disclosing each and every element of the claimed invention. Dr. Mahurkar then had the burden to offer evidence showing he invented the subject matter of his patent before the publication date of the document. Had Dr. Mahurkar not come forward with evidence of an earlier date of invention, the Cook catalog would have been anticipatory prior art under section 102(a) because Dr. Mahurkar's invention date would have been the filing date of his patent.

However, Dr. Mahurkar offered evidence at trial to show that he invented the subject matter of the patent before publication of the Cook reference. He met his burden of production. Consequently, this court turns to an evaluation of the evidence offered by Dr. Mahurkar under the proper burden of persuasion in this infringement action and the rules of law relating to invention dates.

Section 102(g) of Title 35 contains the basic rule for determining priority. 35 U.S.C. § 102(g). Section 102(g) also provides basic protection for the inventive process, shielding in particular the creative steps of conception and reduction to practice. In the United States, the person who first reduces an invention to practice is "prima facie the first and true inventor." *Christie v. Seybold*, 55 F. 69, 76 (6th Cir. 1893) (Taft, J.). However, the person "who first conceives, and, in a mental sense, first invents . . . may date his patentable invention back to the time of its conception, if he connects the conception with its reduction to practice by reasonable diligence on his part, so that they are substantially one continuous act." *Id.* Stated otherwise, priority of invention "goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice." *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993).

To have conceived of an invention, an inventor must have formed in his or her mind "a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). The idea must be "so

clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Id.*

This court has developed a rule requiring corroboration where a party seeks to show conception through the oral testimony of an inventor. This requirement arose out of a concern that inventors testifying in patent infringement cases would be tempted to remember facts favorable to their case by the lure of protecting their patent or defeating another's patent. *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923). While perhaps prophylactic in application given the unique abilities of trial court judges and juries to assess credibility, the rule provides a bright line for both district courts and the PTO to follow in addressing the difficult issues related to invention dates.

In assessing corroboration of oral testimony, courts apply a rule of reason analysis. Under a rule of reason analysis, "[a]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached."

This court does not require corroboration where a party seeks to prove conception through the use of physical exhibits. The trier of fact can conclude for itself what documents show, aided by testimony as to what the exhibit would mean to one skilled in the art.

Reduction to practice follows conception. To show actual reduction to practice, an inventor must demonstrate that the invention is suitable for its intended purpose. *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994). Depending on the character of the invention and the problem it solves, this showing may require test results. *Id.* at 1062. Less complicated inventions and problems do not demand stringent testing. In fact, some inventions are so simple and their purpose and efficacy so obvious that their complete construction is sufficient to demonstrate workability.

Where a party is first to conceive but second to reduce to practice, that party must demonstrate reasonable diligence toward reduction to practice from a date just prior to the other party's conception to its reduction to practice. *Griffith v. Kanamaru*, 816 F.2d 624, 625-26 (Fed. Cir. 1987).

Bard bears the burden of persuasion on the status of the Cook catalog as prior art. Bard must persuade the trier of fact by clear and convincing evidence that the Cook catalog was published prior to Dr. Mahurkar's invention date.

At trial, Dr. Mahurkar offered evidence to demonstrate prior invention in two ways. He offered evidence to show he conceived and reduced to practice his invention before publication of the catalog. He also offered evidence to show that he conceived of his invention prior to the date of publication of the Cook catalog and that he proceeded with reasonable diligence from a date just prior to publication of the catalog to his filing date. Bard, in turn, challenged Dr. Mahurkar's evidence.

With all of the evidence from both sides before the jury, Bard must persuade the jury by clear and convincing evidence that its version of the facts is true. In other words, Bard must persuade the jury that Dr. Mahurkar did not invent prior to publication of the catalog. This is because (1) he did not conceive and reduce his invention to practice before the publication date and (2) he did not conceive and thereafter proceed with reasonable diligence as

required to his filing date. If Bard fails to meet this burden, the catalog is not prior art under section 102(a).

Viewing the evidence of record below in the light most favorable to Bard, this court concludes that no reasonable jury could have found clear and convincing evidence that the Cook catalog was prior art. Dr. Mahurkar testified that he conceived and began work on dual-lumen, flexible, hemodialysis catheters, including the '155 catheter, in 1979. From late 1980 through early 1981, Dr. Mahurkar constructed polyethylene prototype catheters in his kitchen. He bought tubing and various machines for making and testing his catheters.

During this time period, he also tested polyethylene prototypes and used them in flow and pressure drop tests in his kitchen. These tests used glycerine to simulate blood. These tests showed, to the limit of their design, the utility of his claimed invention. Dr. Mahurkar designed these tests to show the efficiency of his structure knowing that polyethylene catheters were too brittle for actual use with humans. But, he also knew that his invention would become suitable for its intended purpose by simple substitution of a soft, biocompatible material. Dr. Mahurkar adequately showed reduction to practice of his less complicated invention with tests which "[did] not duplicate all of the conditions of actual use." *Gordon v. Hubbard*, 347 F.2d 1001, 1006 (CCPA 1965).

Dr. Mahurkar provided corroboration for his testimony. Dr. Mahurkar confidentially disclosed the catheter prototype tips of his '155 invention to Geoffrey Martin, President of Vas-Cath Inc. in 1981, and Brian L. Bates of Cook, Inc. Mr. Martin testified that he received the polyethylene prototype tips from Dr. Mahurkar in 1981. Dr. Mahurkar also produced a letter from Stephen Brushey, an employee of Vas-Cath, dated April 21, 1981, that described several of his catheters. Additionally, Dr. Mahurkar presented a letter from Brian L. Bates of Cook, Inc., dated October 23, 1981. In this letter, Cook was "impressed with the thought and technology which has gone into the fabrication of the prototype material."

In addition to evidence of actual reduction to practice before publication of the Cook catalog, Dr. Mahurkar also showed reasonable diligence from his conception date through the filing of his patent application. From conception to filing, Dr. Mahurkar continuously sought to locate companies capable of extruding his tubing with the soft, flexible materials necessary for human use.

On this record and with the applicable burden of persuasion, no reasonable jury could have found that Bard proved the Cook catalog was prior art. Consequently, the court properly granted Dr. Mahurkar's motion for JMOL of non-anticipation of claim 1 of the '155 patent.

Comments

1. **Proving Date of Invention.** Although *Mahurkar* was a § 102(a) novelty case, the court borrowed extensively from § 102(g) interference practice. In doing so, the court provided a nice discussion of the various components involved in proving date of invention. To summarize, (1) the prima facie first inventor is the party who first reduced to practice, but a party who was second to reduce to practice will be considered the first inventor if he can show that he was the first to conceive and exercised reasonable diligence in reducing his invention to practice; (2) reduction to practice is proven when

the invention works for its intended purpose and there is a contemporaneous appreciation of such; and (3) conception is shown through the presentation of corroborated evidence that the inventor formed in his mind “a definite and permanent idea of the complete and operative invention, as it is thereafter applied in practice.”

a. Conception. An inventor may be able to move the date of invention date back further than his RTP if he can show he conceived of the invention prior to his reducing it to practice. Conception is a term of art in patent law and means the inventor had in his mind “a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.” *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). That is, the inventive idea was be “so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.” *Id.* See also *Kridl v. McCormick*, 105 F.3d 1446, 1449 (Fed. Cir. 1997) (“Conception is the formation ‘in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice.’”); *Mergenthaler v. Scudder*, 1897 C.D. 724, 731 (1897) (setting forth the classic definition of conception). And corroboration is required if the inventor is only relying on oral testimony to prove conception, rather than documentation or physical exhibits. See *Mahurkar*, 79 F.3d at 1577-78. Indeed, the *Mergenthaler* court stated that without such a requirement, there would be a “great temptation to perjury.” 1897 C.D. at 732.

Moreover, conception requires “more than unrecognized accidental creation.” In fact, “an accidental and unappreciated duplication of an invention does not defeat the patent right of one who, though later in time, was the first to recognize that which constitutes the inventive subject matter.” *Silvestri v. Grant*, 496 F.2d 593, 597 (CCPA 1974). Thus, “[t]he date of conception of a prior inventor’s invention is the date the inventor first appreciated the fact of what he made.” *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001).

b. Reduction to Practice. Reduction to practice (“RTP”) can either be (1) constructive; or (2) actual. Constructive RTP is the date on which the application is filed. Actual RTP requires the inventor “prove that: (1) he constructed an embodiment or performed a process that met all the limitations . . . and (2) he determined that the invention would work for its intended purpose.” *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). And whether actual testing is required to prove the invention works for its intended purpose depends on the character and complexity of the invention and the problem it addresses. See *Mahurkar*, 79 F.3d at 1578. Indeed, some inventions may be “so simple and their purpose and efficacy so obvious that their complete construction is sufficient to demonstrate workability.” *Id.* Lastly, “conception and reduction to practice cannot be established nunc pro tunc;” rather, “[t]here must be contemporaneous recognition and appreciation of the invention represented by the counts.” *Breen v. Henshaw*, 472 F.2d 1398, 1401 (CCPA 1973).

If testing is required, actual working conditions may not be necessary. Laboratory tests may be sufficient if they simulate actual working conditions. Neither perfection nor commercial viability is required to show actual RTP. In the Federal Circuit case of *Scott v. Finney*, 34 F.3d 1058 (Fed. Cir. 1994), the court stated that cases dealing with the sufficiency of testing in proving actual RTP “share a common theme.” The court wrote:

In tests showing the invention’s solution of a problem, the courts have not required commercial perfection nor absolute replication of the circumstances of the invention’s actual use. Rather, they have instead adopted a common sense assessment. This common sense approach prescribes more scrupulous testing under circumstances approaching actual use conditions when the problem includes many uncertainties. On the other hand, when the problem to be solved does not present myriad variables, common sense similarly permits little or no testing to show the soundness of the principles of operation of the invention.

Id. at 1063. Not unlike proving conception, the inventor must corroborate his actual reduction to practice.

2. ***Economic Nationalism and Foreign Inventive Activity and §§ 102(g) and 104.*** Historically, American patent law has projected economic nationalism. The early patent acts (e.g., 1793 Act) prohibited foreigners from obtaining patents in the U.S. or required foreign inventors to pay a higher filing fee than American inventors (e.g., 1836 Act). In addition, until the mid-1990s, inventive activity—namely conception and reduction to practice—outside the U.S. could not be used to prove date of invention under § 104. But these statutory provisions were amended with the ratification of North American Free Trade Agreement (NAFTA) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) the formed part of the General Agreement on Tariffs and Trade (GATT). Now inventive activity in any NAFTA or WTO country can be used to show date of invention. (The amendment to § 104 became effective on December 8, 1993 for NAFTA countries and January 1, 1996 for WTO countries, of which there are 151 member states as of this writing.)

In 1999, § 102(g) was amended as part of the American Inventors Protection Act, to reflect the changes made to § 104. Section 102(g) was bifurcated into two subsections, and now reads:

A person shall be entitled to a patent unless—

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person’s invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person’s invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. . . .

Subsection (g)(1)’s language “to the extent permitted in section 104” permits inventors to use foreign-based inventive activity to prove date of invention in the context of an interference—that is, when obtaining patent

rights. But, as we saw in *Hilmer II* (in Section A.5 above), foreign-based inventive activity cannot be used as prior art to defeat patent rights—thus, § 102(g)(2)’s language “made in this country.” There remains a distinction between using foreign-based inventive activity to obtain patent rights in the context of an interference proceeding—the province of § 102(g)(1); and using foreign-based inventive activity to defeat patent rights, which is prohibited under § 102(g)(2).

2. Diligence and Abandonment

In an interference context, diligence and abandonment come into play when one party is the last to reduce to practice, but the first to conceive. For instance, Inventor 1 reduces to practice November 1, 2006 and conceives January 1, 2005. Inventor 2 reduces to practice August 1, 2006, but conceives April 1, 2005. Patent law wants to know why Inventor 1 reduced to practice after Inventor 2 when Inventor 1 conceived first, implying that Inventor 1 may not have sufficiently pursued reducing his invention to practice. Inventor 1 may rebut an assertion of abandonment by showing he was reasonably diligent in reducing his invention to practice from just prior to Inventor 2’s conception to Inventor 1’s reduction to practice. Another period of time when abandonment and diligence can arise is when there is a relatively long gap between reduction to practice and filing date. The policy of diligence and abandonment—as is much of the policy throughout patent law—is to induce early disclosure of the invention or, at least, disclosure sooner than later. The *Griffith* and *Fujikawa* cases explore these important issues.

GRIFFITH v. KANAMARU

816 F.2d 624 (Fed. Cir. 1987)

NICHOLS, Senior Circuit Judge.

Owen W. Griffith (Griffith) appeals the decision of the Board of Patent Appeals and Interferences (board) (Patent Interference No. 101,562) that Griffith failed to establish a *prima facie* case that he is entitled to an award of priority against the filing date of Tsuneo Kanamaru, *et al.* (Kanamaru) for a patent on aminocarnitine compounds. We affirm.

Background

This patent interference case involves the application of Griffith, an Associate Professor in the Department of Biochemistry at Cornell University Medical College, for a patent on an aminocarnitine compound, useful in the treatment of diabetes, and a patent issued for the same invention to Kanamaru, an employee of Takeda Chemical Industries.

Griffith had established conception by June 30, 1981, and reduction to practice on January 11, 1984. Kanamaru filed for a United States patent on November 17, 1982. The board found, however, that Griffith failed to establish reasonable diligence for a *prima facie* case of prior invention and issued an order to show cause as to why summary judgment should not be issued.

The board considered the additional evidence submitted by Griffith pursuant to the show cause order and decided that Griffith failed to establish a

prima facie case for priority against Kanamaru's filing date. This result was based on the board's conclusion that Griffith's explanation for inactivity between June 15, 1983, and September 13, 1983, failed to provide a legally sufficient excuse to satisfy the "reasonable diligence" requirement of 35 U.S.C. § 102(g). Griffith appeals on the issue of reasonable diligence.

Analysis

I

This is a case of first impression and presents the novel circumstances of a university suggesting that it is reasonable for the public to wait for disclosure until the most satisfactory funding arrangements are made. The applicable law is the "reasonable diligence" standard contained in 35 U.S.C. § 102(g) and we must determine the appropriate role of the courts in construing this exception to the ordinary first-in-time rule.

Griffith must establish a *prima facie* case of reasonable diligence, as well as dates of conception and reduction to practice, to avoid summary judgment on the issue of priority. As a preliminary matter we note that, although the board focused on the June 1983 to September 1983 lapse in work, and Griffith's reasons for this lapse, Griffith is burdened with establishing a *prima facie* case of reasonable diligence from immediately before Kanamaru's filing date of November 17, 1982, until Griffith's reduction to practice on January 11, 1984. 35 U.S.C. § 102(g).

On appeal, Griffith presents two grounds intended to justify his inactivity on the aminocarnitine project between June 15, 1983, and September 13, 1983. The first is that, notwithstanding Cornell University's extraordinary endowment, it is reasonable, and as a policy matter desirable, for Cornell to require Griffith and other research scientists to obtain funding from outside the university. The second reason Griffith presents is that he reasonably waited for Ms. Debora Jenkins to matriculate in the Fall of 1983 to assist with the project. He had promised her she should have that task which she needed to qualify for her degree. We reject these arguments and conclude that Griffith has failed to establish grounds to excuse his inactivity prior to reduction to practice.

II

The reasonable diligence standard balances the interest in rewarding and encouraging invention with the public's interest in the earliest possible disclosure of innovation. Griffith must account for the entire period from just before Kanamaru's filing date until his reduction to practice. As one of our predecessor courts has noted:

Public policy favors the early disclosure of inventions. This underlies the requirement for "reasonable diligence" in reducing an invention to practice, not unlike the requirement that, to avoid a holding of suppression or concealment, there be no unreasonable delay in filing an application once there has been a reduction to practice.

Naber v. Cricchi, 567 F.2d 382, 385 n.5 (CCPA 1977).

The board in this case was, but not properly, asked to pass judgment on the reasonableness of Cornell's policy regarding outside funding of research. The correct inquiry is rather whether it is reasonable for Cornell to require the public to wait for the innovation, given the well settled policy in favor of early

disclosure. As the board notes, Chief Judge Markey has called early public disclosure the “linchpin of the patent system.” *Horwath v. Lee*, 564 F.2d 948, 950 (CCPA 1977). A review of caselaw on excuses for inactivity in reduction to practice reveals a common thread that courts may consider the reasonable everyday problems and limitations encountered by an inventor. *See, e.g., Bey v. Kollonitsch*, 806 F.2d 1024 (Fed. Cir. 1986) (delay in filing excused where attorney worked on a group of related applications and other applications contributed substantially to the preparation of Bey’s application); *Reed v. Tornqvist*, 436 F.2d 501 (CCPA 1971) (concluding it is not unreasonable for inventor to delay completing a patent application until after returning from a three week vacation in Sweden, extended by illness of inventor’s father); *Keizer v. Bradley*, 270 F.2d 396 (1959) (delay excused where inventor, after producing a component for a color television, delayed filing to produce an appropriate receiver for testing the component); *Courson v. O’Connor*, 227 F. 890, 894 (7th Cir.1915) (“exercise of reasonable diligence . . . does not require an inventor to devote his entire time thereto, or to abandon his ordinary means of livelihood”); *De Wallace v. Scott*, 15 App. D.C. 157 (1899) (where applicant made *bona fide* attempts to perfect his invention, applicant’s poor health, responsibility to feed his family, and daily job demands excused his delay in reducing his invention to practice); *Texas Co. v. Globe Oil & Refining Co.*, 112 F. Supp. 455 N.D. Ill. 1953) (delay in filing application excused because of confusion relating to war).

Griffith argues that the admitted inactivity of three months between June 15, 1983, and September 13, 1983, which he attributes to Cornell’s “reasonable” policy requiring outside funding and to Griffith’s “reasonable” decision to delay until a graduate student arrived, falls within legal precedent excusing inactivity in the diligence context. We disagree. We first note that, in regard to waiting for a graduate student, Griffith does not even suggest that he faced a genuine shortage of personnel. He does not suggest that Ms. Jenkins was the *only* person capable of carrying on with the aminocarnitine experiment. We can see no application of precedent to suggest that the convenience of the timing of the semester schedule justifies a three-month delay for the purpose of reasonable diligence. Neither do we believe that this excuse, absent even a suggestion by Griffith that Jenkins was uniquely qualified to do his research, is reasonable.

Griffith’s second contention that it was reasonable for Cornell to require outside funding, therefore causing a delay in order to apply for such funds, is also insufficient to excuse his inactivity. The crux of Griffith’s argument is that outside funding is desirable as a form of peer review, or monitoring of the worthiness of a given project. He also suggests that, as a policy matter, universities should not be treated as businesses, which ultimately would detract from scholarly inquiry. Griffith states that these considerations, if accepted as valid, would fit within the scope of the caselaw excusing inactivity for “reasonable” delays in reduction to practice and filing.

These contentions on delay do not fit within the texture and scope of the precedent cited by the parties or discussed in this opinion. Griffith argues this case is controlled by the outcome of *Litchfield v. Eigen*, 535 F.2d 72 (CCPA 1976). We disagree. In *Litchfield*, Judge Rich held that the inventors failed to establish due diligence because of their inactivity between April 1964 and September 1965. *Id.* at 76-77. The court based this conclusion on the finding that the inventors possessed the capacity to test the invention and chose in-

stead to test other compounds. *Id.* Judge Rich did not reach the issue of the alleged budgetary limitations imposed by the sponsor and stated that the inventors failed to show any evidence of such financial limitations and that, therefore, the court could not consider this contention. *Id.*

Griffith's excuses sound more in the nature of commercial development, not accepted as an excuse for delay, than the "hardship" cases most commonly found and discussed *supra*. Delays in reduction to practice caused by an inventor's efforts to refine an invention to the most marketable and profitable form have not been accepted as sufficient excuses for inactivity. Griffith's case is analogous to that in *Seeberger v. Dodge*, 24 App. D.C. 476 (1905). In that case, the inventor was the first to conceive of an improvement in an escalator and was attempting to show diligence. The court noted:

The testimony shows that he [Seeberger] was a man of means, and might have constructed an escalator had he undertaken to do so. Instead of this, his constant effort was to organize corporations, or to interest capital in other ways, for the purpose of engaging in the general manufacture of escalators.

Id. at 484-85.

The court held this unacceptable:

One having the first complete conception of an invention cannot hold the field against all comers by diligent efforts, merely, to organize and procure sufficient capital to engage in the manufacture of his device or mechanism for commercial purposes. This is a different thing from diligence in actual reduction to practice.

Id. at 485.

The comparison we draw is that Cornell University, like Seeberger, has made a clear decision against funding Griffith's project in order to avoid the risks and distractions, albeit different in each case, that would result from directly financing these inventions. Griffith has placed in the record, and relies on, an able article by President Bok of Harvard, *Business and the Academy*, *Harvard Magazine*, May-June 1981, 31, App. at 81. Bok is explaining the policy issues respecting academic funding of scientific research, for the benefit of Harvard's alumni who must, of course, make up by their contributions the University's annual deficit. While much academic research could produce a profit, pursuit of such profit may be business inappropriate for a university though it would be right and proper for a commercial organization. For example, it might produce conflicts between the roles of scientists as inventors and developers against their roles as members of the university faculty. However large the university's endowment may be, it may be better to enlist private funding and let this source of funds develop the commercial utilization of any invention as perhaps, the beneficial owner. If there is a patent, the source of funds may end up assignee of the patent. It seems also implicit in this policy choice that faculty members may not be allowed single-minded pursuit of reduction to practice whenever they conceive some idea of value, and at times the rights of other inventors may obtain a priority that a single-minded pursuit would have averted. Bok says diligent reduction to practice, to satisfy the patent laws, may interfere with a faculty member's other duties. Bok is asking the approval of his alumni, not of the courts. The management of great universities is one thing, at least, the courts have not taken over and do not deem themselves qualified to undertake. Bok does not ask that the patent laws or other intellectual property law be skewed

or slanted to enable the university to have its cake and eat it too, *i.e.*, to act in a noncommercial manner and yet preserve the pecuniary rewards of commercial exploitation for itself.

If, as we are asked to assume, Cornell also follows the policy Bok has so well articulated, it seems evident that Cornell has consciously chosen to assume the risk that priority in the invention might be lost to an outside inventor, yet, having chosen a noncommercial policy, it asks us to save it the property that would have inured to it if it had acted in single-minded pursuit of gain.

III

The board in this case considered primarily Griffith's contention that the Cornell policy was reasonable and therefore acceptable to excuse his delay in reduction to practice. Although we agree with the board's conclusion, it is appropriate to go further and consider other circumstances as they apply to the reasonable diligence analysis of 35 U.S.C. § 102(g). The record reveals that from the relevant period of November 17, 1982 (Kanamaru's filing date), to September 13, 1983 (when Griffith renewed his efforts towards reduction to practice), Griffith interrupted and often put aside the aminocarnitine project to work on other experiments. Between June 1982 and June 1983 Griffith admits that, at the request of the chairman of his department, he was primarily engaged in an unrelated research project on mitochondrial glutathione metabolism. Griffith also put aside the aminocarnitine experiment to work on a grant proposal on an unrelated project. Griffith's statement in the record that his unrelated grant application, if granted, might "support" a future grant request directed to the aminocarnitine project does not overcome the conclusion that he preferred one project over another and was not "continuously" or "reasonably" diligent. Griffith made only minimal efforts to secure funding directly for the aminocarnitine project.

The conclusion we reach from the record is that the aminocarnitine project was second and often third priority in laboratory research as well as the solicitation of funds. We agree that Griffith failed to establish a *prima facie* case of reasonable diligence or a legally sufficient excuse for inactivity to establish priority over Kanamaru.

FUJIKAWA v. WATTANASIN

93 F.3d 1559 (Fed. Cir. 1996)

CLEVENGER, Circuit Judge.

Yoshihiro Fujikawa *et al.* (Fujikawa) appeal from two decisions of the Board of Patent Appeals and Interferences of the United States Patent & Trademark Office (Board) granting priority of invention in two related interferences to Sompong Wattanasin, and denying Fujikawa's motion to add an additional sub-genus count to the interferences. We affirm.

I

These interferences pertain to a compound and method for inhibiting cholesterol biosynthesis in humans and other animals. The compound count recites a genus of novel mevalonolactones. The method count recites a method of inhibiting the biosynthesis of cholesterol by administering to a

“patient in need of said treatment” an appropriate dosage of a compound falling within the scope of the compound count.

The real parties in interest are Sandoz Pharmaceuticals Corporation (Sandoz), assignee of Wattanasin, and Nissan Chemical Industries, Ltd. (Nissan), assignee of Fujikawa.

The inventive activity of Fujikawa, the senior party, occurred overseas. Fujikawa can thus rely only on his filing date, August 20, 1987, to establish priority. 35 U.S.C. § 102(g) (1994). Whether Wattanasin is entitled to priority as against Fujikawa therefore turns on two discrete questions. First, whether Wattanasin has shown conception coupled with diligence from just prior to Fujikawa’s effective filing date until reduction to practice. *Id.* Second, whether Wattanasin suppressed or concealed the invention between reduction to practice and filing. *Id.* With respect to the first question, Fujikawa does not directly challenge the Board’s holdings on Wattanasin’s conception or diligence, but rather contends that the Board incorrectly fixed the date of Wattanasin’s reduction to practice. As for the second question, Fujikawa contends that the Board erred in concluding that Wattanasin had not suppressed or concealed the invention. Fujikawa seeks reversal, and thus to establish priority in its favor, on either ground.

II

The Board divided Wattanasin’s inventive activity into two phases. The first phase commenced in 1979 when Sandoz began searching for drugs which would inhibit the biosynthesis of cholesterol. Inventor Wattanasin was assigned to this project in 1982, and during 1984-1985 he synthesized three compounds falling within the scope of the compound count. When tested *in vitro*, each of these compounds exhibited some cholesterol-inhibiting activity, although not all the chemicals were equally effective. Still, according to one Sandoz researcher, Dr. Damon, these test results indicated that, to a high probability, the three compounds “would be active when administered *in vivo* to a patient to inhibit cholesterol biosynthesis, *i.e.* for the treatment of hypercholesteremia or atherosclerosis.” Notwithstanding these seemingly positive results, Sandoz shelved Wattanasin’s project for almost two years, apparently because the level of *in vitro* activity in two of the three compounds was disappointingly low.

By January 1987, however, interest in Wattanasin’s invention had revived, and the second phase of activity began. Over the next several months, four more compounds falling within the scope of the compound count were synthesized. In October, these compounds were tested for *in vitro* activity, and each of the four compounds yielded positive results. Again, however, there were significant differences in the level of *in vitro* activity of the four compounds. Two of the compounds in particular, numbered 64-935 and 64-936, exhibited *in vitro* activity significantly higher than that of the other two compounds, numbered 64-933 and 64-934.

Soon after, in December 1987, the three most active compounds *in vitro* were subjected to additional *in vivo* testing. For Sandoz, one primary purpose of these tests was to determine the *in vivo* potency of the three compounds relative to that of Compactin, a prior art compound of known cholesterol-inhibiting potency. From the results of the *in vivo* tests, reproduced in the margin, Sandoz calculated an ED₅₀ for each of the compounds and compared

it to the ED₅₀ of Compactin. Only one of the compounds, compound 64-935, manifested a better ED₅₀ than Compactin: an ED₅₀ of 0.49 as compared to Compactin's ED₅₀ of 3.5. All of the tests performed by Sandoz were conducted in accordance with established protocols.

During this period, Sandoz also began to consider whether, and when, a patent application should be filed for Wattanasin's invention. Several times during the second phase of activity, the Sandoz patent committee considered the question of Wattanasin's invention but decided that it was too early in the invention's development to file a patent application. Each time, however, the patent committee merely deferred decision on the matter and specified that it would be taken up again at subsequent meetings. Finally, in January 1988, with the *in vivo* testing completed, the Committee assigned Wattanasin's invention an "A" rating which meant that the invention was ripe for filing and that a patent application should be prepared. The case was assigned to a Ms. Geisser, a young patent attorney in the Sandoz patent department with little experience in the pharmaceutical field.

Over the next several months the Sandoz patent department collected additional data from the inventor which was needed to prepare the patent application. This data gathering took until approximately the end of May 1988. At that point, work on the case seems to have ceased for several months until Ms. Geisser began preparing a draft sometime in the latter half of 1988. The parties dispute when this preparation began. Fujikawa contends that it occurred as late as October, and that Ms. Geisser was spurred to begin preparing the draft application by the discovery that a patent to the same subject matter had been issued to a third party, Picard. Fujikawa, however, has no evidence to support that contention. In contrast, Sandoz contends that Ms. Geisser began the draft as early as August, and that she was already working on the draft when she first heard of Picard's patent. The evidence of record, and in particular the testimony of Ms. Geisser, supports that version of events. In any event, the draft was completed in November and, after several turn-arounds with the inventor, ultimately filed in March of 1989.

Both Wattanasin and Fujikawa requested an interference with Picard. The requests were granted and a three-party interference between Picard, Fujikawa, and Wattanasin was set up. Early in the proceedings, however, Picard filed a request for an adverse judgment presumably because he could not antedate Fujikawa's priority date. What remained was a two-party interference between Fujikawa and Wattanasin. Ultimately, for reasons not significant to this appeal, the interference was divided into two interferences: one relating to the method count and one relating to the compound count. The Board decided each of these interferences adverse to Fujikawa.

With respect to the compound count, the Board made two alternative findings regarding reduction to practice. First, it found that the *in vitro* results in October 1987 showed sufficient practical utility for the compound so as to constitute a reduction to practice as of the date of those tests. In the alternative, the Board held, the *in vivo* tests which showed significant activity in the 64-935 compound at doses of 1.0 and 0.1 mg were sufficient to show practical utility. Consequently, Wattanasin had reduced the compound to practice, at the latest, as of December 1987. Since Fujikawa did not challenge Wattanasin's diligence for the period between Fujikawa's effective filing date of August 20, 1987 and Wattanasin's reduction to practice in either October or

December 1987, the Board held that Wattanasin was *de facto* the first inventor of the compound count. Finally, the Board found that the seventeen month period (counting from the *in vitro* testing) or fifteen month period (counting from the *in vivo* testing) between Wattanasin's reduction to practice and filing was not sufficient to raise an inference of suppression or concealment given the complexity of the invention, and therefore awarded priority of the compound count to Wattanasin. In reaching this conclusion, the Board rejected Fujikawa's argument that Wattanasin was spurred to file by Picard because it held that spurring by Picard, a third party, had no legal effect in a priority dispute between Fujikawa and Wattanasin.

With respect to the method count, the Board determined that Wattanasin reduced to practice in December 1987 on the date that *in vivo* testing of the 64-935 compound was concluded. In reaching that conclusion, the Board first noted that a reduction to practice must include every limitation of the count. Consequently, Wattanasin's early *in vitro* testing could not constitute a reduction to practice of the method count, since that count recites administering the compound to a "patient." The *in vivo* testing, however, met the limitations of the count since the word "patient" was sufficiently broad to include the laboratory rats to whom the compounds were administered. The *in vivo* testing also proved that 64-935 had practical utility because the compound displayed significant cholesterol inhibiting activity at doses of 1.0 and 0.1 mg. Given this date of reduction to practice, the Board again held that Wattanasin was the *de facto* first inventor of the count and that the delay in filing of fifteen months was not sufficient to trigger an inference of suppression or concealment. The Board therefore awarded priority of the method count to Wattanasin.

III.

* * *

B.

Turning to the method count, the Board found that Wattanasin reduced the method to practice in December 1987 when successful *in vivo* testing of the compound was completed. This finding, too, was based on testimony that the *in vivo* data for one of the compounds tested, 64-935, showed significant cholesterol inhibiting activity in the laboratory rats tested.

Fujikawa challenges the Board's holding by referring to an anomaly in the test data of the 64-935 compound which it contends undercuts the reliability of the *in vivo* tests. In particular, Fujikawa points to the fact that the compound's potency was less at a dosage of 0.3 mg than it was at a dosage of 0.1 mg. On the basis of this aberration, Fujikawa's expert, Dr. Holmlund, testified that this test data was unreliable and could not support a finding that the compound was pharmacologically active.

It is clear from the Board's opinion, however, that to the extent Dr. Holmlund was testifying that this aberration would lead one of ordinary skill to completely reject these test results, the Board did not accept his testimony. This decision of the Board was not clear error. Admittedly, the decreased potency at 0.3 mg is curious. The question remains, however, as to how much this glitch in the data would undercut the persuasiveness of the test results as a whole in the mind of one of ordinary skill. Each party presented

evidence on this point and the Board resolved this disputed question of fact by finding that the test results as a whole were sufficient to establish pharmacological activity in the minds of those skilled in the art. In doing so, the Board properly exercised its duty as fact finder, and we therefore affirm its finding on this point.

As noted above, Fujikawa does not challenge the Board's conclusions that Wattanasin conceived prior to Fujikawa's effective date or that Wattanasin pursued his invention with diligence prior to Fujikawa's date until his reductions to practice in October and December 1987. Consequently, we affirm the Board's finding that Wattanasin has shown conception coupled with diligence from just prior to Fujikawa's effective date of August 20, 1987 up to the date he reduced the invention to practice in October 1987, for the compound, or December 1987, for the method.

IV

Having determined that Wattanasin was the *de facto* first inventor, the remaining question before the Board was whether Wattanasin had suppressed or concealed the invention between the time he reduced to practice and the time he filed his patent application. Suppression or concealment of the invention by Wattanasin would entitle Fujikawa to priority. 35 U.S.C. § 102(g).

Suppression or concealment is a question of law which we review *de novo*. Our case law distinguishes between two types of suppression and concealment: cases in which the inventor deliberately suppresses or conceals his invention, and cases in which a legal inference of suppression or concealment is drawn based on "too long" a delay in filing a patent application.

Fujikawa first argues that there is evidence of intentional suppression or concealment in this case. Intentional suppression refers to situations in which an inventor "designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public." *Id.* (quoting *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858)). Admittedly, Sandoz was not overly efficient in preparing a patent application, given the time which elapsed between its reduction to practice in late 1987 and its ultimate filing in March 1989. Intentional suppression, however, requires more than the passage of time. It requires evidence that the inventor intentionally delayed filing in order to prolong the period during which the invention is maintained in secret. Fujikawa presented no evidence that Wattanasin delayed filing for this purpose. On the contrary, all indications are that throughout the period between reduction to practice and filing, Sandoz moved slowly (one might even say fitfully), but inexorably, toward disclosure. We therefore hold that Wattanasin did not intentionally suppress or conceal the invention in this case.

Absent intentional suppression, the only question is whether the 17 month period between the reduction to practice of the compound, or the 15 month period between reduction to practice of the method, and Wattanasin's filing justify an inference of suppression or concealment. *See id.* The Board held that these facts do not support such an inference. As the Board explained: "In our view, this hiatus in time is not sufficiently long to raise the inference that Wattanasin suppressed or concealed the invention considering the nature and complexity of the invention here."

Fujikawa attacks this finding of the Board on two grounds. First, it contends that the Board should not have held that a 15 or 17 month delay is *per se* insufficient to raise an inference of suppression or concealment without examining the circumstances surrounding the delay and whether, in view of those circumstances, Wattanasin's delay was reasonable. Second, Fujikawa argues that the Board failed to consider evidence that Wattanasin was spurred to file by the issuance of a patent to a third party, Picard, directed to the same genus of compounds invented by Wattanasin. Evidence that a first inventor was spurred to disclose by the activities of a second inventor has always been an important factor in priority determinations because it creates an inference that, but for the efforts of the second inventor, "the public would never have gained knowledge of [the invention]." *Brokaw*, 429 F.2d at 480. Here, however, the Board expressly declined to consider the evidence of spurring because it held that spurring by a third party who is not a party to the interference is irrelevant to a determination of priority as between Wattanasin and Fujikawa. We first address Fujikawa's arguments concerning spurring.

A

We are not certain that the Board is correct that third party spurring is irrelevant in determining priority. After all, "[w]hat is involved here is a policy question as to which of the two rival inventors has the greater right to a patent." *Brokaw*, 429 F.2d at 480. Resolution of this question could well be affected by the fact that one of the inventors chose to maintain his invention in secrecy until disclosure by another spurred him to file, even when the spurrier was a third party not involved in the interference. We need not resolve that question here, however, because we hold that no reasonable fact finder could have found spurring on the facts of this case. The only evidence in the record on the question of spurring is the testimony of Ms. Geisser who expressly testified that she had already begun work on the Wattanasin draft application before she learned of Picard's patent, in other words, that she had not been spurred by Picard. Consequently, we leave the question of the relevance of third-party spurring for another case.

B

Fujikawa's other argument also requires us to examine the evidence of record in this case. As Fujikawa correctly notes, this court has not set strict time limits regarding the minimum and maximum periods necessary to establish an inference of suppression or concealment. Rather, we have recognized that "it is not the time elapsed that is the controlling factor but the total conduct of the first inventor." *Young v. Dworkin*, 489 F.2d 1277, 1285 (CCPA 1974) (Rich, J., concurring). Thus, the circumstances surrounding the first inventor's delay and the reasonableness of that delay are important factors which must be considered in deciding questions of suppression or concealment.

Fujikawa again correctly notes that the Board's opinion gives short shrift to the question of whether this delay on the facts of this case was reasonable. In seeking reversal of the Board's decision, Fujikawa asks us to assess the factual record for ourselves to determine whether Wattanasin engaged in sufficient disclosure-related activity to justify his 17-month delay in filing.

The facts of record, however, do not support Fujikawa's position.

In our view, the circumstances in this case place it squarely within the class of cases in which an inference of suppression or concealment is not warranted. We acknowledge, of course, that each case of suppression or concealment must be decided on its own facts. Still, the rich and varied case law which this court has developed over many years provides some guidance as to the type of behavior which warrants an inference of suppression or concealment. In this case Wattanasin delayed approximately 17 months between reduction to practice and filing. During much of that period, however, Wattanasin and Sandoz engaged in significant steps towards perfecting the invention and preparing an application. For example, we do not believe any lack of diligence can be ascribed to Wattanasin for the period between October and December 1987 when *in vivo* testing of the invention was taking place. *See Young*. Similarly, at its first opportunity following the *in vivo* testing, the Sandoz patent committee approved Wattanasin's invention for filing. This takes us up to the end of January 1988.

Over the next several months, until May 1988, the Sandoz patent department engaged in the necessary collection of data from the inventor and others in order to prepare Wattanasin's patent application. We are satisfied from the record that this disclosure-related activity was sufficient to avoid any inference of suppression or concealment during this period. Also, as noted above, the record indicates that by August 1988, Ms. Geisser was already at work preparing the application, and that work continued on various drafts until Wattanasin's filing date in March 1989. Thus, the only real period of unexplained delay in this case is the approximately three month period between May and August of 1988.

Given a total delay of 17 months, an unexplained delay of three months, the complexity of the subject matter at issue, and our sense from the record as a whole that throughout the delay Sandoz was moving, albeit slowly, towards filing an application, we conclude that this case does not warrant an inference of suppression or concealment. Consequently, we affirm the Board on this point.

C

Finally, Fujikawa contends that assuming *in vitro* tests are sufficient to establish reduction to practice, Wattanasin reduced the compound count to practice in 1984 when he completed *in vitro* testing of his first three compounds falling within the scope of the count. If so, Fujikawa argues, the delay between reduction to practice and filing was greater than four years, and an inference of suppression or concealment is justified.⁹

We reject this argument in view of *Paulik v. Rizkalla*. In *Paulik*, we held that a suppression or concealment could be negated by renewed activity prior to an opposing party's effective date. There, inventor Paulik reduced his invention to practice and submitted an invention disclosure to his employer's patent department. For four years the patent department did nothing with the disclosure. Then, just two months before Rizkalla's effective date, the patent department allegedly picked up Paulik's disclosure and worked diligently to prepare a patent application which it ultimately filed. *See id.* We held that although Paulik could not rely on his original date of reduction to

9. This argument, of course, relates only to the compound count, since, as explained above, the method count was not reduced to practice until the *in vivo* testing in December 1987.

practice to establish priority, he could rely on the date of renewed activity in his priority contest with Rizkalla. In large measure, this decision was driven by the court's concern that denying an inventor the benefit of his renewed activity, might "discourage inventors and their supporters from working on projects that had been 'too long' set aside, because of the impossibility of relying, in a priority contest, on either their original work or their renewed work." *Id.* at 1275-76.

Paulik's reasoning, if not its holding, applies squarely to this case. A simple hypothetical illustrates why this is so. Imagine a situation similar to the one facing Sandoz in early 1987. A decisionmaker with limited funds must decide whether additional research funds should be committed to a project which has been neglected for over two years. In making this decision, the decisionmaker would certainly take into account the likelihood that the additional research might yield valuable patent rights. Furthermore, in evaluating the probability of securing those patent rights, an important consideration would be the earliest priority date to which the research would be entitled, especially in situations where the decisionmaker knows that he and his competitors are "racing" toward a common goal. Thus, the right to rely on renewed activity for purposes of priority would encourage the decisionmaker to fund the additional research. Conversely, denying an inventor the benefit of renewed activity would discourage the decisionmaker from funding the additional research.

Here, Wattanasin returned to his abandoned project well before Fujikawa's effective date and worked diligently towards reducing the invention to practice a second time. For the reasons explained above, we hold that, on these facts, Wattanasin's earlier reduction to practice in 1984 does not bar him from relying on his earliest date of renewed activity for purposes of priority.

Comments

1. **Diligence.** Diligence is not always a relevant when proving date of invention. It becomes important when a party is the first to conceive, but the second to reduce practice. (Recall, Griffith conceived first, but reduced to practice after Kanamaru, and therefore was required to prove diligence.) The diligence requirement wants to know what the party (*e.g.*, Griffith)—who was first to conceive—was doing between his conception and reduction to practice.

Diligence is measured from the time just prior to conception of the party who first reduced to practice (Party B) and ends at the reduction to practice date of the party who first conceived (Party A), *i.e.*, the party attempting to prove diligence. Oftentimes, Party B cannot prove a conception date. In this situation, Party's B's conception date is merged into its reduction to practice date, which can be either actual or constructive reduction to practice (the application filing date). And diligence is measured just prior to reduction to practice of Party B. The inventor does not need to show a continuous effort; he must provide an explanation for the entire period in question. There are a variety of ways to prove diligence, including ongoing laboratory experimentation. The question is whether the applicant was pursuing his goal in a reasonable manner.

2. **Abandonment.** As shown in *Mahurkar*, a party who is the first to reduce to practice is considered the first to invent. But, an inventor who abandons his invention—even though he is the first to reduce to practice—may lose his right of priority. Abandonment is consistent with the foundational policy of early disclosure that is built in to several other patent law doctrines. An applicant can abandon either explicitly or the court could infer abandonment if the applicant was dilatory. Importantly, delay (unless extremely excessive) alone is typically not enough to infer abandonment.
3. **Foreign-Based Inventive Activity.** In the *Fujikawa* case, note that Fujikawa's earliest invention date is the date he filed his application in the U.S. This is because, as discussed in the Comments following *Mahurkar*, at the time the case was decided, U.S. patent law, namely § 104, did not allow for foreign inventive activity such as conception and reduction to practice to be used to prove an earlier date of invention; conception and reduction to practice had to occur in the U.S. for it to be used as proof of date of invention. This is also the most likely explanation as to why Kanamaru relied on his U.S. filing date, rather than earlier conception and actual reduction to practice—both of which likely occurred in Japan.

CHAPTER

5

Statutory Bars

INTRODUCTION

This chapter is concerned with *statutory bars*, which are embodied in 35 U.S.C. § 102(b).¹ Under § 102(b), an inventor will be barred from obtaining a patent if, more than one year before the filing date of his patent application, he or a third-party sells, offers for sale, or publicly uses the claimed invention (or an obvious variation thereof) in the United States, or patents, or describes in a printed publication the claimed invention (or an obvious variation thereof) anywhere in the world. Statutory bars operate independently of novelty, and thus can attach even if an inventor satisfies the novelty requirement. The timeframe for statutory bars is one year before the application is filed; this date is known as the *critical date*. Thus, § 102(b) focuses on inventor and third-party activity prior to the critical date.

The idea that an inventor can engage in activity that defeats his patent rights dates back to the late 18th century. Under Section 1 of the Patent Act of 1793, an inventor was entitled to a patent if, among other things, his invention was not in use before the date of application. In the historically important case of *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), Justice Story—patent law’s great 19th century jurist—gave meaning to this language and identified its underlying policies, thus providing a rationale for what is today § 102(b) and statutory bars. Justice Story expressed a utilitarian view of the patent system, one designed primarily to promote the public good.² And this goal could be

1. Section 102(d) is also a statutory bar section, and applies to an applicant who first files and obtains a patent in a foreign jurisdiction, and then files in the U.S. more than 12 months after filing in the foreign jurisdiction. In particular, § 102(d) applies (1) when an applicant obtains a foreign patent before filing in the U.S. and (2) files in the U.S. 12 months after filing in the foreign jurisdiction. Section 102(d) is relatively insignificant compared to § 102(b), and therefore is not covered in this chapter.

2. In cases prior to *Pennock*, Justice Story expressed more of a natural rights theory. In *Lowell v. Lewis*, for example, he wrote that “let the damages be estimated as high, as they can be, consistently with the rule of law on this subject, if the plaintiff’s patent has been violated; wrongdoers may not reap the fruits of the labor and genius of other men.” 15 F. Cas. 1018, 1019 (C.C. Mass. 1817). See also *Ex parte Wood*, 22 U.S. 603, 608 (1824) (stating “[t]he inventor has . . . a property in his inventions; a property which is often of very great value, and of which the law intended to give him the absolute enjoyment and possession”).

furthered by disclosing to the public innovations “at as early a period as possible, having a due regard to the rights of the inventor.” *Id.* at 19. With this premise, Justice Story stressed that an inventor should not be “permitted to hold back from the knowledge of the public the secrets of his invention,” while also commercially exploiting his invention, because:

if he should for a long period of years retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure; and then, and then only, when the danger of competition should force him to secure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any farther use than what should be derived under it during his fourteen years; it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.

Id. at 19. Promoting early disclosure, preventing the removal of inventions from the public that the public have justifiably come to expect are freely available, and preventing the inventor from commercially exploiting the exclusivity of his invention beyond the statutory term are policies underlying § 102(b), and are as relevant today as they were in the 19th century. The Federal Circuit has identified an additional policy, namely giving “the inventor a reasonable amount of time following sales activity (set by statute as 1 year) to determine whether a patent is a worthwhile investment.” *General Electric Co. v. United States*, 654 F.2d 55, 61 (Ct. Cl. 1981).

Keep these policies in mind as you proceed through the materials in this chapter. The two principal statutory bars under § 102(b) are on-sale and public use, which are addressed in Sections A and B, respectively.

STATUTE: Conditions for patentability; novelty and loss of right to patent

35 U.S.C. § 102(b)

A. ON-SALE BAR

Under § 102(b), an inventor will be barred from obtaining patent rights if he or a third party sold or offered for sale the claimed invention more than one year before the patent application is filed. This is known as the “on-sale” bar, which, while easy enough to state, contains numerous sub-issues that have been the subject of extensive litigation. For instance, what constitutes an “offer” under § 102(b)? Does the offer have to be “accepted” for the bar to apply? How are licenses and assignments treated? These questions are addressed in the principal case, *Plumtree*, and the Comments that follow.

An additional issue—and perhaps the most difficult—is, assuming an offer is made, at what developmental stage must an invention be before the one-year clock is triggered? Does the invention have to be built and work for its intended purpose; a mere conception; or somewhere in between? The issue of developmental stage of invention and why it is important are explored in *Pfaff*, *Space Systems*, and the Comments thereafter.

1. Developmental Stage of the Claimed Invention

PFAFF v. WELLS ELECTRONICS

525 U.S. 55 (1998)

STEVENS, J., delivered the opinion for a unanimous Court.

Section 102(b) of the Patent Act of 1952 provides that no person is entitled to patent an “invention” that has been “on sale” more than one year before filing a patent application. We granted certiorari to determine whether the commercial marketing of a newly invented product may mark the beginning of the 1-year period even though the invention has not yet been reduced to practice.

I

On April 19, 1982, petitioner, Wayne Pfaff, filed an application for a patent on a computer chip socket. Therefore, April 19, 1981, constitutes the critical date for purposes of the on-sale bar of 35 U.S.C. § 102(b); if the 1-year period began to run before that date, Pfaff lost his right to patent his invention.

Pfaff commenced work on the socket in November 1980, when representatives of Texas Instruments asked him to develop a new device for mounting and removing semiconductor chip carriers. In response to this request, he prepared detailed engineering drawings that described the design, the dimensions, and the materials to be used in making the socket. Pfaff sent those drawings to a manufacturer in February or March 1981.

Prior to March 17, 1981, Pfaff showed a sketch of his concept to representatives of Texas Instruments. On April 8, 1981, they provided Pfaff with a written confirmation of a previously placed oral purchase order for 30,100 of his new sockets for a total price of \$91,155. In accord with his normal practice, Pfaff did not make and test a prototype of the new device before offering to sell it in commercial quantities.³

The manufacturer took several months to develop the customized tooling necessary to produce the device, and Pfaff did not fill the order until July 1981. The evidence therefore indicates that Pfaff first reduced his invention to practice in the summer of 1981. The socket achieved substantial commercial success before Patent No. 4,491,377 (the ‘377 patent) issued to Pfaff on January 1, 1985.⁴

3. At his deposition, respondent’s counsel engaged in the following colloquy with Pfaff:

Q: Now, at this time [late 1980 or early 1981] did we [sic] have any prototypes developed or anything of that nature, working embodiment?

A: No.

Q: It was in a drawing. Is that correct?

A: Strictly in a drawing. Went from the drawing to the hard tooling. That’s the way I do my business.

Q: “Boom boom”?

A: You got it.

Q: You are satisfied, obviously, when you come up with some drawings that it is going to go — “it works”?

A: I know what I’m doing, yes, most of the time.

4. Initial sales of the patented device were:

1981 \$350,000

1982 \$937,000

After the patent issued, petitioner brought an infringement action against respondent, Wells Electronics, Inc., the manufacturer of a competing socket. Wells prevailed on the basis of a finding of no infringement. When respondent began to market a modified device, petitioner brought this suit, alleging that the modifications infringed six of the claims in the '377 patent.

After a full evidentiary hearing before a Special Master, the District Court held that two of those claims (1 and 6) were invalid because they had been anticipated in the prior art. Nevertheless, the court concluded that four other claims (7, 10, 11, and 19) were valid and three (7, 10, and 11) were infringed by various models of respondent's sockets. Adopting the Special Master's findings, the District Court rejected respondent's § 102(b) defense because Pfaff had filed the application for the '377 patent less than a year after reducing the invention to practice.

The Court of Appeals reversed, finding all six claims invalid. Four of the claims (1, 6, 7, and 10) described the socket that Pfaff had sold to Texas Instruments prior to April 8, 1981. Because that device had been offered for sale on a commercial basis more than one year before the patent application was filed on April 19, 1982, the court concluded that those claims were invalid under § 102(b). That conclusion rested on the court's view that as long as the invention was "substantially complete at the time of sale," the 1-year period began to run, even though the invention had not yet been reduced to practice.

Because other courts have held or assumed that an invention cannot be "on sale" within the meaning of § 102(b) unless and until it has been reduced to practice, *see, e.g., Timely Products Corp. v. Arron*, 523 F.2d 288, 299-302 (C.A.2 1975), and because the text of § 102(b) makes no reference to "substantial completion" of an invention, we granted *certiorari*.

II

The primary meaning of the word "invention" in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea. The statute does not contain any express requirement that an invention must be reduced to practice before it can be patented. Neither the statutory definition of the term in § 100 nor the basic conditions for obtaining a patent set forth in § 101 make any mention of "reduction to practice." The statute's only specific reference to that term is found in § 102(g), which sets forth the standard for resolving priority contests between two competing claimants to a patent. That subsection provides:

In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Thus, assuming diligence on the part of the applicant, it is normally the first inventor to conceive, rather than the first to reduce to practice, who establishes the right to the patent.

It is well settled that an invention may be patented before it is reduced to practice. In 1888, this Court upheld a patent issued to Alexander Graham Bell

even though he had filed his application before constructing a working telephone. Chief Justice Waite's reasoning in that case merits quoting at length:

It is quite true that when Bell applied for his patent he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line, but in his specification he did describe accurately and with admirable clearness his process, that is to say, the exact electrical condition that must be created to accomplish his purpose, and he also described, with sufficient precision to enable one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect, receive the words, and carry them to and deliver them at the appointed place. The particular instrument which he had, and which he used in his experiments, did not, under the circumstances in which it was tried, reproduce the words spoken, so that they could be clearly understood, but the proof is abundant and of the most convincing character, that other instruments, carefully constructed and made exactly in accordance with the specification, without any additions whatever, have operated and will operate successfully. A good mechanic of proper skill in matters of the kind can take the patent and, by following the specification strictly, can, without more, construct an apparatus which, when used in the way pointed out, will do all that it is claimed the method or process will do. . . .

The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection. It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation. *The Telephone Cases*, 126 U.S. 1, 535-536 (1888).

When we apply the reasoning of *The Telephone Cases* to the facts of the case before us today, it is evident that Pfaff could have obtained a patent on his novel socket when he accepted the purchase order from Texas Instruments for 30,100 units. At that time he provided the manufacturer with a description and drawings that had "sufficient clearness and precision to enable those skilled in the matter" to produce the device. The parties agree that the sockets manufactured to fill that order embody Pfaff's conception as set forth in claims 1, 6, 7, and 10 of the '377 patent. We can find no basis in the text of § 102(b) or in the facts of this case for concluding that Pfaff's invention was not "on sale" within the meaning of the statute until after it had been reduced to practice.

III

Pfaff nevertheless argues that longstanding precedent, buttressed by the strong interest in providing inventors with a clear standard identifying the onset of the 1-year period, justifies a special interpretation of the word "invention" as used in § 102(b). We are persuaded that this nontextual argument should be rejected.

As we have often explained, most recently in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989), the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time. The balance between the interest in motivating innovation and enlightenment by rewarding invention with patent

protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception.

Consistent with these ends, § 102 of the Patent Act serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term.

We originally held that an inventor loses his right to a patent if he puts his invention into public use before filing a patent application. “His voluntary act or acquiescence in the public sale and use is an abandonment of his right” *Pennock v. Dialogue*, 2 Pet. 1, 24 (1829) (Story, J.). A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar.

Nevertheless, an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially. In 1878, we explained why patentability may turn on an inventor’s use of his product.

It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. *Any attempt to use it for a profit, and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent.* *Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877) (emphasis added).

The patent laws therefore seek both to protect the public’s right to retain knowledge already in the public domain and the inventor’s right to control whether and when he may patent his invention. The Patent Act of 1836, 5 Stat. 117, was the first statute that expressly included an on sale bar to the issuance of a patent. Like the earlier holding in *Pennock*, that provision precluded patentability if the invention had been placed on sale at any time before the patent application was filed. In 1839, Congress ameliorated that requirement by enacting a 2-year grace period in which the inventor could file an application.

In *Andrews v. Hovey*, 123 U.S. 267, 274 (1887), we noted that the purpose of that amendment was “to fix a period of limitation which should be certain”; it required the inventor to make sure that a patent application was filed “within two years from the completion of his invention,” *ibid.* In 1939, Congress reduced the grace period from two years to one year.

Petitioner correctly argues that these provisions identify an interest in providing inventors with a definite standard for determining when a patent

application must be filed. A rule that makes the timeliness of an application depend on the date when an invention is “substantially complete” seriously undermines the interest in certainty.¹¹ Moreover, such a rule finds no support in the text of the statute. Thus, petitioner’s argument calls into question the standard applied by the Court of Appeals, but it does not persuade us that it is necessary to engraft a reduction to practice element into the meaning of the term “invention” as used in § 102(b).

The word “invention” must refer to a concept that is complete, rather than merely one that is “substantially complete.” It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of *The Telephone Cases* and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.

We conclude, therefore, that the on sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. An inventor can both understand and control the timing of the first commercial marketing of his invention. The experimental use doctrine, for example, has not generated concerns about indefiniteness, and we perceive no reason why unmanageable uncertainty should attend a rule that measures the application of the on sale bar of § 102(b) against the date when an invention that is ready for patenting is first marketed commercially. In this case the acceptance of the purchase order prior to April 8, 1981, makes it clear that such an offer had been made, and there is no question that the sale was commercial rather than experimental in character.

Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.¹⁴ In this

11. The Federal Circuit has developed a multifactor, “totality of the circumstances” test to determine the trigger for the on sale bar. *See, e.g., Micro Chemical, Inc. v. Great Plains Chemical Co.*, 103 F.3d 1538, 1544 (C.A. Fed. 1997) (stating that, in determining whether an invention is on sale for purposes of 102(b), “all of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighed against the policies underlying section 102(b)”)”; *see also UMC Electronics Co. v. United States*, 816 F.2d 647, 656 (1987) (stating the on sale bar “does not lend itself to formulation into a set of precise requirements”). As the Federal Circuit itself has noted, this test “has been criticized as unnecessarily vague.” *Seal Flex, Inc. v. Athletic Track & Court Construction*, 98 F.3d 1318, 1323, n.2 (C.A. Fed. 1996).

14. The Solicitor General has argued that the rule governing on sale bar should be phrased somewhat differently. In his opinion, “if the sale or offer in question embodies the invention for which a patent is later sought, a sale or offer to sell that is primarily for commercial purposes and that occurs more than one year before the application renders the invention unpatentable. *Seal Flex, Inc. v. Athletic Track and Court Constr.*, 98 F.3d 1318, 1325 (Fed. Cir. 1996) (Bryson, J., concurring in part and concurring in the result).” It is true that evidence satisfying this test might be sufficient to prove that the invention was ready for patenting at the time of the sale if it is clear that no aspect of the invention was developed after the critical date. However, the possibility of additional development after the offer for sale in these circumstances counsels against adoption of the rule proposed by the Solicitor General.

case the second condition of the on sale bar is satisfied because the drawings Pfaff sent to the manufacturer before the critical date fully disclosed the invention.

The evidence in this case thus fulfills the two essential conditions of the on sale bar. As succinctly stated by Learned Hand:

[I]t is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly. *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (C.A. 2 1946).

The judgment of the Court of Appeals finds support not only in the text of the statute but also in the basic policies underlying the statutory scheme, including § 102(b). When Pfaff accepted the purchase order for his new sockets prior to April 8, 1981, his invention was ready for patenting. The fact that the manufacturer was able to produce the socket using his detailed drawings and specifications demonstrates this fact. Furthermore, those sockets contained all the elements of the invention claimed in the '377 patent. Therefore, Pfaff's '377 patent is invalid because the invention had been on sale for more than one year in this country before he filed his patent application. Accordingly, the judgment of the Court of Appeals is affirmed.

SPACE SYSTEMS/LORAL, INC. v. LOCKHEED MARTIN CORP.

271 F.3d 1076 (Fed. Cir. 2001)

NEWMAN, Circuit Judge.

Space Systems/Loral, Inc. (herein "SSL") appeals the decision of the United States District Court for the Northern District of California, granting summary judgment in favor of Lockheed Martin Corporation based on the court's ruling of invalidity of SSL's United States Patent No. 4,537,375. Because the district court misapplied the law of "on sale," 35 U.S.C. § 102(b), we reverse the summary judgment and remand for further proceedings.

BACKGROUND

The '375 patent is directed to an attitude control system for maintaining the position and orientation of a satellite. A satellite in orbit may drift out of position due to influences such as gravitational effects of the sun and moon and pressure from the solar wind, generally called "disturbance transients." To return the satellite to its correct orbit and orientation various on-board devices are employed, such as momentum/reaction wheels or thrusters, which are small rocket engines. Such corrective maneuvers are called "station keeping." Imbalances in thruster power or misalignments with respect to the satellite's center of mass, which may change as fuel is consumed, tend to introduce new errors in position or orientation during station keeping maneuvers. Such new errors require further correction after the primary correcting maneuver is made. The novel method of station keeping de-

scribed in the '375 patent is called the "prebias" technique. By this technique a correction for thruster imbalances is made before the primary station keeping maneuver is performed, using data stored from previous maneuvers. If any attitude inaccuracies remain they are subjected to a further correction, but as a result of the prebias step substantially less fuel is required overall than would be consumed without the prebias compensatory action. Conservation of on-board fuel prolongs the effective life of a satellite. . . . The district court held that the invention claimed in the '375 patent was on sale more than one year before the patent application was filed, rendering the patent invalid pursuant to § 102(b). Since the '375 application date is April 21, 1983, the "critical date" for the on sale bar is April 21, 1982.

The relevant events are not in dispute. Ford Aerospace and Communications Corp., a predecessor of SSL and the initial assignee of the '375 patent, entered into a contract with Société Nationale Industrielle Aérospatiale, a French company that had contracted with the Arab Satellite Communications Organization to develop the "Arabsat" satellite system. Ford was responsible for several aspects of the Arabsat system, including the satellite attitude control system.

Dr. Fred Chan, a Ford employee, conceived of the prebias method of satellite station keeping as a potential improvement over the design that was originally intended to be used. On March 19, 1982 Ford sent Aérospatiale a document entitled "Engineering Change Proposal" (ECP) which described the prebiasing idea and how Dr. Chan proposed to achieve it, by the steps of storing an estimated disturbance torque, performing a first thruster modulation in response to the stored value, detecting the net position error, and then performing a second modulation in response to the net position error and the stored value. Included were Dr. Chan's rough drawings, along with an estimate of the cost of developing the system. The district court held that this submission was an invalidating on sale event. Applying *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, (1998), the court ruled that the ECP was a commercial offer of sale, and that the invention was ready for patenting because "SSL admitt[ed] that Dr. Chan had legal conception of every element of every claim of the '375 patent at the time the ECP was submitted to Aérospatiale." The court held that it was irrelevant that the inventor was uncertain whether the system could be made to work.

DISCUSSION

In this case there was no dispute as to what transpired; the issue was whether the criteria of the on sale bar were met. In *Pfaff, supra*, the Supreme Court held that the on sale bar arises when the invention is both (1) ready for patenting and (2) the subject of a commercial offer for sale. SSL states that neither of these criteria was met. SSL states that at the time the engineering proposal was sent to Aérospatiale and for many months thereafter, Dr. Chan's idea was not ready for patenting for its feasibility was not yet known and it had

not been enabled. Dr. Chan testified that at the time he sent the proposal to Aerospatiale he had conceived of the idea but he did not know whether he could make it work. He testified that the method for generating a value had to be developed, and that he was not sure he could establish a stable control loop. He stated that it was not until many months later, after development and testing of an engineering model, that he determined that the idea would work.

Lockheed presented no evidence disputing Dr. Chan's testimony, and does not assign error to the district court's statement that it could not conclude as a matter of law that the engineering proposal was an "enabling disclosure." Instead, Lockheed states that the bar arises, as a matter of law, "if an inventor offers for sale a product which has reached the 'conception stage.'" Lockheed stresses that "Because SSL had conceived the invention as of March 19, 1982, it could have filed a patent application—the invention was ready for patenting." Lockheed states that conception embraces enablement, and since SSL conceded conception at the time of the Engineering Change Proposal, it also conceded enablement. Thus Lockheed led the district court into error, for the district court ruled that all that is required for an invention to be ready for patenting is "legal conception of every element of every claim." The court described "legal conception" as a mental act, and held that it is not necessary to enable an invention that is fully conceived, in order for the invention to be ready for patenting. Lockheed states that this is the law of *Pfaff*. That is incorrect.

In *Pfaff* the Court explained that two ways to show that an invention is ready for patenting are if it has been actually reduced to practice, or if "prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." 525 U.S. at 67-68. The Court noted that it must be "clear that no aspect of the invention was developed after the critical date." *Id.* at 68 n.14.

Lockheed argues that Dr. Chan's rough drawings showed the essential principles of the invention, although in lesser detail than was later available and included in the patent application. SSL responds that many months of development were required in order to learn the information that was essential to an operable invention, and that the drawings do not show an enabled invention. Lockheed states that its position that conception alone suffices in order to satisfy the *Pfaff* requirement of ready for patenting is supported by the Court's statements in *Pfaff* that "invention . . . refers to the inventor's conception rather than to a physical embodiment of [the] idea," 525 U.S. at 60. However, the Court in defining "invention" was not saying that conception alone equals "ready for patenting." The Court later explained that "The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.' It is true that reduction to practice ordinarily provides the best evidence that an invention is complete . . . it does not follow that proof of reduction to practice is necessary in every case." 525 U.S. at 66.

The Court thus held that reduction to practice was not necessary in every case; but the Court did not hold that a conception, having neither a reduction

to practice nor an enabling description, is ready for patenting as a matter of law. To be “ready for patenting” the inventor must be able to prepare a patent application, that is, to provide an enabling disclosure as required by 35 U.S.C. § 112. For a complex concept such as the prebias technique, wherein the inventor himself was uncertain whether it could be made to work, a bare conception that has not been enabled is not a completed invention ready for patenting. Although conception can occur before the inventor has verified that his idea will work, *see Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228, (Fed. Cir. 1994), when development and verification are needed in order to prepare a patent application that complies with § 112, the invention is not yet ready for patenting.

Lockheed argues that since Dr. Chan’s proposal included the system’s four steps that are set forth in the claim, the idea was “ready for patenting” as a matter of law, even if it were not then enabled. However, the patent statute requires an enabling disclosure of how to make and use the invention. The fact that a concept is eventually shown to be workable does not retrospectively convert the concept into one that was “ready for patenting” at the time of conception. As we have observed, the Court recognized this distinction when it stated in *Pfaff* that the on sale bar does not arise when there is “additional development after the offer for sale.” 525 U.S. at 68 n.14. The district court erred in ruling that the prebias invention was ready for patenting upon conception as communicated in the engineering proposal. The judgment based thereon can not stand; thus we need not reach the question of whether a commercial offer of sale was made.

Comments

1. **The “On-Sale” Bar Test.** The Supreme Court in *Pfaff v. Wells Electronics, Inc.* established a two-part test for determining whether the claimed invention was on sale under § 102(b). First, “the product must be the subject of a commercial offer for sale”; second, “the invention must be ready for patenting.” The time frame for on-sale activity is more than one year before the filing date of the application in question, a date commonly known as the critical date.
2. **“Ready for Patenting.”** The second part of the *Pfaff* test focuses on the developmental stage of the invention at the time of on sale activity. The *Pfaff* Court affirmed that an invention need not be reduced to practice—that is, work for its intended purpose—to be subject to the on-sale bar. Rather, the invention must only be “ready for patenting” to trigger the one-year clock. An invention will be deemed “ready for patenting” if either it was reduced to practice or subject to an enabling disclosure such as engineering drawings or other documented evidence. An invention is reduced to practice when the patentee has an embodiment that meets

every limitation and operates for its intended purpose. *Eaton v. Evans*, 204 F.3d 1094, 1097 (Fed. Cir. 2000). And an invention works for its intended purpose when there is a demonstration of the workability or utility of the claimed invention. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (Fed. Cir. 1996).

One way to measure “ready for patenting,” as the court in *Space Systems* noted, is to ask if the inventor is able to prepare a patent application that would comply with the enablement requirement of § 112. See *Space Systems* (stating to be “ready for patenting the inventor must be able to prepare a patent application, that is, to provide an enabling disclosure as required by 35 U.S.C. § 112”); *Robotic Vision Systems, Inc. v. View Engineering, Inc.*, 249 F.3d 1307, 1312, 1314 (Fed. Cir. 2001) (affirming district court finding that “the invention was ready for patenting because the inventor’s disclosure was also an enabling disclosure, *i.e.*, one that was sufficiently specific to enable his co-worker, who was a person skilled in the art, to practice the invention”). The invention in *Space Systems* was not ready for patenting.

In *Honeywell Int’l, Inc. v. Universal Avionics Systems, Inc.*, 488 F.3d 982 (Fed. Cir. 2007), the patented technology related to “terrain warning systems,” which help prevent pilots from flying into mountains or hillsides. Prior to the critical date, Honeywell entered into negotiations with Gulfstream and Canadair, two commercial aircraft manufacturers, to test its system with human pilots in an actual cockpit setting. Honeywell used design notes, computer simulations, test aircraft, and demonstrations to those with expertise in air safety such as pilots. There was also a videotape of the invention in use aboard an actual aircraft, which shows the invention in operation. Nonetheless, the Federal Circuit held Honeywell did not violate the on sale bar because the developmental stage of the invention was not ready for patenting, and therefore, step two of *Pfaff* was not satisfied.

3. **Why Do We Care About Developmental Stage of the Invention?** One reason developmental stage is important is to provide the inventor with some certainty regarding when his attempted commercial activity triggers the one-year clock. Consider Judge Smith’s dissent in *UMC Electronics Co. v. United States*, 816 F.2d 647, 664 (Fed. Cir. 1987), wherein he expressed concerns about the majority’s holding that something less than reduction to practice (“RTP”) of the claimed invention will suffice to trigger the clock:

It is the users of the patent system who will suffer the impact of the panel majority decision. The question is not theoretical; it is of great practical importance.

Those inventors who have sought financing, or who have contacted potential customers, or who have engaged in other normal business activities before they have made a workable device will not know how the time limit for filing a patent application will be measured or where the line will be drawn between raw idea and proved invention. Inventors do not normally try to patent something they have not yet found workable. The patent law, and particularly section 112, does not favor it. Most inventors do not hire a patent lawyer until they have something that works, by which time, according to the panel majority, it may be too late.

* * *

It is not clear why this change is being wrought on the community of inventors and the public without providing some alternative measure of certainty. The “all circumstances” rule evoked by the panel majority means that the critical question in more and more cases can only be answered with finality by a judicial determination in which there is no further appeal.

Reduction to practice lends itself to greater certainty, but it can arguably be manipulated by inventors, who could just stop short of RTP, yet engage in exploitative conduct. But once you allow something less than RTP, such as conception, certainty is sacrificed. Perhaps the *Pfaff* Court, as discussed in *Space Systems*, thought “ready for patenting” was a viable compromise.

2. What Constitutes an Offer for Sale?

PLUMTREE SOFTWARE, INC. v. DATAMIZE, LLC

475 F.3d 1152 (Fed. Cir. 2006)

DYK, Circuit Judge.

Plumtree Software, Inc. (“Plumtree”) filed this declaratory judgment action against Datamize, LLC (“Datamize”) in the United States District Court for the Northern District of California. The district court . . . granted summary judgment in favor of Plumtree on the ground that Datamize’s patents were invalid under the on sale bar doctrine, 35 U.S.C. § 102(b). Datamize now appeals. We vacate and remand for further proceedings on the merits.

BACKGROUND

I

This case involves two Datamize patents, U.S. Patent Nos. 6,460,040 (“’040 patent”) and 6,658,418 (“’418 patent”). Datamize principal Kevin Burns is the named inventor of the patents, which were continuations of his U.S. Patent No. 6,014,137 (“’137 patent”). The patents are entitled “Authoring System for Computer-based Information Delivery System” and share a common specification.

The patented invention is a computer program that is used to create other computer programs (an “authoring tool”). The invention encompasses both the method of creating the computer program and the software for creating the computer program. The ’040 patent contains method claims, and the ’418 patent is asserted to contain both method and apparatus claims. The authoring tool may be used to create customized kiosks. As an example, the patents explain the authoring tool might be used to create electronic kiosks used at ski resorts to provide information to customers about ski conditions, local hotels, and restaurants through a touch screen or key pad. The patented invention is not the kiosk itself, but is the software for, and the method of, creating the kiosk.

Plumtree is a computer software company that produces “corporate portal” software. The corporate portal is web-based software that brings together various applications and information into a customized desktop screen that employees of an organization can separately access. Plumtree primarily markets its corporate portal software to companies that want to organize their corporate intranet sites.

* * *

III

Plumtree's summary judgment motion established the following undisputed facts.

In early 1993 Emmett and Kevin Burns formed Multimedia Adventures ("MA") (which later assigned its patents to Datamize). By December 1994 Kevin Burns had completed development of the authoring tool which could be used to create an interactive kiosk system. On January 17, 1995, representatives from MA gave a presentation to representatives from the Ski Industry of America ("SIA"), sponsors of a ski industry trade show, offering to create a kiosk for the trade show. On January 25, 1995, SIA sent a letter to MA confirming that MA would provide a kiosk at the trade show in exchange for SIA's "waiving the \$10,000 sponsorship fee associated with participation in the electronic information center." The trade show was held on March 3-7, 1995, in Las Vegas, NV, shortly after the February 27, 1995, critical date, and the kiosk was displayed when it was completed near the end of the first day of the show. The record establishes that the SkiPath kiosk was created with the authoring system and that the authoring system "embodied all the claims of all three of Datamize's patents."

* * *

[T]he district court considered Plumtree's motion for summary judgment. The court held both the '040 and '418 patents invalid under the on sale bar rule. The court concluded that "the on sale bar [was] triggered by the facts of this case" because there was "an agreement to 'perform' a method claim" before the critical date. The basis for this holding was the fact that "[a]t the January 17, 1995, meeting, MA offered to provide its interactive electronic kiosk system during the March 1995 trade show." The court found that MA received consideration because "MA was granted a 'prime location' and its fee was waived in exchange for the display of MA's kiosk." *Id.* The court noted that MA's meeting with SIA on January 17, 1995, and the subsequent agreement both occurred before the February 27, 1995, critical date. The court then stated that "the agreement with SIA embodied all of the claims of the '040 and '418 patents" because "the kiosk at the trade show embodied all of the claims." Accordingly, the court granted summary judgment in favor of Plumtree.

DISCUSSION

* * *

II

A claimed invention is considered to be on sale under § 102(b) if the invention is sold or offered for sale more than one year before the filing date of the patent application. Here the '040 and '418 patents claim priority to a provisional application that was filed on February 27, 1996. Thus, for purposes of the on sale bar, the critical date is February 27, 1995.

The facts pertinent to the on sale bar issue are as follows. By December 1994 Kevin Burns, the inventor of the '040 and '418 patents, had completed development of the authoring tool ultimately reflected in the patent claims. In the winter of 1994 his company, MA, learned that the SIA was going to hold a trade show in Las Vegas, Nevada in March 1995. As part of the show, SIA

planned to include an example of a “ski store of the future” called the “Mountain Visions” store.

On January 17, 1995, representatives from MA gave a presentation to the representatives from SIA at SIA’s headquarters in Virginia. At the time of the presentation, the authoring tool had been reduced to practice, but MA had not yet used the authoring tool to create a kiosk product. The slides used during MA’s presentation refer to “proprietary authoring tools” that “allow rapid updating” and “support new technologies as they appear.” However, Emmett Burns later testified that he could not “recall telling SIA any of the particulars of the authoring tool at the SIA meeting.” He stated that he did not explain how the authoring tool allowed for “rapid updating” because “even if [h]e explained any of it[,] [t]hese people . . . are not technology people; and they go into a different space if you start to get into that.” Rather, Emmett Burns testified that the purpose of the presentation was to show SIA what the ultimate kiosk product, entitled “SkiPath,” “would be like.”

On January 25, 1995, SIA sent a letter to MA confirming the agreement that MA would “participat[e] as [a] sponsor of the ‘interactive’ portion of the electronic information center of Mountain Visions at SIA.” The letter stated that in exchange for SIA “waiving the \$10,000 sponsorship fee associated with participation in the electronic information center,” MA agreed to:

1. Provide software/hardware package necessary to produce the interactive touch-screen information center as presented to SIA on January 17, 1995 in McLean, VA.
2. Provide multiples of this software/hardware package to allow for multiple customer access in the information center.
3. Work to the best of their ability to put the other product sponsors participating in the concept store on the interactive system, as presented [] January 17th, at no charge to these companies. SIA will work to facilitate this effort wherever possible.
4. Provide looped advertising/entertainment video on 3/4 inch VHS for the overhead monitor system. SIA would help to acquire entertainment segments if necessary.
5. Exhibit within the trade show. SIA will facilitate getting Multimedia Adventures an appropriate booth space to exhibit and sell your products.

On January 26, 1995, Kevin Burns “filled out an exhibit space contract for [MA’s] exhibit space at the tradeshow” and paid \$2,430 in exhibit space fees. The exhibit space contract stated that “the type of product” MA would display was a “computer kiosk.” Emmett Burns later testified that the agreement between SIA and MA was that in exchange for space at the trade show, MA would “put the system in the store.” He explained that “the system” was “the multimedia kiosk” (SkiPath).

The trade show was held on March 3-7, 1995 (after the February 27, 1995, critical date) in Las Vegas, NV. Kevin Burns testified that “a Mulitmedia Adventures product” was demonstrated and that there was a demonstration of the “kiosk system,” which was called “SkiPath.” The record establishes that “SkiPath [was] created with the authoring system” and that the authoring system embodied all the claims of all three of Datamize’s patents. Kevin Burns also testified, somewhat confusingly, that “the network kiosk system that was demonstrated in March of 1995 at the Las Vegas show embod[ied] all the claims” of the ’040 and ’418 patents. Although Kevin Burns began creating

SkiPath before the January 17 meeting, the programming and testing of the SkiPath product was not completed until the end of the first day of the trade show. Thus, the record is not clear whether the patented process was used before the critical date.

III

The Supreme Court in *Pfaff v. Wells Electronics, Inc.* has set forth a two-part test for determining whether there was a sale or offer for sale for purposes of § 102(b). First, “the product must be the subject of a commercial [sale or] offer for sale.” *Id.* Second, “the invention must be ready for patenting.” *Id.* The second condition is met by “proof of reduction to practice before the critical date.” *Id.* Here the parties agree that the authoring tool was reduced to practice in the winter of 1994. Accordingly, we need only consider the first prong of the *Pfaff* test.

A commercial sale or offer for sale necessarily involves consideration. *See Group One, Ltd. v. Hallmark Cards, Inc.*; Restatement (Second) of Contracts § 71 (1981). We agree with the district court that MA received valid consideration. SIA awarded MA floor space at the trade show and waived \$10,000 sponsorship fee normally charged to show participants. Datamize argues that waiver of the \$10,000 sponsorship fee did not constitute consideration because Plumtree did not demonstrate that the fee waiver was “somehow due to the invention.” We do not find this argument persuasive.

However, on this record, we cannot sustain the district court’s conclusion that the method claims are invalid under the on sale bar rule. The district court reasoned that “the agreement with SIA embodied all of the claims of the ’040 and ’418 patents” because “the kiosk at the trade show embodied all of the claims.” In so holding, the district court relied on Kevin Burns’s testimony that “the network kiosk system that was demonstrated in March of 1995 at the Las Vegas show embod[ied] all the claims” of the ’040 and ’418 patents. These statements reflect confusion as to the nature of the patented product. Here the invention reflected in the method claims is a process for creating a kiosk system, not the kiosk system itself. The kiosk system itself is not patented. The court’s focus on whether the kiosk system somehow embodied the claims of the patent was misplaced, and the district court’s reasoning does not support a grant of summary judgment. Nor does the record support the ultimate result reached by the district court.

In our view, Plumtree could meet the first prong of the *Pfaff* test under either of two alternative theories. First, Plumtree could demonstrate that before the critical date MA made a commercial offer to perform the patented method (even if the performance itself occurred after the critical date). Second, Plumtree could demonstrate that before the critical date MA in fact performed the patented method for a promise of future compensation. Under the second theory, Plumtree would not need to prove that the contract itself required performance of the patented method. We address these alternative theories in turn.

Under the first theory, Plumtree would have to demonstrate that before the critical date MA made a commercial offer to perform the patented method. A commercial offer is “one which the other party could make into a binding contract by simple acceptance (assuming consideration).” *Group One*, 254 F.3d at 1048. Under this standard, it is clear that the offeror must be legally bound

to perform the patented method if the offer is accepted. See *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1050 (Fed. Cir. 2001) (stating that there was no offer where communication did not “indicate LTC’s intent to be bound” (citing Restatement (Second) of Contracts § 26 (1981)). Whether there has been a commercial offer is governed by federal common law.

Whether MA made a commercial offer to perform the patented method is governed by our decision in *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1327 (Fed. Cir. 2001), where before the critical date Scaltech made a commercial offer to perform a patented method. There we stated that “the fact that the process itself was not offered for sale but only offered to be used by the patentee . . . does not take it outside the on sale bar rule.” *Id.* at 1328. We reasoned that “[t]he on sale bar rule applies to the sale of an ‘invention,’ and in this case, the invention was a process.” *Id.* We then asked whether there was a “commercial offer” and whether the offer was “of the patented invention.” *Id.* We concluded that Scaltech’s offer before the critical date to perform the patented method implicated the on sale bar because the commercial “offer for sale . . . satisf[ied] each claim limitation of the patent.” *Id.* at 1329-30.

Here, as in *Scaltech*, there has been a commercial offer before the critical date of February 27, 1995, because there was a binding contract between MA and SIA. The more difficult question is whether the commercial offer was “of the patented invention.” We have stated that “the invention that is the subject matter of the offer for sale must satisfy each claim limitation of the patent.” *Id.* at 1329. Datamize admits that “SkiPath [was] created with the authoring system” and that the authoring system “embodied all the claims of all three of Datamize’s patents.” On its face, however, the written agreement between MA and SIA did not unambiguously require use of the patented method. The agreement did require MA to “provide the software/hardware package necessary to produce the interactive touch-screen information center as presented to SIA on January 17, 1995 in McLean, Virginia.” This reference to the software/hardware package is ambiguous as to whether it required MA to provide the kiosk system software or to perform the patented method. Moreover, Plumtree has made no showing that extrinsic evidence would compel an interpretation that MA was bound to perform the patented method. Therefore, the record does not provide a basis for summary judgment on this issue.

We now turn to the second possible theory. Even if Plumtree did not agree before the critical date to perform the patented process, Plumtree could prevail on summary judgment if it demonstrated that MA in fact performed each of the steps of the patented process before the critical date pursuant to the contract. In *In re Kollar*, 286 F.3d 1326 (Fed. Cir. 2002), this court considered whether granting a license to perform a patented method violated the on sale bar. After concluding that there was no sale under the particular facts of that case, we noted that “[a]ctually performing the process itself for consideration would . . . trigger the application of § 102(b).” *Id.* We have explained that “the intent of [§ 102(b)] is to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed.” *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983); see also *In re Kollar*, 286 F.3d at 1333 (“Surely a sale by the patentee . . . of a product made by the claimed process would constitute . . . a sale because that party is commercializing the

patented process in the same sense as would occur when the sale of a tangible patented item takes place.”). Performing the steps of the patented method for a commercial purpose is clearly an attempt to profit from the commercial use of an invention. Consequently, performing the patented method for commercial purposes before the critical date constitutes a sale under § 102(b).

However, *Plumtree* has not on this record established that MA actually performed all of the patented steps before the critical date pursuant to the contract. While it is apparent that Kevin Burns used the authoring tool to create the kiosk system, the kiosk system was not finished until after the critical date, and it is unclear whether Burns performed each of the patented method steps before the critical date. Accordingly, summary judgment was not appropriate in this case.

CONCLUSION

For the foregoing reasons, we conclude that the district court erred in granting summary judgment pursuant to § 102(b) because the record contains insufficient facts to determine whether the patented process was sold or offered for sale before the critical date. Accordingly, we vacate the district court’s summary judgment ruling and remand for further proceedings.

Comments

1. **“Commercial Offer for Sale” vs. Assignments and Licenses.** Unlike *Space Systems*, the *Plumtree* court did not have to decide if the invention was “ready for patenting” because it was already reduced to practice at the time of the alleged offer. But the court did have to decide whether a commercial offer for sale was made. Prior to *Pfaff*, it was not entirely clear what constituted an offer under § 102(b), and the *Pfaff* court did not address the issue. But, as noted in *Plumtree*, the Federal Circuit has subsequently defined commercial offer for sale by applying traditional contract principles. The court held that “the offer must meet the level of an offer for sale in the contract sense as understood by the commercial community.” *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1046-47 (Fed. Cir. 2001).

This test needs to be placed in context. For example, an on-sale bar does not arise from assignment that is executed to raise funds to be used to further develop or refine the invention. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1267 (Fed. Cir. 1986) (assignment does not violate § 102(b)). There is a distinction between offering the patent itself for sale and what is claimed in the patent. The former, which provides its owner with the right to exclude (the property right), does not invoke § 102(b). This rule reflects the business realities ordinarily surrounding the selling of business assets, including patent rights. Also, because § 102(b) relates to a sale of a product, not prospective licensing activity, an offer to license or a mere transfer of know-how will not invoke § 102(b). See *In re Kollar*, 286 F.3d 1326, 1331 (Fed. Cir. 2002) (holding an offer to license a patent claiming an invention after future research and development had occurred, without more, is not an offer to sell the invention). Of course, just calling something a “license” does not

make it so, particularly if the “license” masks a sale that would immediately transfer the product to the “buyer” as if it were sold.

This distinction between license and sell was at issue in *Elan Corp. v. Andrx Pharmaceuticals, Inc.*, 366 F.3d 1336 (Fed. Cir. 2004). Elan owned a patent on a formulation of naproxen, an anti-inflammatory drug. Prior to the critical date, Elan wrote a letter regarding the patented naproxen formulation to a prospective licensee, Lederle Laboratories, stating:

On the licensing side, we are actively seeking a partner and believe Lederle’s marketing strengths make you ideal in this respect. Ideally, we want to have our partner determined this year so that they can actively participate in the planning of the clinical studies, even though Elan would remain responsible for conducting them. As I indicated to you, we see any license as involving two types of payment—a licensing fee in the form of recoverable advance royalties and a charge for the clinical program as patients become enrolled. On the former, the total licensing fee would be \$2.75 million dollars, payable: (i) \$500,000 on contract signature, (ii) \$500,000 on I.N.D. filing, (iii) 750,000 on N.D.A. filing, and (iv) \$1,000,000 on N.D.A. approval, all recoverable against a 5% running royalty by withholding one-third of each payment due. On the clinical side, we would ask for a payment of \$250,000 upon enrollment of each 50 new patients, up to a maximum of \$2.5 million dollars.

The Federal Circuit held this language did not constitute an offer for sale under § 102(b) because the letter did not offer naproxen tablets for sale, but only granted a license under the patent and offered an opportunity to be a partner in the clinical test and marketing of the naproxen at some indefinite point in the future. Regarding the language in the letter, the court stated while no particular language is required to transform an offer to license to an offer for sale, “a communication that fails to constitute a definite offer to sell the product and to include material terms is not an ‘offer’ in the contract sense. *Restatement (Second) of Contracts* § 33(3) (1981).” *Id.* at 1341. According to the court, Elan’s “letter lacked any mention of quantities, time of delivery, place of delivery, or product specifications beyond the general statement that the potential product would be a 500 mg once-daily tablet containing naproxen.” *Id.* In addition, “the dollar amounts recited in the fourth paragraph of the letter are clearly not price terms for the sale of tablets, but rather the amount that Elan was requesting to form and continue a partnership. Indeed, the letter explicitly refers to the total as a ‘licensing fee.’” *Id.* The court concluded by warning that “if Elan had simply disguised a sales price as a licensing fee it would not avoid triggering the on sale bar.” *Id.*

2. **Subject Matter of the Sale.** Whatever is offered for sale must be compared with what is ultimately claimed. Consistent with the policies underlying § 102(b), the subject matter of the offer for sale must either fully anticipate or render obvious what is eventually claimed. *See Scaltech, Inc. v. Retec/Tetra LLC*, 178 F.3d 1378, 1383 (Fed. Cir. 1999) (stating the “‘invention’ which has been offered for sale must, of course, be something within the scope of the claim”); *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002) (stating on sale bar applies if “the product sold or offered for sale anticipated the claimed invention or rendered it obvious”). In other words, an inventor does not run afoul of § 102(b) if he offered for

sale something significantly different than what he claimed. This was Plumtree's problem.

In *Sparton v. U.S.*, 399 F.3d 1321 (Fed. Cir. 2005), the Navy entered into a contract with Sparton for the procurement of a sonobuoy, a device that is used to detect, locate, and classify the source of underwater sounds, such as those generated by submarines. Sparton subsequently submitted an Engineering Change Proposal ("ECP") to the Navy under its existing contract, proposing to incorporate dual depth operating capability into the existing sonobuoy by modifying the design. The sonobuoy device described in the ECP included a *multi-piece release plate* for either retaining or deploying the sonobuoy internal components within or from the sonobuoy housing. But shortly after the ECP was issued, Sparton developed, and later tested, a sonobuoy having a *single-piece release plate*. This single-piece release plate performed better than previous release plates and was ultimately used in the sonobuoy Sparton delivered to the Navy under the contract.

Sparton obtained two patents that each contained claim limitations drawn to a single piece release plate for a sonobuoy. In 1992, Sparton filed suit in the Claims Court against the United States to recover money damages for the government's unlicensed use of Sparton's patented inventions. The government maintained that the patents were invalid under § 102(b)'s on sale bar. The Federal Circuit held that the patented invention was not the subject of the offer for sale prior to the critical date. According to the court, the offer for sale was the submission of an ECP incorporating dual depth operating capability. The ECP included a description of the dual depth sonobuoy deployment design, including drawings. This description and drawings contained a release plate mechanism. But the court noted that:

[t]he parties disagree as to what type of release plate was identified. The specific release plate mechanism proposed in the ECP is not relevant to our analysis, because, as the Claims Court noted, the government concedes, and the parties do not dispute, the release plate mechanism described in the [patents-in-suit] is not the release plate that was part of the original design proposed in the ECP; in other words, the . . . contract does not include a release plate that meets the description of the release plate limitation of the claimed inventions. This fact is of utmost importance, as both sides agree that what was offered in the ECP was not the patented invention. . . . Accordingly, there is nothing to suggest that prior to the critical date of March 29, 1972, Sparton made an offer for anything other than dual-depth sonobuoys having the release plate mechanism described in the ECP.

Id. at 1323.

3. ***Seller's Knowledge.*** The *Space Systems* court seemed to rely in part on the fact that at the time the alleged offer was made, Dr. Chan was uncertain about whether the claimed invention worked. But with respect to the inventor's (or seller's) knowledge of the product offered for sale, the Federal Circuit has adopted more of an objective test. The court has held a § 102(b) offer will exist even though the offer does not specifically identify the characteristics of the claimed invention or the seller and buyer do not recognize the significance of the characteristics at the time of the offer. *See*

Abbott Laboratories v. Geneva Pharmaceuticals, Inc., 182 F.3d 1315, 1318-19 (Fed. Cir. 1999). The underlying point of the on-sale bar is that the seller attempted to commercially exploit the claimed invention, and the potential buyer's understanding of the invention is irrelevant in this regard. Indeed, the inventor is not required to have "complete confidence" in the operability of his invention for the on sale bar to apply. *See also Scaltech* (stating "[w]e note that there is no requirement that the offer specifically identify these [claim] limitations. . . . Nor is there a requirement that Scaltech must have recognized the significance of these limitations at the time of offer"); *Robotic Vision Systems, Inc. v. View Engineering, Inc.*, 249 F.3d 1307, 1312 (Fed. Cir. 2001) (stating "[n]otably absent from [the *Pfaff*] test is a requirement that an inventor have complete confidence that his invention work will work for its intended purpose. . . . We did not hold that lack of skepticism regarding the 'workability of an invention' was an evidentiary requirement. It will be a rare case indeed in which an inventor has no uncertainty concerning the workability of his invention before he has reduced it to practice").

B. PUBLIC-USE BAR

The public-use bar, like its neighbor, the on-sale bar, focuses on inventor and third-party activity. A "public use" more than one year before the filing date will defeat patent rights, but what actually constitutes a "public use" is an inquiry not free from difficulty. As you will see in *Egbert* and *Motionless*, the threshold for "public use" is quite low.

EGBERT v. LIPPMANN

104 U.S. 333 (1882)

Mr. Justice WOODS.

This suit was brought for an alleged infringement of the complainant's patent, No. 5216, dated Jan. 7, 1873, for an improvement in corset-springs.

The original letters bear date July 17, 1866, and were issued to Samuel H. Barnes. The reissue was made to the complainant, under her then name, Frances Lee Barnes, executrix of the original patentee.

* * *

The evidence on which the defendants rely to establish a prior public use of the invention consists mainly of the testimony of the complainant.

She testifies that Barnes invented the improvement covered by his patent between January and May, 1855; that between the dates named the witness and her friend Miss Cugier were complaining of the breaking of their corset-steels. Barnes, who was present, and was an intimate friend of the witness, said he thought he could make her a pair that would not break. At their next interview he presented her with a pair of corset-steels which he himself had

made. The witness wore these steels a long time. In 1858 Barnes made and presented to her another pair, which she also wore a long time. When the corsets in which these steels were used wore out, the witness ripped them open and took out the steels and put them in new corsets. This was done several times.

. . . [T]hese steels embodied the invention afterwards patented by Barnes and covered by the reissued letters-patent on which this suit is brought.

Joseph H. Sturgis, another witness for complainant, testifies that in 1863 Barnes spoke to him about two inventions made by himself, one of which was a corset-steel, and that he went to the house of Barnes to see them. Before this time, and after the transactions testified to by the complainant, Barnes and she had intermarried. Barnes said his wife had a pair of steels made according to his invention in the corsets which she was then wearing, and if she would take them off he would show them to witness. Mrs. Barnes went out, and returned with a pair of corsets and a pair of scissors, and ripped the corsets open and took out the steels. Barnes then explained to witness how they were made and used.

* * *

We observe, in the first place, that to constitute the public use of an invention it is not necessary that more than one of the patented articles should be publicly used. The use of a great number may tend to strengthen the proof, but one well-defined case of such use is just as effectual to annul the patent as many. . . .

We remark, secondly, that, whether the use of an invention is public or private does not necessarily depend upon the number of persons to whom its use is known. If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person.

We say, thirdly, that some inventions are by their very character only capable of being used where they cannot be seen or observed by the public eye. An invention may consist of a lever or spring, hidden in the running gear of a watch, or of a ratchet, shaft, or cog-wheel covered from view in the recesses of a machine for spinning or weaving. Nevertheless, if its inventor sells a machine of which his invention forms a part, and allows it to be used without restriction of any kind, the use is a public one. So, on the other hand, a use necessarily open to public view, if made in good faith solely to test the qualities of the invention, and for the purpose of experiment, is not a public use within the meaning of the statute.

Tested by these principles, we think the evidence of the complainant herself shows that for more than two years before the application for the original letters there was, by the consent and allowance of Barnes, a public use of the invention, covered by them. He made and gave to her two pairs of corset-steels, constructed according to his device, one in 1855 and one in 1858. They were presented to her for use. He imposed no obligation of secrecy, nor any condition or restriction whatever. They were not presented for the purpose of experiment, nor to test their qualities. No such claim is set up in her testimony. The invention was at the time complete, and there is no evidence that it was afterwards changed or improved. The donee of the steels used them for

years for the purpose and in the manner designed by the inventor. They were not capable of any other use. She might have exhibited them to any person, or made other steels of the same kind, and used or sold them without violating any condition or restriction imposed on her by the inventor.

According to the testimony of the complainant, the invention was completed and put into use in 1855. The inventor slept on his rights for eleven years. Letters-patent were not applied for till March, 1866. In the mean time, the invention had found its way into general, and almost universal, use. A great part of the record is taken up with the testimony of the manufacturers and venders of corset-steels, showing that before he applied for letters the principle of his device was almost universally used in the manufacture of corset-steels. It is fair to presume that having learned from this general use that there was some value in his invention, he attempted to resume, by his application, what by his acts he had clearly dedicated to the public.

* * *

We are of opinion that the defense of two years' public use, by the consent and allowance of the inventor, before he made application for letters-patent, is satisfactorily established by the evidence.

Mr. Justice MILLER dissenting.

The sixth section of the act of July 4, 1836, c. 357, makes it a condition of the grant of a patent that the invention for which it was asked should not, at the time of the application for a patent, "have been in public use or on sale with the consent or allowance" of the inventor or discoverer. Section fifteen of the same act declares that it shall be a good defense to an action for infringement of the patent, that it had been in public use or on sale with the consent or allowance of the patentee before his application. This was afterwards modified by the seventh section of the act of March 3, 1839, c. 88, which declares that no patent shall be void on that ground unless the prior use has been for more than two years before the application.

This is the law under which the patent of the complainant is held void by the opinion just delivered. The previous part of the same section requires that the invention must be one "not known or used by others" before the discovery or invention made by the applicant. In this limitation, though in the same sentence as the other, the word "public" is not used, so that the use by others which would defeat the applicant, if without his consent, need not be public; but where the use of his invention is by his consent or allowance, it must be public or it will not have that affect.

The reason of this is undoubtedly that, if without his consent others have used the machine, composition, or manufacture, it is strong proof that he was not the discoverer or first inventor. In that case he was not entitled to a patent. If the use was with his consent or allowance, the fact that such consent or allowance was first obtained is evidence that he was the inventor, and claimed to be such. In such case, he was not to lose his right to a patent, unless the use which he permitted was such as showed an intention of abandoning his invention to the public. It must, in the language of the act, be in public use or on sale.

The word public is, therefore, an important member of the sentence. A private use with consent, which could lead to no copy or reproduction of the machine, which taught the nature of the invention to no one but the party to whom such consent was given, which left the public at large as ignorant of this as it was before the author's discovery, was no abandonment to the public, and did not defeat his claim for a patent. If the little steep spring inserted in a single pair of corsets, and used by only one woman, covered by her outer-clothing, and in a position always withheld from public observation, is a public use of that piece of steel, I am at a loss to know the line between a private and a public use.

The opinion argues that the use was public, because, with the consent of the inventor to its use, no limitation was imposed in regard to its use in public. It may be well imagined that a prohibition to the party so permitted against exposing her use of the steel spring to public observation would have been supposed to be a piece of irony. An objection quite the opposite of this suggested by the opinion is, that the invention was incapable of a public use. That is to say, that while the statute says the right to the patent can only be defeated by a use which is public, it is equally fatal to the claim, when it is permitted to be used at all, that the article can never be used in public. . . .

MOTIONLESS KEYBOARD CO. v. MICROSOFT CORP.

486 F.3d 1376 (Fed. Cir. 2007)

RADER, Circuit Judge.

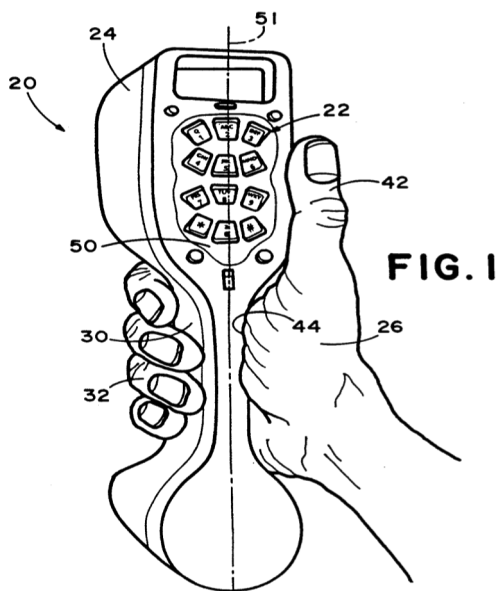
On summary judgment, the U.S. District Court for the District of Oregon determined . . . on summary judgment . . . that the 5,178,477 and 5,332,322 patents were invalid based on public use under 35 U.S.C. § 102(b). . . . Because the trial court misapplied the concept of public use . . . this court reverses its invalidity rulings.

I

MKC owns the '477 and '322 patents. The '477 patent, entitled "Ergonomic Keyboard Input Device," claims an ergonomic keyboard designed to accommodate the architecture of the human hand. According to the invention, the keyboard requires only slight finger gestures to actuate the keys. The '322 patent, entitled "Ergonomic Thumb-Actuable Keyboard for Hand-Grippable Device," issued as a continuation-in-part of the '477 patent. [Figure 1 of the '322 patent is below.] This patent claims a hand-held device that frees the thumb to actuate the keys in multiple and differentiated ways.

Thomas L. Gambaro is the sole inventor of both the '477 and the '322 patents. Mr. Gambaro invented the novel ergonomic keyboard technology on a part-time basis while also working in other jobs such as graphic artist and dishwasher. In fact, Mr. Gambaro developed some of the ergonomic keyboard technology while he lived in a friend's attic. As an independent inventor, Mr. Gambaro developed his technology advances without the benefit of a well-funded laboratory and then traversed the patent system on a limited budget.

During his inventive work, Mr. Gambaro developed different prototype models of his keyboard technology. Eventually, on February 22, 1987,



Mr. Gambaro developed the Cherry Model 5. Shortly after developing the Cherry Model 5, Mr. Gambaro entered into a business partnership with Mr. Keith Coulter. Thereafter, Mr. Gambaro and Mr. Coulter set out to gain financial support to further develop and patent the keyboard technology.

Thus, Mr. Gambaro began to demonstrate the Cherry Model 5 to potential investors. He also demonstrated the device to a friend, Ms. Kathie Roberts. While the potential investors signed two-year non-disclosure agreements (NDAs), Ms. Roberts did not. Mr. Gambaro entered into some of the NDAs with potential investors in 1987, meaning those agreements expired in 1989. Additionally, Mr. Gambaro disclosed the Cherry Model 5 to Ms. Sheila Lanier on June 25, 1990 to conduct typing tests. While Mr. Gambaro showed the Cherry Model 5 to his business partner, numerous potential investors, a friend and a typing tester, according to the record, only Ms. Lanier used the device to transmit data to a computer. In due course, Mr. Gambaro assigned both patents to MKC.

MKC sued Microsoft, Nokia, and Saitek for infringement of the '477 and '322 patents in the U.S. District Court for the District of Oregon. Specifically, MKC alleged that Microsoft's "Strategic Commander" game controller infringed claims 1, 2, 5, 6, and 8 of the '477 patent. MKC also alleged that Microsoft's "Sidewinder Precision 2," "Sidewinder Force Feedback 2," and various Saitek game joysticks infringed claims 1, 2, 3 and 5 of the '322 patent.

The defendants collectively moved for summary judgment of invalidity of both patents based on public use under 35 U.S.C. § 102(b). The District Court entered summary judgment construing the claims of the '477 and '322 patents. Based on its reading of the patents, the trial court . . . invalidated the '477 and '322 patents based on public use under 35 U.S.C. § 102(b).

MKC appeals the invalidity ruling on the '477 patent [and] also appeals the court's invalidity rulings on the '322 patent.

II

The meaning of the statutory terms “on sale” or “public use” within section 35 U.S.C. § 102(b) is a question of law that this court reviews without deference. In reviewing summary judgment rulings on infringement and invalidity, this court “need[s] to determine de novo whether the evidence in the record raises any genuine disputes about material facts. An evidentiary dispute is genuine if a jury could decide the issue either way, and its verdict would survive a motion for judgment as a matter of law.” *General Elec. Co. v. Nintendo Co., Ltd.*, 179 F.3d 1350, 1353 (Fed. Cir. 1999).

IV

MKC appeals the district court grant of summary judgment that the 477 and 322 patents are invalid for public use under 35 U.S.C. § 102(b):

A person shall be entitled to a patent unless—

(b) the invention was patented or described in a printed publication in this or a foreign country or *in public use* or on sale in this country, more than one year prior to the date of the application for patent in the United States.

35 U.S.C. § 102(b) (emphasis added). Because the applicant filed the ’477 patent on June 6, 1991, the critical date for the invalidity analysis is June 6, 1990. The critical date for the ’322 patent is January 11, 1992. To sustain the invalidity determination, the record must show that an embodiment of the patented invention was in public use as defined by the statute before the critical date.

The district court found that MKC admitted that the Cherry Model 5 embodied the ’477 patent and the ’322 patent as of February 22, 1987. Even assuming that MKC admitted that the Cherry Model 5 embodied each claim of the ’477 and ’322 patents—a question this court need not decide—this court concludes that there was no “public use” under 35 U.S.C. § 102(b). Therefore, the district court’s grant of summary judgment of invalidity for public use was improper.

The record shows that the inventor disclosed the Cherry Model 5 to his business partner, potential investors, a friend, and a typing tester before the critical date. While the potential investors signed NDAs, some of the NDAs expired in 1989—again prior to the critical dates for each patent. Thus, this court must examine, in the context of the district court’s summary judgment ruling of invalidity, whether these disclosures and demonstrations were public uses within the meaning of the statutory bar.

Public use includes “any [public] use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor.” *In re Smith*, 714 F.2d 1127, 1134 (Fed. Cir. 1983) (citing *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881)). In *Pfaff v. Wells Elecs., Inc.*, the Supreme Court noted that both the “on sale” and “public use” bars were based on the same policy considerations. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998). Specifically, “[t]he [Supreme] Court noted that both the on sale and public use bars of § 102(b) stem from the same ‘reluctance to allow an inventor to remove existing knowledge from public use.’” *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005).

The district court found that Mr. Gambaro had disclosed the Cherry Model 5 to potential investors in order to obtain capital. As such, the district court

reasoned that these disclosures showed the invention entered the public domain prior to the critical date because Mr. Gambaro's business partner was under no obligation to keep the Cherry Model 5 secret. Further, the disclosures to potential investors showed that Mr. Gambaro attempted to obtain capital to develop his invention. The district court found the NDAs inconsequential because "a confidentiality agreement will not preclude application of the public use doctrine, if the device was disclosed for commercial purposes." *Id.* (citing *Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 390 (Fed. Cir. 1984)). MKC admits to a series of limited disclosures to potential investors to raise capital to develop the invention and prosecute the patent application. However, MKC further contends that the disclosures did not involve the Cherry Model 5 or its use as claimed in the '477 or '322 patents.

"The classical standard for assessing the public nature of a use was established in *Egbert v. Lippman*, 104 U.S. 333 (1881). In *Egbert*, the inventor of a corset spring gave two samples of the invention to a lady friend, who used them for more than two years before the inventor applied for a patent." *Invitrogen*, 424 F.3d at 1382. Although the inventor in *Egbert* did not obtain any commercial advantage, the Court determined that the invention had been used for its intended purpose for over a decade without limitation or confidentiality requirements. Thus, even though not in public view, the invention was in public use. *Id.* In *Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5 (1939), the Court found "the ordinary use of a machine or the practice of a process in a factory in the usual course of producing articles for commercial purposes is a public use." *Id.* at 20. On the other hand, in *TP Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir. 1984), this court found that premature installation of an inventive orthodontic appliance in several patients without a written confidentiality agreement was not a public use due to the expectation of confidentiality inherent in the dentist-patient relationship. This case again presents the question of the meaning of public use under 35 U.S.C. § 102(b).

In this case, Mr. Gambaro disclosed his Cherry Model 5 to his business partner, a friend, potential investors, and a typing tester (Ms. Lanier). In all these disclosures, except in the case of Ms. Lanier, however, the Cherry Model 5 was not connected to a computer or any other device. In the case of Ms. Lanier, the Cherry Model 5 was used to conduct typing tests on July 25, 1990, and thereby connected to a computer for its intended purpose. With respect to the '477 patent, the typing test occurred after the critical date of June 6, 1990. With respect to the '322 patent, Ms. Lanier appears to have performed a one-time typing test to assess typing speed. The typing test by Ms. Lanier allegedly performed on July 25, 1990 and, according to a synopsis of NDAs in the record, Ms. Lanier signed an NDA on the same day. The critical date for the '322 patent is January 11, 1992. In this case, the one time typing test coupled with a signed NDA and no record of continued use of the Cherry Model 5 by Ms. Lanier after July 25, 1990 did not elevate to the level of public use. Thus, the Cherry Model 5 was never in public use. All disclosures, except for the one-time typing test, only provided a visual view of the new keyboard design without any disclosure of the Cherry Model 5's ability to translate finger movements into actuation of keys to transmit data. In essence, these disclosures visually displayed the keyboard design without putting it into use. In short, the Cherry Model 5 was not in public use as the term is used in section 102(b) because the device, although visually disclosed and only tested

one time with a NDA signed by the typing tester, was never connected to be used in the normal course of business to enter data into a system.

Unlike the situations in *Egbert* and *Electric Storage Battery*, where the inventions were used for their intended purpose, neither the inventor nor anyone else ever used the Cherry Model 5 to transmit data in the normal course of business. The entry of data did not ever occur outside of testing and the tester signed an NDA. The Cherry Model 5 was not used in public, for its intended purpose, nor was the Cherry Model 5 ever given to anyone for such public use. Thus, the disclosures in this record do not rise to the level of public use.

Comments

1. **How Public Is “Public Use”?** The public use bar applies when the “device used in public includes every limitation of the later claimed invention, or by obviousness if the differences between the claimed invention and the device used would have been obvious to one of ordinary skill in the art.” *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002). Also, the *Motionless* court made clear that to constitute public use, the invention must be used for its intended purpose. The court was able to distinguish *Egbert* and *Electric Storage Battery* on this basis, because “neither the inventor nor anyone else ever used the Cherry Model 5 to transmit data in the normal course of business.”

But how public must the use be? The *Egbert* Court assumed a minimalist approach to public use. The public use was by Samuel Barnes’ wife, Frances, of apparently a single embodiment of the invention that could not be seen by the “public eye.” Frances was the public. (Sturgis’ involvement just made it easier to prove public use, yet Frances alone was enough for the majority.) Thus, *Egbert* established that public use will be found when one person other than the inventor, engages in one non-private use of one article. The public-use threshold is low, but clean and easier to apply than a test requiring, for example, an “unreasonable number of people or articles” before the public-use bar attaches. Once you move beyond one person, one article, the test becomes more difficult to apply. But ease of application can lead to potentially harsh results. Also, Samuel and Frances were romantically involved (or, as the court said, were “intimate friend[s]”) and eventually married. Thus, couldn’t one argue that there was an implied expectation of confidentiality inherent in their relationship, much like the dentist-patient relationship in *TP Laboratories*, relied upon by the court in *Motionless*? Of course, by the time of the marriage, Frances had already engaged in public use.

2. **Private Uses.** A patentee can take precautions against application of the public-use bar. For instance, a private use, under the inventor’s control, and not for commercial purposes, will not invoke 102(b). As Judge Learned Hand wrote in *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), “[i]t is indeed true that an inventor may continue for more than a year to practice his invention for his private

purposes of his own enjoyment and later patent it. But that is, properly considered, not an exception to the doctrine, for he is not then making use of his secret to gain a competitive advantage over others; he does not thereby extend the period of his monopoly.” Applying this principle to *Egbert*, it may have been deemed a private use if Frances (instead of Samuel) were the inventor in *Egbert*, told no one of the corset, and simply used the corset for its intended purpose. What if Frances were the inventor and told Samuel about her corset invention? Presumably, this disclosure would not be public use under *Motionless* because the corset was not *used* for its intended purpose.

Private uses of an invention by the inventor or confidential-based uses are excluded from the purview of § 102(b). Recall, the patentee in *Motionless* avoided a finding of public use by employing NDA agreements. And in *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261 (Fed. Cir. 1986), the invention was the “Rubik’s Cube,” the popular puzzle of years ago. The inventor was a graduate student who built several embodiments of the invention, and displayed them to his roommates and another graduate student. He also revealed the invention to his employer. The Federal Circuit held this was not a public use because they were under the control of the inventor who did not allow unrestricted use and “had not given over the invention for free.” *Id.* at 1266.

In *Invitrogen v. Biocrest*, 424 F.3d 1374 (Fed. Cir. 2005), the patentee used the claimed process before the critical date, in its own laboratories, to produce cells that would be used within the company for other projects. The record also showed that the patentee kept its use of the claimed process confidential. The process was known only within the company. The patentee did not sell the claimed process or any products made with it. Nonetheless, the district court determined that use of the claimed invention in the patentee’s general business of widespread research generated commercial benefits, and therefore, § 102(b) applied. The patentee argued, however, that its secret internal use was not “public use” because it neither sold nor offered for sale the claimed process or any product derived from the process, nor did it otherwise place into the public domain either the process or any product derived from it. The Federal Circuit agreed, stating the “fact that Invitrogen secretly used cells internally to develop future products that were never sold, without more, is insufficient to create a public use bar to patentability.” *Id.* at 1383.

3. ***Commercial Exploitation of Products Made from Secret Processes.*** The commercial exploitation of a product made from a secret process leads to an invalidating public use. In the well-known case of *Metallizing*, Judge Hand addressed this issue and candidly wrote that the inventor “must content himself with either secrecy, or legal monopoly.” 153 F.2d at 520. It is of little moment that the public learned little if anything about the process. *Id.*

COMPARATIVE PERSPECTIVE

Prejudicial Disclosures Under the European Patent Convention

The EPC is less generous to the patent applicant than American patent law in terms of types of disclosures that can defeat patent rights. Under Article 55, novelty will not be defeated if the invention was disclosed “no earlier than six months” before the European patent application was filed *and* the disclosure “was due to, or in consequence of” either (1) “an evident abuse in relation to the applicant or his legal predecessor” or the (2) “applicant or his legal predecessor displayed the invention at an officially recognized, international exhibition.” Under American patent law, the grace period is one year and any type of activity within that one year grace period cannot defeat patent rights.

The temporal condition of Article 55 requires a disclosure of the invention six months prior to the filing of the European patent application. This clause does not expressly address the question of what happens when priority applications are in play, namely, is it six months prior to the actual filing of the European application or six months prior to the filing of a priority application upon which the European application relies. The Enlarged Board of Appeal sided with the former, stating: “For the calculation of the six-month period referred to in Article 55 EPC, the relevant date is the date of the actual filing of the European patent application; the date of priority is not to be taken account of in calculating this period.” *University Patents*, G03/98. The Board provided several reasons. First, Article 89, which governs priority, only expressly mentions Articles 54 and 60, not Article 55. Thus, said the Board, “neither the wording of Article 55 EPC nor that of Article 89 EPC provides for the period for non-prejudicial disclosures to be calculated from the priority date.” The Board rejected the argument that Article 89 implicitly refers to Article 55. This argument is based on Article 89’s express mention of Article 54(2) and (3), which in turn expressly mentions Article 55. According to the Board, this argument is unpersuasive because “Article 89 EPC associates the effect of the priority right not with the state of the art but with three specifically named provisions, which do not include Article 55 EPC. That is where it differs from Article 56, which refers generically to the notion of the state of the art for the purpose of deciding whether there has been an inventive step.” Lastly, the Board rejected the argument that it is “unreasonable that the fate of an application should be conditional on whether it was originally filed with a national office or with the EPO.” The Board thought this argument was “beside the point” and stated “on the assumption that a provision in line with Article 55 EPC applies to the national office, all that matters is whether the application being assessed is a first filing or a subsequent application filed more than six months after the disclosure. Only the first filing enjoys protection against abusive disclosure, not the subsequent application, regardless of whether it is filed with the EPO or with a national office.” (The Board did note that the national courts of Switzerland and Germany are in accord with the Board’s interpretation, but the Netherlands dates the six-month period from date of priority.)

An “evident abuse in relation to the application” requires the existence of a confidential relationship or one based on trust, either as part of an express written agreement or implicitly formed based on the relationship or business dealings of the relevant parties. *See* European Patent Office Guidelines for Examination D-V 3.1.3.2 (“The basic principle to be adopted is that subject-matter has not been made available to the public by use or in any other way if there is an express or tacit agreement on secrecy which has not been broken (reference should be made to the particular case of a non-prejudicial disclosure arising from an evident abuse in relation to the applicant, in accordance with Art. 55(1)(a)), or if the circumstances of the case are such that such secrecy derives from a relationship of good faith or trust. Good faith and trust are factors which may occur in contractual or commercial relationships.”) For instance, negotiations between parties related to an inchoate or unpatented invention will likely lead to a finding of implied confidentiality. The abuse in question refers to a breach of this relationship, but the focus of the breach is not on the intent of the breaching party, but rather the effect of the breach “unjustifiably injuring the rights of the actual person entitled.” ¹EUROPEAN PATENT CONVENTION: A COMMENTARY 139 (M. Singer & D. Stauder eds., 2003). Moreover, an abuse can occur if the invention was obtained unlawfully (*e.g.*, theft) from the inventor or a third party who was in a confidential relationship with the inventor. The United Kingdom Patent Act of 1977 assumes this position more explicitly than the EPC. *See* § 2(4)(a). But the UK Patent Act expressly notes that § 2 (and many other sections) “are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention.” In this particular instance, the EPC is more generous to the inventor than the American patent code. Under 35 U.S.C. § 102, not only is independent third-party disclosure capable of defeating patent rights, but a third party who steals (or pirates) the invention or obtains it by fraud and subsequently discloses can defeat patent rights.

The second form of non-prejudicial disclosure relates to inventions disclosed at officially recognized conventions (or exhibitions). The exhibition must be recognized by the Convention on International Exhibitions (“CIE”). *See* <http://www.bie-paris.org/main/index.php?p=214&m2=227> (last visited March 13, 2007). This provision of Article 55 is seldom used, because, according to Singer and Stauder, “[e]xhibitions that satisfy the requirements specified in the [CIE] are extremely rare.” ¹ EUROPEAN PATENT CONVENTION: A COMMENTARY 140 (M. Singer & D. Stauder eds., 2003).

C. EXPERIMENTAL USE

A patentee may rebut a finding of public use by asserting he was engaged in experimental use, an argument frequently employed by patentees in the face of a public use or on-sale allegation. An invention cannot be in public use or

on-sale in the legal sense of these terms if it were subject to ongoing experimentation. The factors that comprise an experimental use defense are explored in the following principal cases.

CITY OF ELIZABETH v. AMERICAN NICHOLSON PAVEMENT CO.

97 U.S. (7 Otto) 126 (1878)

Justice BRADLEY delivered the opinion of the court.

This suit was brought by the American Nicholson Pavement Company against the city of Elizabeth, N.J., George W. Tubbs, and the New Jersey Wood-Paving Company, a corporation of New Jersey, upon a patent issued to Samuel Nicholson, . . . for a new and improved wooden pavement . . . [I]n the specification, it is declared that the nature and object of the invention consists in providing a process or mode of constructing wooden block pavements upon a foundation along a street or roadway with facility, cheapness, and accuracy, and also in the creation and construction of such a wooden pavement as shall be comparatively permanent and durable, by so uniting and combining all its parts, both superstructure and foundation, as to provide against the slipping of the horses' feet, against noise, against unequal wear, and against rot and consequent sinking away from below. . . . The patent has four claims, the first two of which, which are the only ones in question, are as follows:

I claim as an improvement in the art of constructing pavements:

1. Placing a continuous foundation or support, as above described, directly upon the roadway; then arranging thereon a series of blocks, having parallel sides, endwise, in rows, so as to leave a continuous narrow groove or channel-way between each row, and then filling said grooves or channel-ways with broken stone, gravel, and tar, or other like materials.
2. I claim the formation of a pavement by laying a foundation directly upon the roadway, substantially as described, and then employing two sets of blocks: one a principal set of blocks, that shall form the wooden surface of the pavement when completed, and an auxiliary set of blocks or strips of board, which shall form no part of the surface of the pavement, but determine the width of the groove between the principal blocks, and also the filling of said groove, when so formed between the principal blocks, with broken stone, gravel, and tar, or other like material.

The bill charges that the defendants infringed this patent by laying down wooden pavements in the city of Elizabeth, N.J., constructed in substantial conformity with the process patented, and prays an account of profits, and an injunction.

* * *

They averred that the alleged invention of Nicholson was in public use, with his consent and allowance, for six years before he applied for a patent, on a certain avenue in Boston called the Mill-dam; and contended that said public use worked an abandonment of the pretended invention.

* * *

To determine this question, it is necessary to examine the circumstances under which this pavement was put down, and the object and purpose that Nicholson had in view. It is perfectly clear from the evidence that he did not intend to abandon his right to a patent. He had filed a caveat in August, 1847, and he constructed the pavement in question by way of experiment, for the purpose of testing its qualities. The road in which it was put down, though a public road, belonged to the Boston and Roxbury Mill Corporation, which received toll for its use; and Nicholson was a stockholder and treasurer of the corporation. The pavement in question was about seventy-five feet in length, and was laid adjoining to the toll gate and in front of the toll-house. It was constructed by Nicholson at his own expense, and was placed by him where it was, in order to see the effect upon it of heavily loaded wagons, and of varied and constant use; and also to ascertain its durability, and liability to decay. Joseph L. Lang, who was toll-collector for many years, commencing in 1849, familiar with the road before that time, and with this pavement from the time of its origin, testified as follows:

Mr. Nicholson was there almost daily, and when he came he would examine the pavement, would often walk over it, cane in hand, striking it with his cane, and making particular examination of its condition. He asked me very often how people liked it, and asked me a great many questions about it. I have heard him say a number of times that this was his first experiment with this pavement, and he thought that it was wearing very well. The circumstances that made this locality desirable for the purpose of obtaining a satisfactory test of the durability and value of the pavement were: that there would be a better chance to lay it there; he would have more room and a better chance than in the city; and, besides, it was a place where most everybody went over it, rich and poor. It was a great thoroughfare out of Boston. It was frequently traveled by teams having a load of five or six tons, and some larger. As these teams usually stopped at the toll-house, and started again, the stopping and starting would make as severe a trial to the pavement as it could be put to.

This evidence is corroborated by that of several other witnesses in the cause; the result of the whole being that Nicholson merely intended this piece of pavement as an experiment, to test its usefulness and durability. Was this a public use, within the meaning of the law?

An abandonment of an invention to the public may be evinced by the conduct of the inventor at any time, even within the two years named in the law. The effect of the law is, that no such consequence will necessarily follow from the invention being in public use or on sale, with the inventor's consent and allowance, at any time within two years before his application; but that, if the invention is in public use or on sale prior to that time, it will be conclusive evidence of abandonment, and the patent will be void.

But, in this case, it becomes important to inquire what is such a public use as will have the effect referred to. That the use of the pavement in question was public in one sense cannot be disputed. But can it be said that the invention was in public use? The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as such a use.

Now, the nature of a street pavement is such that it cannot be experimented upon satisfactorily except on a highway, which is always public.

When the subject of invention is a machine, it may be tested and tried in a building, either with or without closed doors. In either case, such use is not a public use, within the meaning of the statute, so long as the inventor is engaged, in good faith, in testing its operation. He may see cause to alter it and improve it, or not. His experiments will reveal the fact whether any and what alterations may be necessary. If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished. And though, during all that period, he may not find that any changes are necessary, yet he may be justly said to be using his machine only by way of experiment; and no one would say that such a use, pursued with a bona fide intent of testing the qualities of the machine, would be a public use, within the meaning of the statute. So long as he does not voluntarily allow others to make it and use it, and so long as it is not on sale for general use, he keeps the invention under his own control, and does not lose his title to a patent.

It would not be necessary, in such a case, that the machine should be put up and used only in the inventor's own shop or premises. He may have it put up and used in the premises of another, and the use may inure to the benefit of the owner of the establishment. Still, if used under the surveillance of the inventor, and for the purpose of enabling him to test the machine, and ascertain whether it will answer the purpose intended, and make such alterations and improvements as experience demonstrates to be necessary, it will still be a mere experimental use, and not a public use, within the meaning of the statute.

Whilst the supposed machine is in such experimental use, the public may be incidentally deriving a benefit from it. If it be a grist-mill, or a carding-machine, customers from the surrounding country may enjoy the use of it by having their grain made into flour, or their wool into rolls, and still it will not be in public use, within the meaning of the law.

But if the inventor allows his machine to be used by other persons generally, either with or without compensation, or if it is, with his consent, put on sale for such use, then it will be in public use and on public sale, within the meaning of the law.

If, now, we apply the same principles to this case, the analogy will be seen at once. Nicholson wished to experiment on his pavement. He believed it to be a good thing, but he was not sure; and the only mode in which he could test it was to place a specimen of it in a public roadway. He did this at his own expense, and with the consent of the owners of the road. Durability was one of the qualities to be attained. He wanted to know whether his pavement would stand, and whether it would resist decay. Its character for durability could not be ascertained without its being subjected to use for a considerable time. He subjected it to such use, in good faith, for the simple purpose of ascertaining whether it was what he claimed it to be. Did he do any thing more than the inventor of the supposed machine might do, in testing his invention? The public had the incidental use of the pavement, it is true; but was the invention in public use, within the meaning of the statute? We think not. The proprietors of the road alone used the invention, and used it at Nicholson's

request, by way of experiment. The only way in which they could use it was by allowing the public to pass over the pavement.

Had the city of Boston, or other parties, used the invention, by laying down the pavement in other streets and places, with Nicholson's consent and allowance, then, indeed, the invention itself would have been in public use, within the meaning of the law; but this was not the case. Nicholson did not sell it, nor allow others to use it or sell it. He did not let it go beyond his control. He did nothing that indicated any intent to do so. He kept it under his own eyes, and never for a moment abandoned the intent to obtain a patent for it.

In this connection, it is proper to make another remark. It is not a public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it. In England, formerly, as well as under our Patent Act of 1793, if an inventor did not keep his invention secret, if a knowledge of it became public before his application for a patent, he could not obtain one. To be patentable, an invention must not have been known or used before the application; but this has not been the law of this country since the passage of the act of 1836, and it has been very much qualified in England. Therefore, if it were true that during the whole period in which the pavement was used, the public knew how it was constructed, it would make no difference in the result.

It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. Any attempt to use it for a profit, and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent. . . .

**ELECTROMOTIVE DIVISION OF GENERAL MOTORS
CORP. v. TRANSPORTATION SYSTEMS DIVISION
OF GENERAL ELECTRIC CO.**

417 F.3d 1203 (Fed. Cir. 2005)

MICHEL, Chief Judge.

The Electromotive Division of General Motors Corporation ("EMD") appeals the United States District Court for the Eastern District of Michigan's grant of summary judgment of invalidity of United States Patent Nos. 5,169,242 and 5,567,056 ("the '242 and '056 patents," respectively) under the on sale bar of 35 U.S.C. § 102(b). The '242 patent is generally directed to compressor bearings for use in turbochargers for diesel locomotive engines. The '056 patent relates generally to planetary bearings for use in turbo-charger planetary drive trains. Because the patented compressor and planetary bearings were subject to pre-critical date sales that were commercial and not primarily experimental, we agree with the district court that the '242 and

'056 patents have been proven invalid as a matter of law under the on sale bar of § 102(b). Accordingly, we affirm the district court's grant of summary judgment of invalidity of both patents in favor of the Transportation Systems Division of General Electric Company and Daido Industrial Bearings, Ltd.

I. BACKGROUND

A. EMD's General Design and Testing Procedures

EMD is a division of General Motors Corporation focused on the design and production of locomotives. As part of that business, EMD designs and manufactures component parts for locomotive engines, including the two kinds of bearings at issue in this case. Both types of bearings are embedded in turbochargers, which are in turn embedded in the engines of locomotives that EMD sells.

After developing a new bearing, EMD typically initiates a two-phase testing program before releasing the new bearing for commercial production. In the first phase, termed Reliability Growth Testing, EMD tests its new bearings indoors at its engineering facilities on multiple unit turbocharger cells ("in-house program"). The purpose of the in-house program is to ascertain the durability and reliability of the new bearings.

Upon completion of the in-house program, EMD commences the second phase of testing, termed Reliability Verification Testing ("field program"). This testing occurs outdoors under actual use conditions. That is, after EMD integrates the new bearings into existing orders, the customer railroads use the new bearings in their routine operations. The purpose of this second phase is to verify durability.

During the field program, EMD does not engage in ongoing monitoring or periodic inspections of its new bearings because they are buried inside turbochargers and cannot readily be examined by visual inspection. Rather, EMD inspects the new bearings only if a particular turbocharger fails and is sent back to EMD. In such case, EMD disassembles the failed turbocharger to assess whether the failure was caused by the new bearings or some other part.

B. Events Involving the New Compressor Bearings

In the late 1980s, EMD developed a new compressor bearing for use in diesel locomotive turbochargers. On July 17, 1989, James L. Blase, an EMD employee and one of the named inventors on the two asserted patents, reported during an internal meeting that he had tested the new compressor bearings for approximately 3000 hours in a twelve-cylinder multiple unit locomotive engine. The minutes of that meeting document that the in-house program had been completed. Thus, EMD decided to proceed with the field program by substituting the new compressor bearings into locomotive orders previously placed by Norfolk Southern, Go Transit, and LXXO railroads.¹

EMD contacted Norfolk Southern, Go Transit, and LXXO for permission to substitute the prior art bearings, originally to be used in the purchased

1. In the fall of 1988 and spring of 1989, EMD sold a total of forty-six locomotives to Norfolk Southern, Go Transit, and LXXO, scheduling delivery for late 1989 and early 1990. Norfolk Southern ordered thirty-three locomotives, Go Transit ordered twelve locomotives, and LXXO ordered one locomotive.

locomotives, with the new compressor bearings. According to Mr. Blase, the three railroads agreed to accept the new bearings. None of the three companies, however, signed a confidentiality agreement or any other contract consenting to participate in the field program. They likewise were not given any design details or other documentation regarding the new compressor bearings. Further, Norfolk Southern, Go Transit, and LXO were not restricted or supervised in their use of the new compressor bearings and were not under any obligation to collect data, keep progress records, or even operate the subject locomotives during the time of the field program.

After arranging for the substitution, EMD prepared internal memos documenting the change to be made in the Norfolk Southern, Go Transit, and LXO orders. For example, a July 19, 1989 internal memo stated: "Orders 887007 [for Norfolk Southern], C484 [for Go Transit], and 899110 [for LXO] are to have Turbocharger 40014638 replaced by Turbocharger 40021524. . . . The turbocharger and EMD make component schedules must be revised to reflect this change." A different July 19, 1989 memo stated that "the drawings and bills of material for these orders must be changed to include this new bearing. This will be accomplished with an expedited RFC. Jim Korenchan will write this RFC and get it to the drafting room by 7-19-89." Similarly, a July 25, 1989 internal memo stated: "This new bearing addresses all known failure modes and MUST be included in upcoming 12-710GA engines. The orders affected are the [Norfolk Southern] GP59 order No. 887007, Go Transit order no. C484, and LXO no. 899110."

On August 28, 1989, EMD modified its original specification of February 1, 1989 for the Norfolk Southern order, agreeing to supply more new compressor bearings to Norfolk Southern than originally planned for in its prior locomotive order. In particular, EMD noted that it "will provide spare parts for [Norfolk Southern]'s GP59 loco motives," including the "Turbo" of part number 40021531. The specified Turbo included the new compressor bearings.

Between January 1989 and November 1989, EMD purchased a total of 303 new compressor bearings from Allison Gas & Turbine ("Allison"), another division of General Motors Corporation, for a price of \$298.80 each. Allison manufactured these bearings according to specifications provided by EMD. After receiving the new compressor bearings from Allison, EMD substituted them into locomotives previously sold to Norfolk Southern, Go Transit, and LXO. Thereafter, EMD shipped the subject locomotives to the three railroads.

On November 27, 1990, EMD filed a patent application for its new compressor bearings. Based upon this filing date, the critical date for applying the on sale bar for the '242 patent is November 27, 1989. The '242 patent issued on December 8, 1992. Claims 1 through 7 of the '242 patent are directed to a turbocharger assembly, and claims 8 through 18 are directed to the new compressor bearings.

On August 19, 1991, EMD released the new compressor bearings for production. All locomotive sales involving diesel engines after August 1991 included the new compressor bearings. Before this release, however, EMD employed prior art bearings in all customer orders, except the Norfolk Southern, Go Transit, and LXO orders discussed above. EMD likewise did not advertise, market, or create promotional materials for the new compressor bearings prior to the August 1991 release.

C. Events Involving the New Planetary Bearings

In September 1992, EMD designed a new planetary bearing for use in turbocharger planetary drive trains. In January 1993, EMD initiated the in-house program for this new bearing type. In March 1993, EMD decided to proceed with the field program. To do so, EMD approached Union Pacific railroad for permission to substitute its new planetary bearings for prior art bearings in an order for two locomotives that Union Pacific placed earlier in 1992. Union Pacific allegedly agreed. Nevertheless, it did not sign a confidentiality agreement or any other type of a contract consenting to participate in the field program. Union Pacific also was not placed under any restrictions or supervision regarding the use of the locomotives containing new planetary bearings. Nor was Union Pacific given any design details for the new planetary bearings or required to monitor or document its usage of the subject locomotives during the field program.

On July 6, 1993, EMD ordered 105 new planetary bearings at \$88.87 per bearing from its supplier Glacier, now Daido Industrial Bearings, Ltd. ("Daido"). On August 6, 1993, EMD installed six planetary bearings that it had purchased from Daido into turbochargers for the two locomotives destined for Union Pacific. EMD shipped those locomotives to Union Pacific that same day. On September 7, 1994, EMD released the planetary bearings for production, meaning that the new planetary bearings were included in all future locomotive sales involving turbocharger planetary drive trains.

On September 29, 1994, EMD filed a patent application for its new planetary bearings. Based upon this filing date, the critical date for the '056 patent is September 29, 1993. The '056 patent issued on October 22, 1996. Claims 1 through 6 of the '056 patent are directed to the new planetary bearings, while claim 7 is directed to a turbocharger planetary drive train.

D. Trial Court Proceedings

... In May 2004, the district court granted GE's and Daido's motions and denied EMD's cross-motion. The district court held that EMD's purchase of new compressor bearings from Allison before the critical date was a commercial sale within the meaning of § 102(b). The district court also held that both EMD's substitution of new compressor bearings in place of prior art bearings in sales made to Norfolk Southern, Go Transit, and LXX prior to the critical date and its sale of spare compressor bearings to Norfolk Southern prior to the critical date separately raised the on sale bar. As for the planetary bearings, the district court concluded that Daido's sale of the planetary bearings to EMD prior to the critical date and EMD's substitution of two sets of new planetary bearings for prior art bearings in locomotives sold to Union Pacific prior to the critical date were each invalidating sales under § 102(b).

The district court considered whether the objective indicia suggesting experimentation precluded the on sale bar for either the '242 or '056 patent, ultimately concluding that they did not. The district court found that the various transactions between EMD, Allison, Daido, and EMD's four railroad customers were no different than normal commercial sales. The district court also found that EMD exercised no control over its customers' use of the new bearings after they were sold. The district court further found that there was little evidence of experimentation given that (1) neither EMD nor its custo-

mers maintained any test data, progress reports, or other records; (2) EMD sold a large number of new compressor and planetary bearings during the periods of alleged experimentation; and (3) EMD inspected failed turbochargers in the ordinary course of business, not as part of any experimental protocol. Lastly, the district court found that the field program was unnecessary because EMD had established that both types of new bearings were durable through the in-house program.

II. DISCUSSION

* * *

B. Evidence of Experimentation

GE contends that EMD's sale of spare compressor bearings cannot be the subject of experimentation. We are persuaded by this contention, noting in particular that the record does not reveal when or how Norfolk Southern intended to use the spare compressor bearings. There also was no evidence showing that Norfolk Southern replaced even one of the compressor bearings found in locomotives that EMD considered part of its field program with one of the spare compressor bearings. Such replacement must have occurred prior to the production release of the new compressor bearings in August 1991. Any replacement after that date certainly could not qualify as experimentation because EMD incorporated the new compressor bearings into all diesel engine locomotive orders following production release. Therefore, for the reasons set forth below, we conclude that EMD's sale of spare compressor bearings to Norfolk Southern was not primarily for experimentation and thus that the district court did not err in holding the '242 patent invalid under § 102(b).

Regarding planetary bearings, EMD argues that, at a minimum, a genuine issue of fact exists as to whether the sale of the new planetary bearings was primarily for experimentation, pointing out that (1) completion of the field program was required under EMD's policy before releasing a new bearing for production; (2) neither monitoring nor inspection was necessary because the purpose of the field program was merely to verify durability; (3) inspection was not even possible because the new planetary bearings were embedded in the turbochargers housed inside locomotive engines; and (4) failed turbochargers were returned to EMD for teardown and inspection. EMD also analogizes the facts here to those in *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544 (Fed. Cir. 1990), and *EZ Dock*, 276 F.3d 1347. In both cases, which involved durability testing, we rejected an assertion of the on sale bar.

GE responds that the field program was unnecessary because the new planetary bearings had already been shown to work for their intended purpose during the in-house program. GE also asserts that durability testing under actual use conditions was not required because durability is not a claim limitation in the '056 patent. Additionally, GE contends that the district court correctly found, despite EMD's subjective intent to experiment, that the objective evidence revealed that EMD's sale to Union Pacific was not primarily for experimentation, noting, inter alia, that EMD did not control Union Pacific's use of the new planetary bearings and that the field program lacked the customary objective indicia associated with experimentation such as test records.

At the outset, we observe that EMD purchased the new planetary bearings from Daido to use in filling Union Pacific's pre-critical date locomotive order, which was to contain new planetary bearings instead of prior art bearings. Thus, we reason that the sale from Daido to EMD ("upstream sale") and the sale from EMD to Union Pacific ("downstream sale") are so inextricably linked that we cannot identify the purpose for the Daido's upstream sale without examining the purpose for EMD's downstream sale. Our analysis concerning whether the new planetary bearings were the subject of an invalidating sale under § 102(b), consequently, hinges on the purpose for the sale from EMD to Union Pacific.

It is important to recognize that this court has limited experimentation sufficient to negate a pre-critical date public use or commercial sale to cases where the testing was performed to perfect claimed features, or, in a few instances like the case here, to perfect features inherent to the claimed invention. *See, e.g., EZ Dock*, 276 F.3d at 1353 (experimentation focused on durability of claimed polyethylene floating dock in turbulent water of the Mississippi River, although durability was not a claim limitation); *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1320 (Fed. Cir. 1996) (experimentation focused on durability of claimed all-weather activity mat under harsh weather conditions, but durability was not a claim limitation); *Manville*, 917 F.2d at 550-51 (experimentation focused on durability of claimed self-centering, lightpole luminaire under severe winter conditions in Wyoming, even though durability was not a claim limitation). Here, EMD designed its field program to verify durability, a feature, although unclaimed, we hold is inherent to the new planetary bearings. Hence, evidence showing that EMD's field program has the requisite objective indicia of experimentation may negate EMD's pre-critical date sale of the new planetary bearings to Union Pacific.²

Few decisions address how to determine if a pre-critical date public use or sale is experimental rather than a public use or sale under § 102(b), even though the doctrine has been in existence since *City of Elizabeth v. Pavement Co.*, 97 U.S. 126 (1878).³ But certain things are settled. Significantly, an inventor's subjective intent to experiment cannot establish that his activities are, in fact, experimental.

When sales are made in an ordinary commercial environment and the goods are placed outside the inventor's control, an inventor's secretly held subjective intent to "experiment," even if true, is unavailing without objective evidence to support the contention. Under such circumstances, the customer at a minimum must be made aware of the experimentation.

LaBounty Mfg. v. United States ITC, 958 F.2d 1066, 1072 (Fed. Cir. 1992). Thus, while EMD officials may have subjectively believed they were conducting

2. It is well-settled that an accused infringer carries the burden of proving invalidity by clear and convincing evidence. When the accused infringer alleges invalidity under § 102(b) based upon a pre-critical date public use or commercial sale, however, an inventor may introduce evidence showing that his public use or sale was primarily for purposes of experimentation, thus neutralizing the accused infringer's showing.

3. Although *City of Elizabeth* involved a pre-critical date public use of the claimed invention, we have applied experimentation not only in that context but also in the on sale context. *See In re Hamilton*, 882 F.2d 1576, 1580 (Fed. Cir. 1989).

experimentation under actual use conditions, their beliefs cannot establish that EMD's sales were primarily for experimentation.

We have generally looked to objective evidence to show that a pre-critical date sale was primarily for experimentation. For example, in *T.P. Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir. 1984), we indicated that various objective indicia may be considered in determining whether the inventors engaged in experimentation:

The length of the test period is merely a piece of evidence to add to the evidentiary scale. The same is true with respect to whether payment is made for the device, whether a user agreed to use secretly, whether records were kept of progress, whether persons other than the inventor conducted the asserted experiments, how many tests were conducted, how long the testing period was in relationship to tests of other similar devices.

Id. at 971-72.

Recently, we catalogued and consolidated all these considerations into a list of thirteen objective factors: (1) the necessity for public testing; (2) the amount of control over the experiment retained by the inventor; (3) the nature of the invention; (4) the length of the test period; (5) whether payment was made; (6) whether there was a secrecy obligation; (7) whether records of the experiment were kept; (8) who conducted the experiment; (9) the degree of commercial exploitation during testing; (10) whether the invention reasonably requires evaluation under actual conditions of use; (11) whether testing was systematically performed; (12) whether the inventor continually monitored the invention during testing; and (13) the nature of the contacts made with potential customers. *Allen Eng'g*, 299 F.3d at 1353. This list is not exhaustive, and all of the experimentation factors may not apply in a particular case. They simply represent various kinds of evidence relevant to the question of whether pre-critical date activities involving the patented invention—either public use or sale—were primarily experimental and not commercial.

This court, however, has held or at least suggested that certain evidentiary showings can be dispositive of the question of experimentation. In *In re Hamilton*, 882 F.2d 1576 (Fed. Cir. 1989), we stated:

First, we may agree with [the inventor] that control is not the “lodestar” test in all cases involving experimental use. It is nonetheless an important factor. The experimental use doctrine operates in the inventor's favor to allow the inventor to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application. If it is not the inventor or someone under his control or “surveillance” who does these things, there appears to us no reason why he should be entitled to rely upon them to avoid the statute.

Id. at 1581 (emphasis in original). We observed that nothing in the record showed that the *Hamilton* inventor knew what, if anything, the customer was doing in terms of testing the invention. As a result, we concluded that the inventor's purpose in making the sale was not primarily experimental.

Following *Hamilton*, this court again emphasized the importance of control in *Lough v. Brunswick Corp.*, 86 F.3d 1113 (Fed. Cir. 1996). In particular, this court said that an inventor must show control over the alleged testing to establish experimentation. *Id.* at 1120. Additionally, the *Lough* court placed critical emphasis on experimental records. After listing various objective

indicia of experimentation, which included both whether records or progress reports were made concerning the testing and the extent of control the inventor maintained over the testing, this court stated: “The last factor of control is critically important, because, if the inventor has no control over the alleged experiments, he is not experimenting. If he does not inquire about the testing or receive reports concerning the results, similarly, he is not experimenting.” *Id.* The *Lough* court also stated: “When one distributes his invention to members of the public under circumstances that evidence a near total disregard for supervision and control concerning its use, the absence of these minimal indicia of experimentation require a conclusion that the invention was in public use.” *Id.* at 1122 (emphasis added). Hence, this court held, based primarily upon the absence of control and records, that the inventor’s public use of the claimed invention was not experimental.

Two years after *Lough*, in a concurring opinion in *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340 (Fed. Cir. 1998), Judge Bryson urged that control and recordkeeping are vital to a showing of experimentation. “Certain factors, such as the requirement that the inventor control the testing, that detailed progress records be kept, and that the purported testers know that testing is occurring, are critical to proving experimental purpose.” *Id.* at 1380 (citing *Lough*, 86 F.3d at 1120). Judge Bryson stressed awareness by the purported testers that testing is occurring. He suggested or at least implied that consideration of these three factors form the first, and potentially decisive, step in determining whether a public use or sale was primarily experimental. Indeed, we discern that Judge Bryson applied only these three factors to conclude that the on sale bar applied.

The facts of this case are analogous to those in *U.S. Environmental Products, Inc. v. Westall*, 911 F.2d 713 (Fed. Cir. 1990). In *Westall*, this court affirmed a district court’s conclusion that a patent was invalidated by a sale more than one year before the filing date. That conclusion was based primarily on (1) the lack of written progress records and the failure to adhere to a testing schedule; (2) the inventor’s failure to maintain control over the testing; and (3) promotion of the invention during the testing. In this case, as in *Westall*, the evidence shows that neither the in-house tests . . . nor the field tests . . . were under the control of the inventor or his company. There is little or no evidence of any written progress records; indeed, the inventor was apparently never provided with any test results. Finally, the communications between [a company with which the inventor was associated] and [the customer] throughout the purported testing period emphasized commercial sales and projections, not controlled experimentation.

Id. at 1381 (internal citation omitted).

We agree with Judge Bryson that a customer’s awareness of the purported testing in the context of a sale is a critical attribute of experimentation. If an inventor fails to communicate to a customer that the sale of the invention was made in pursuit of experimentation, then the customer, as well as the general public, can only view the sale as a normal commercial transaction. Indeed, our predecessor court recognized in *In re Dybel*, 524 F.2d 1393, 1401 (C.C.P.A. 1975), that “[an inventor’s] failure to communicate to any of the purchasers or prospective purchasers of his device that the sale or offering was for experimental use is fatal to his case.” And, “we have held that the assertion of experimental sales, at a minimum, requires that customers must be made aware

of the experimentation.” *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1186 (Fed. Cir. 1993). Accordingly, we hold not only that customer awareness is among the experimentation factors, but also that it is critical.

Our precedent has treated control and customer awareness of the testing as especially important to experimentation. Indeed, this court has effectively made control and customer awareness dispositive. *See, e.g., Lough*, 86 F.3d at 1120; *Hamilton*, 882 F.2d at 1581. Accordingly, we conclude that control and customer awareness ordinarily must be proven if experimentation is to be found.

We now consider the facts of this case. First, the record, as the district court noted, is devoid of any evidence that EMD, or Union Pacific under EMD’s direction, controlled the field program for its new planetary bearings. EMD did not provide any protocols to Union Pacific directing their use of locomotives containing the new planetary bearings. EMD likewise neither supervised nor restricted Union Pacific’s use of the new planetary bearings in any way. Mr. Blase testified that the railroads involved in the field testing were not required to run the subject locomotives under any specific conditions.

The record also shows that EMD made no attempt to monitor the conditions under which Union Pacific used the “test” locomotives. EMD explains away its lack of oversight by arguing that the field program was conducted solely to verify the durability of its new planetary bearings as measured by the number of turbocharger failures, not by the daily use of its new planetary bearings. Such an argument is, however, unconvincing. EMD did not request or receive any comments or data from Union Pacific concerning the operation or durability of its new planetary bearings. Without obligating Union Pacific to provide such feedback, it cannot be reasonably said that EMD exercised any monitoring over the field program.

That Union Pacific returned failed turbochargers to EMD for teardown and inspection is insufficient to establish EMD’s control over the field program. Union Pacific voluntarily returned failed turbochargers under the basic warranty given by EMD to all of its customers. It was not, however, under any obligation to do so. Mr. Blase testified that EMD requested the return of failed components from all customers in the ordinary course of business. Union Pacific thus would have returned all failed turbochargers whether it was participating in experimentation or was merely an ordinary customer. What is more, EMD’s teardown reports focused only on the appearance and features of the new planetary bearings without any correlation to the field conditions. Nothing in the teardown reports thus distinguish them from any other failure reports prepared outside the field program. Accordingly, the district court did not err in finding that EMD exercised no control over Union Pacific’s use of the new bearings.

Second, the record is insufficient, even on summary judgment, to objectively establish Union Pacific’s awareness of the field program. The only evidence regarding communications with Union Pacific concerning the field program comes from Mr. Blase’s deposition testimony and an internal memo he prepared. In his deposition, Mr. Blase testified:

Q: Okay. Now when you would generally send out or do field verification or reliability verification in the field, were there agreements that customers entered into in connection with those?

- A: The customer would understand that — that the — that what they were receiving would be a reliability verification test.
- Q: Would you tell them which components were associated with that?
- A: We would indicate to them which components are under reliability — reliability verification test, yes.
- Q: You would tell them that.
- A: Sure.
- Q: Okay. Did they sign any type of secrecy agreement or confidentiality agreement in connection with that?
- A: I do not know that.
- Q: Okay. Who would know that?
- A: The—the correspondence with the customer would be handled through the sales department as far as I know.
- Q: And who was in the sales department during this timeframe?
- A: I don't recall.

Similarly, in his memo, Mr. Blase stated under the heading “Status of Public Disclosure” that “upon applying for field test on a customer’s locomotive, the customer is made aware that there is an experimental part in the turbochargers they are receiving, yet details of the part are not fully disclosed.” Apart from this single sentence, Mr. Blase did not otherwise describe EMD’s communications with any customer or state exactly what Union Pacific was told, if anything.

Neither Mr. Blase’s testimony nor his memo establishes awareness by Union Pacific that the new planetary bearings were substituted into their pre-existing order for the purpose of testing those bearings in actual use rather than as part of a commercial sale. Mr. Blase’s testimony simply suggests the possibility that an unidentified EMD employee may have engaged in a conversation with one or more unidentified employees of Union Pacific about substituting the new planetary bearings.

Further, the record fails to show any objective evidence supporting Mr. Blase’s inference that Union Pacific was “aware” of the field testing. It does not contain even the hint of a written agreement with Union Pacific, testimony from any representative of Union Pacific describing the railroad’s awareness of the field program, or any other form of corroborating documentation held by Union Pacific regarding the field program. The lack of such evidence to corroborate Mr. Blase’s conclusory testimony and memo thus validates the lack of customer awareness.

The facts here are closely analogous to those in *Lough*, where, as noted above, this court rejected an inventor’s claim that a pre-critical date public use of his liquid seal assembly invention was made for experimentation. In *Lough*, the inventor distributed six prototypes of his liquid seal assembly invention to his friends for use in their boats. After distribution, the *Lough* inventor did not maintain any supervision over his friends’ use of the liquid seal assemblies or follow-up with them for comments as to the operability of the liquid seal assemblies. Similarly, EMD allowed Union Pacific unsupervised use of the new planetary bearings. EMD neither monitored the conditions under which Union Pacific used the new planetary bearings nor solicited any feedback from Union Pacific regarding the bearings’ performance. What is more, EMD, like the inventor in *Lough*, did not maintain any records of the alleged testing or require Union Pacific to do so. As we stated in *Lough*, “Lough’s failure to monitor the use

of his prototypes by his acquaintances, in addition to the lack of records or reports from those acquaintances concerning the operability of the devices, compel the conclusion that, as a matter of law, he did not engage in experimental use.” 86 F.3d at 1122. We are equally compelled to conclude as a matter of law that EMD did not engage in any experimentation on its new planetary bearings.

Finally, contrary to EMD’s contention, *Manville* and *EZ Dock* do not control the outcome here, even though both cases involve durability testing of inventions under actual use conditions which we held to be experimental. *EZ Dock* and *Manville* are factually distinguishable, especially with respect to control, recordkeeping, and customer awareness.

In *EZ Dock*, two inventors designed a floating dock made of polyethylene. They later installed one at a customer’s fishing camp located in an area of the Mississippi River that experienced heavy boat traffic and turbulent water flow. Unlike the inventors in *EZ Dock* who routinely inspected the installed polyethylene floating dock over the course of a summer, EMD did nothing to control, monitor, or systematize the field testing of its new planetary bearings. EMD did not require Union Pacific to follow any protocols when using the subject locomotive s. EMD likewise did not examine the new planetary bearings on any schedule. Instead, it did so only when a turbocharger failed.

Additionally, while shopping at one of the inventor’s office supply stores to buy a copier, the *EZ Dock* customer noticed the polyethylene floating docks being stored in the window and approached that inventor requesting to purchase one. Here, EMD approached Union Pacific, a long-time customer, requesting permission to substitute the new planetary bearings into an order that Union Pacific had previously placed. The customer in *EZ Dock* thus was aware that the polyethylene floating dock was not commercially available, but instead experimental. The same cannot be said for Union Pacific given that the record contains only vague, conclusory, and uncorroborated testimony about Union Pacific’s awareness of the experimental nature of the field program. Moreover, the sale in *EZ Dock* was an isolated, unexpected occurrence. The *EZ Dock* inventor clearly was not intending to sell the polyethylene floating dock, much less earn a profit from the sale, as evidenced by the fact he charged only 75 percent of the final retail price. In contrast, there is no evidence to suggest that EMD discounted the price of the locomotive Union Pacific ordered to offset the risk that the new planetary bearings might fail. Therefore, the record suggests that EMD made the substitution as part of a commercial sale to make money, not primarily to experiment.

Finally, the inventors in *EZ Dock* had not tested the polyethylene floating dock in turbulent water for any length of time. They had only floated it in the Mississippi River on occasion and installed several at a marina where the water conditions were fairly stable. They did not know whether their polyethylene floating dock would be durable under heavier water flow conditions, thus establishing a need for the turbulent water testing. EMD, in comparison, had tested the new planetary bearings in the in-house program and already knew they were durable. In light of these significant factual differences, it is clear that EMD’s reliance on *EZ Dock* is misplaced.

Turning to *Manville*, the plaintiff’s employees invented a new, self-centering lightpole luminaire and installed one in a rest area being built along an interstate highway in Wyoming, but not yet open to the public. The *Manville* plaintiff directly controlled the testing by installing the luminaire in the fall,

removing it in the spring, and thoroughly examining it following this testing period. By contrast, EMD did not control or systematize Union Pacific's use of the subject locomotives. Union Pacific was not placed under any restrictions or obligations concerning its use of the new planetary bearings; it was free to use the subject locomotives daily or not at all, in hot, dry climates or cold, wet climates, with maximum loads or load-free.

Also, the State of Wyoming knew of the experimental and confidential nature of Manville's installation of the luminaire. Indeed, Manville specifically informed a Wyoming official that its use of one luminaire on one pole at one site in Wyoming was experimental. The State of Wyoming likewise received a drawing of the luminaire containing a confidentiality notice. Here, the situation was quite the reverse. Mr. Blase gave only vague, conclusory, and uncorroborated testimony regarding Union Pacific's possible awareness of the experimentation. Such testimony, however, cannot establish what Union Pacific really knew about the purpose of the sale, especially without correspondence with Union Pacific or other documentation.

In addition, Manville lacked confidence that the luminaire would perform in its intended environment because Manville only tested a single luminaire on a pole in the backyard of its Ohio factory for a few days, not under Wyoming winter conditions of high wind and ice for any extended period of time. In contrast, EMD subjected its new planetary bearings to the in-house program, which simulated actual use conditions over extended periods of time. EMD also failed to point to any evidence, like the internal memo written by a Manville employee, objectively explaining why actual conditions were impossible to replicate through its in-house program.

Finally, the State of Wyoming agreed to purchase the luminaire only if it proved operable after the winter. As a result, the State of Wyoming withheld payment until the results of the weather-related testing were known. Here, Union Pacific neither conditioned its purchase of the locomotive on the operability of the new planetary bearings nor withheld payment in an amount corresponding to the cost of the new planetary bearings pending the results of the field program. Viewing all of the differences between the facts in *Manville* and those implicated here, we conclude that EMD's reliance on *Manville*, like its reliance on *EZ Dock*, is misplaced.

Because the facts do not show the existence of control or customer awareness, we do not consider the other experimentation factors. We conclude, as a matter of law, that EMD's sale to Union Pacific of the new planetary bearings was not made primarily for experimentation. We, therefore, conclude that Daido's sale to EMD could not have been made primarily for experimentation, since the purpose for the upstream sale was to make the downstream sale possible. Accordingly, the district court did not err in holding the '056 patent invalid under the on sale bar of § 102(b).

LISLE CORP. v. A.J. MANUFACTURING CO.

398 F.3d 1306 (Fed. Cir. 2005)

LOURIE, Circuit Judge.

A.J. Manufacturing Company ("A.J.") appeals from the decision of the United States District Court for the Northern District of Illinois denying A.J.'s

motion for judgment as a matter of law (“JMOL”) after a jury found the ’776 patent was not shown to be invalid for public use. We affirm.

BACKGROUND

The patent in this appeal relates to an inner tie rod tool. Most automobiles today are equipped with a rack and pinion steering control system. A component of the rack and pinion steering control system is the inner tie rods. As the patent explains, “[s]ervicing of such a rack and pinion steering system often requires removal and replacement of the tie rods.” Due to the location of the tie rods and the variety of nut shapes holding the tie rods in place, removal of that component can be tedious with prior art tools. The patented invention alleviates the need for automobile mechanics to completely dismantle steering control systems and keep multiple prior art tie rod tools for various inner tie rod designs.

* * *

Lisle and A.J., the parties to this dispute, are manufacturers and competitors in the field of automotive tools. Lisle owns the ’776 patent, and on October 1, 2002, Lisle filed suit accusing A.J. of infringing the patent by manufacturing and selling its YA3000A tool. In its Answer, A.J. denied infringing the patent and asserted that the patent was invalid.

[After ruling on summary judgment motions relating to infringement,] a jury trial was held on the single issue of whether the ’776 patent was invalid on the ground of public use under 35 U.S.C. § 102(b). On February 12, 2004, the jury found the ’776 patent was not shown to be invalid on the ground of public use. The district court denied A.J.’s motion for JMOL of invalidity of the ’776 patent after the jury rendered its verdict.

DISCUSSION

A patent is presumed to be valid. 35 U.S.C. § 282 (2000). Nonetheless, a patent can be found invalid if “the invention was in . . . public use . . . in this country more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b). Experimental use negates patent invalidity for public use; when proved, it may show that particular acts do not constitute a public use within the meaning of § 102. Although the determination of whether a patent is invalid for public use is a question of law that we review *de novo*, the disputed facts found to support that determination are reviewed for substantial evidence.

* * *

II. Invalidity

A.J. appeals from the denial of its motion for JMOL of invalidity of the ’776 patent on the ground of public use and requests that we overturn a jury verdict concluding otherwise. The undisputed facts are that sometime in May 1989 Lisle became interested in developing an improved tie rod tool. The early prototype tool was similar to A.J.’s product, and Lisle does not dispute that the prototype tool would have fallen within the scope of the claims of the ’776 patent. It is established law that that which infringes, if later, anticipates if earlier. However, on or about December 12, 1989, Lisle delivered the prototype tool to four different automobile repair shops in Omaha, Nebraska. Lisle

did not receive any payment for those tools. Upon distributing the tool, Lisle also did not require any of the mechanics to enter into a formal confidentiality agreement. On June 26, 1992, over thirty months after the first prototype tool was delivered, Lisle filed the application leading to the '776 patent.

A.J. asserts that based on the substantial evidence it presented at trial, the district court should have set aside as a matter of law the jury's verdict that the '776 patent was not shown to be invalid for public use. A.J.'s primary argument for reversing the jury's verdict is that Lisle failed to demonstrate the requisite level of control over the work of the mechanics with the prototype tool to support an experimental use defense. To support its position, A.J. cites the lack of a formal confidentiality agreement, the lack of restrictions placed on the use of the prototype tool by the mechanics, and the absence of any documentary evidence regarding the actual testing of the prototype tool. A.J. also contends that the district court erred by providing a jury instruction with an erroneous standard for rebutting a *prima facie* case of invalidity for public use. Based on that purported legal error, A.J. seeks a new trial on the issue of invalidity for public use.

We affirm the district court's denial of A.J.'s motion for JMOL of invalidity. The parties accept that, were the deliveries of the prototype tools to the automobile repair shops not to constitute experimental use, they would be evidence of public use. After all, the mechanics were members of the relevant public. However, substantial evidence supports the jury's findings of fact in favor of Lisle on the question of experimental use, and those findings support the conclusion of lack of public use. To counter A.J.'s attempt to show public use, Lisle relies on the testimony of Mr. Danny Williams, co-inventor of the '776 patent and an engineer for Lisle, which was presented to the jury. Williams testified that he needed to know how well the wrench disc would fit on the inner tie rod socket and whether the prototype tool would fit in the confined location of the tie rod in different automobile models. Williams also stated that, under company protocol, he and other engineers at Lisle would have contacted the mechanics who were given the prototype tool every two to four weeks by telephone or in person to receive testing feedback. Williams further testified that he modified the design of the retainer in the prototype tool and added additional wrench disc sizes based on comments he received from the outside mechanics. Finally, Williams explained that although there was no formal confidentiality agreement between Lisle and the mechanics who were given the prototype tools, Lisle had prior working relationships with those mechanics. Williams also believed that the mechanics knew that the prototype tool was given to them for experimental purposes.

The jury was also presented with "General Meeting Reports" that were drafted by the president of Lisle, Mr. John Lisle. The reports gave updates on the then-current status of the tie rod tool project, plans for future testing, concerns regarding the commercial viability of the tools, and suggestions from outside mechanics regarding how to improve the design of the tool. Mr. Marvin Negley, Manager of Engineering at Lisle, also testified that those reports were based on information that Mr. Lisle received during weekly management meetings. While we express no view as to whether we as fact-finders might have concluded that this evidence was sufficient to rebut a *prima facie* case of public use, we agree with Lisle that the submitted testimony and reports do constitute substantial evidence from which a reasonable jury could find that Lisle rebutted

the *prima facie* case of public use and thus A.J. failed to prove by facts supported by clear and convincing evidence that the '776 patent was invalid for public use.

Relying upon *TP Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984), A.J. also assigns legal error to the jury instruction because it did not require Lisle to produce “convincing evidence” of experimental use. Instead, the jury instruction only required Lisle to come forward with “evidence” of experimental use. According to A.J., the jury instruction “was tantamount to an instruction that virtually *any* evidence of experimental use would suffice to negate *prima facie* public use.”

We reject A.J.’s request for a new trial because of an allegedly improper jury instruction. “We review the adequacy of the jury instructions for prejudicial legal error,” and we find none here. On numerous occasions, this court has recognized that a party challenging a patent’s validity has the burden of proving by clear and convincing evidence that the patent is invalid, and that that burden does not shift at any time to the patent owner. Nonetheless, if the challenging party presents a *prima facie* case of public use, the patentee must come forward with “convincing evidence” of experimental use to counter that showing. *Id.* (stating that “the challenger [does not have] the burden of proving that the use is experimental”). In other words, the patentee must simply produce sufficient rebuttal evidence to prevent the party challenging the patent’s validity from meeting its burden of proving by clear and convincing evidence that the invention was in public use. “Convincing” evidence can meet that need. We hasten to note, however, that the statement in *TP Laboratories* regarding “convincing evidence” cited by A.J. did not set forth a new legal standard regarding the burden of production for patentees to rebut a *prima facie* case of public use, nor did it impose a burden of production comparable to the clear and convincing evidence required to invalidate a patent.

Applying these standards, we conclude that although the district court might have specified in the jury instruction that the patentee needed to provide sufficient evidence to rebut the *prima facie* case of public use, its failure to do so was harmless. For the same reasons that we affirm the district court’s denial of A.J.’s motion for JMOL, we conclude that “convincing evidence” was presented whereby a reasonable jury could have found that A.J.’s *prima facie* case of public use was rebutted.

Comments

1. *The Policies of Experimental Use.* The common law experimental use doctrine can be traced to the early 19th century. See REPORT FROM THE HON. HENRY L. ELLSWORTH TO THE SECRETARY OF STATE AND TRANSMITTED TO THE SELECT COMMITTEE ON THE PATENT LAWS 175, 179 (1836) (comparing the American and the British approach toward public use, stating “[o]ur courts have adopted a more liberal policy, and very justly decided that public experiments to test the value of the invention, do not destroy the right on the ground of publicity”).

The first policy underlying the experimental use doctrine is to provide the inventor with time to test his invention. This policy results in social benefits (society receives a more refined and commercially ready invention) and permits inventors to determine if the invention is worth

the time and expense of preparing and prosecuting a patent application. An additional policy seeks to preclude an inventor from extending the term of the patent's statutory life while commercially exploiting the invention. It is important to emphasize that activity that would typically result in a finding of public use must be experimental in nature and, the scope and length of the activity must be reasonable in terms of that purpose. If the purpose was experimental and the activity reasonable, it is not legally significant that the inventor benefits incidentally from the activity. *See In re Hamilton*, 882 F.2d 1576, 1581 (Fed. Cir. 1989) ("The experimental use doctrine operates in the inventor's favor to allow *the inventor* to refine his invention or to assess its value relative to the time and expense of prosecuting a patent application. If it is not the inventor or someone under his control or 'surveillance' who does these things, there appears to us no reason why he should be entitled to rely upon them to avoid the statute.") (emphasis in original).

2. **Experimental Use's Multi-Factor Test.** The courts have adopted a multi-factored approach to experimental use. Consider the 13 factors set forth in *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002): (1) the necessity for public testing; (2) the amount of control over the experiment retained by the inventor; (3) the nature of the invention; (4) the length of the test period; (5) whether payment was made; (6) whether there was a secrecy obligation; (7) whether records of the experiment were kept; (8) who conducted the experiment; (9) the degree of commercial exploitation during testing; (10) whether the invention reasonably requires evaluation under actual conditions of use; (11) whether testing was systematically performed; (12) whether the inventor continually monitored the invention during testing; and (13) the nature of the contacts made with potential customers. While no one factor is dispositive, control is an extremely important consideration. The *Electromotive* court, citing Judge Bryson's concurrence in *C.R. Bard*, also highlighted the importance of detailed progress records and knowledge by the purported testers that testing is occurring. In fact, Judge Bryson went so far as to suggest that these three factors (including control) form the first, and potentially decisive, step in determining whether a public use or sale was primarily experimental.

Mr. Nicholson had several factors working for him in *City of Elizabeth*. It was necessary to have a lengthy testing period due to the nature of the invention — durability was a key feature. Also, the public's exposure to the invention was of little relevance because the invention was intended to be used in a public place and had to be tested in its intended environment. And perhaps most importantly, the inventor exercised a sufficient amount of control during the experimental period. Recall Mr. Lang's testimony: "Mr. Nicholson was there almost daily, and when he came he would examine the pavement, would often walk over it, cane in hand, striking it with his cane, and making particular examination of its condition. He asked me very often how people liked it, and asked me a great many questions about it."

In *Lisle Corp.*, the patentee was able to show sufficient control. The court affirmed a finding of experimental use even though there was no formal

confidentiality agreement between Lisle and the mechanics. Williams, whose testimony was crucial, noted that Lisle and the mechanics had prior working relationships, and that Lisle would have contacted the mechanics every two to four weeks for testing feedback. There were also “General Meeting Reports” drafted by the president of Lisle, which provided updates of “tie rod” project. The relationship between Lisle and the mechanics was informal, not the formal or highly structured arrangements you would see in larger corporate entities. The Federal Circuit has stated “less formal and seemingly casual experiments can be expected” with individual or small business units,” and that these types of experiments “may be deemed legally sufficient to avoid the public use bar, but only if they demonstrate the presence of the same basic elements that are required to validate experimental use.” *Lough*, 86 F.3d at 1121.

The patentees in *Electromotive* and *Lough* (cited in *Electromotive*) were not as fortunate. *Lough* involved an individual inventor, Lough, who provided prototypes of his invention to friends and acquaintances, but with no provision or contract for follow-up involvement during the alleged experimentation. Lough neither monitored the alleged experiments, nor kept records or reports from his friends and acquaintances concerning how well his invention operated. Even though Lough was an individual inventor who never commercialized his invention, the court found public use:

Lough in effect provided the prototype seal assemblies to members of the public for their free and unrestricted use. The law does not waive statutory requirements for inventors of lesser sophistication. When one distributes his invention to members of the public under circumstances that evidence a near total disregard for supervision and control concerning its use, the absence of these minimal indicia of experimentation require a conclusion that the invention was in public use.

Lough, 86 F.3d at 1122. Mr. Lough to not exert the requisite control, the most important factor in proving experimental use.

3. **When Is Experimental Use No Longer Experimental?** Generally, experimental use ends when reduction to practice begins. *See RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061 (Fed. Cir. 1989). But when issues of durability are relevant, an inventor may have to test his invention in its intended environment for several years, such as Mr. Nicholson. And even if no improvements are needed after this period, the inventor will still be deemed to have engaged in experimental use. *See City of Elizabeth*, 97 U.S. 126, 135 (1877) (“If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished. And though, during all that period, he may not find that any changes are necessary, yet he may be justly said to be using his machine only by way of experiment; and no one would say that such a use, pursued with a bona fide intent of testing the qualities of the machine, would be a public use, within the meaning of the statute.”). *See also Aerovox Corp. v. Polymet Mfg.*, 67 F.2d 860, 863 (2d Cir. 1933) (Hand, J.) (stating “it did not appear that Nicholson, the inventor, delayed for any other reason than to learn how well his pavement would wear; apparently it was already as good as he hoped to make it”); *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 551 (Fed. Cir. 1990) (noting “[w]hen

durability in an outdoor environment is inherent to the purpose of an invention, then further testing to determine the invention's ability to serve that purpose will not subject the invention to a section 102(b) bar").

D. THIRD-PARTY ACTIVITY

In addition to inventor activity (so-called self-induced statutory bars), third-party actions can defeat patent rights, even if the third party has no legal relationship with the inventor. In fact, as held in *Lorenz* and *Evans*, a statutory bar will be found when the invention was obtained through improper means or arguably unethical commercial behavior. When reading these cases, ask yourself which § 102(b) policy is served by permitting third-party activity to bar patent rights.

LORENZ v. COLGATE-PALMOLIVE-PEET CO.

167 F.2d 423 (3d Cir.1948)

BIGGS, Circuit Judge.

. . . In the District Court Lorenz and Wilson (Lorenz), persons interested in Lorenz Patent No. 2,084,446, one of two interfering patents, brought suit under R.S. Sec. 4918, 35 U.S.C.A. § 66, against Colgate-Palmolive-Peet Company (Colgate), the owner of the other interfering patent, Ittner, No. 1,918,603. . . . Both patents cover a process for the manufacture of soap and the recovery of glycerine. . . .

The interference between Lorenz and Ittner in the Patent Office arose under the following circumstances. Lorenz had filed an application for his process in the Patent Office on January 24, 1920. Shortly thereafter he communicated the substance of the disclosures of his application to Ittner, who was Colgate's chief chemist, in order that Colgate might exploit the process if it so desired. After examination Ittner expressed himself as uninterested in the process. Next, the Patent Office rejected Lorenz's application and he abandoned the prosecution of the application. On July 18, 1933, Patent No. 1,918,603 was issued to Ittner on an application filed by him on February 19, 1931. Lorenz, learning of the Ittner patent, filed a petition in the Patent Office to revive his original application. This petition was rejected. On November 8, 1934, more than a year after the issuance of the Ittner patent, Lorenz filed a new application in which he adopted as his own nineteen claims of Ittner's patent, asserting that the subject matter of Ittner's patent had been disclosed by him to Ittner in 1920. The Patent Office declared an interference. The examiner of interferences decided in Lorenz's favor and for reasons which need not be gone into here no appeal was taken.

* * *

We proceed immediately to an examination of the defense of prior public use. . . .

The court below found that:

It clearly appears from the undisputed testimony and the documentary evidence offered in support thereof that the process of the patent was in public use in the factory of the defendant from November 1931 until November 1932, approximately one year, but more than two years prior to the Lorenz application of November 8, 1934. This use was preceded by several months of experimentation, but commercial production of soap and glycerine by the process of the patent was accomplished in November of 1931 and continued thereafter until 1932, when the use of the process was either discontinued or abandoned. This public use, although it did not enrich the art, was sufficient under the statute to preclude the issuance of a valid patent. . . .

. . . Agreeing with Lorenz that under the peculiar circumstances of this case an unusually heavy burden rests upon Colgate in order to prove prior public use, we have made generous allowance for the difficulties which Lorenz encountered in procuring evidence to rebut Colgate's proof of prior public use. But we cannot say that the court below erred in finding that the process of Lorenz's patent was in public use in Colgate's plant for a period of a year more than two years preceding the filing of Lorenz's second patent application on November 8, 1934. . . .

We come then to the question whether the public use under the circumstances was such as to be within the purview of R.S. Sec. 4886. Lorenz contends that it was not such a use; that Congress did not intend the provision of the statute to bar the grant of a valid monopoly to an inventor whose disclosures have been "pirated" by the person to whom he confided them. . . .

Colgate asserts that its use was neither fraudulent nor piratical and that the disclosures made by Lorenz to Ittner in 1920 carried no pledge, express or implied, that Ittner or Colgate should not make use of Ittner's invention; that Lorenz had filed a patent application and that Ittner knew this and that otherwise Ittner would have refused to receive the disclosures; that since these were made under a then pending application Ittner and Colgate were at liberty to make use of Lorenz's process and answer to Lorenz in a patent infringement suit for profits or damages; that no confidential or trust relationship in Lorenz's favor was or could be imposed on either Ittner or Colgate under the circumstances. We are aware of the ordinary practice under which manufacturers refuse to receive an inventor's disclosures unless there is a pending patent application which covers the discovery. This proper practice is one which usually inures to the benefit of both inventor and manufacturer since it settles in written terms the nature of the disclosure and lessens the probability of future disputes. In the case at bar, however, Ittner immediately rejected Lorenz's disclosures as commercially impractical only to make substantial commercial use of them some eleven years later. The circumstances of the instant case are therefore unusual and reflect a very different pattern from that which customarily ensues when an inventor makes a disclosure to a manufacturer. Usually if the manufacturer declares himself interested in the process a contract is drawn up whereby the rights of the parties are fixed for the periods of manufacture both prior to the issuance of the patent as well as thereafter. No such opportunity was given to Lorenz in the case at bar because of Ittner's rejection of the process as soon as it had been disclosed to him.

We do not doubt that Lorenz's disclosures were made to Ittner with the implicit understanding that if Ittner was to make use of them an arrangement

was to be effected whereby Lorenz was to be compensated. Certainly Lorenz was not offering his process to Ittner gratis. Under these circumstances we cannot say that an inventor may not invoke the aid of a court of equity to impose an accounting on the manufacturer, provided the inventor moves to protect his rights with reasonable promptness. We think it clear that Ittner received the disclosures *cum onere* and that Colgate cannot now be heard to assert that it owes no duty to Lorenz.

But Colgate's position in this regard is not really an issue in the instant case. The scope which Congress intended the public use statute to have is the important question. Here the defense of prior public use in reality is asserted on behalf of the public, albeit by Colgate. Was it the intention of Congress that public use by one who employs a process in breach of a fiduciary relationship, who tortiously appropriates it or who pirates it, should bar the inventor from the fruits of his monopoly? Lorenz asserts that there is no case in point and that the question is an original one. He relies on certain cases beginning with *Pennock v. Dialogue*.

* * *

On consideration of these authorities, and we can find no others even as pertinent, and weighing the policy embodied in the statute we are forced to the conclusion that the decisions of the Supreme Court in *Klein v. Russell* and in *Andrews v. Hovey* on rehearing, and that of the Circuit Court of Appeals for the Second Circuit in *Eastman v. Mayor of New York* point the way to the ruling which we must make on this point. The prior public use proviso of R.S. Sec. 4886 was enacted by Congress in the public interest. It contains no qualification or exception which limits the nature of the public use. We think that Congress intended that if an inventor does not protect his discovery by an application for a patent within the period prescribed by the Act, and an intervening public use arises from any source whatsoever, the inventor must be barred from a patent or from the fruits of his monopoly, if a patent has issued to him. There is not a single word in the statute which would tend to put an inventor, whose disclosures have been pirated, in any different position from one who has permitted the use of his process. . . . As Judge Coxe said in the *Eastman* case, isolated instances of injustice may result if the law be strictly applied, but the inventor's remedy is sure. He is master of the situation and by prompt action can protect himself fully and render the defense of prior public use impossible: "If (the inventor) fails to take so simple and reasonable a precaution why should it not be said that the risk is his own and that he cannot complain of the consequences of his own supineness?" Moreover, it is apparent that if fraud or piracy be held to prevent the literal application of the prior-public-use provision a fruitful field for collusion will be opened and the public interest which [the statute] is designed to protect will suffer. While we cannot fail to view Lorenz's predicament with sympathy, we may not render our decision on such a basis. For these reasons we hold, as did the court below, that the Lorenz patent is void by reason of prior public use.

EVANS COOLING SYSTEMS, INC. v. GENERAL MOTORS CORP.**125 F.3d 1448 (Fed. Cir. 1997)**

MICHEL, Circuit Judge.

Evans Cooling Systems, Inc. and Patent Enforcement Fund, Inc. (collectively, “Evans”) appeal the September 30, 1996 order of the United States District Court for the District of Connecticut granting summary judgment to General Motors Corporation (“GM”) of invalidity based on the “on sale” bar under 35 U.S.C. § 102(b). Because there were no materially disputed questions of fact regarding whether the patented invention was offered for sale more than one year prior to the critical date and because we decline to create an exception to the on sale bar for those instances in which a third party misappropriates the invention and later places the invention on sale or causes an innocent third party to place the invention on sale, we affirm.

BACKGROUND

United States Patent Number 5,255,636 (“the ’636 patent”) issued on October 26, 1993 and claims an aqueous reverse flow cooling system for internal combustion engines. An understanding of the technology is not necessary to this appeal and we therefore do not discuss it. John Evans, the named inventor, admits he conceived the patented invention in 1984 and reduced it to practice in 1986. Mr. Evans did not file a patent application, however, until July 1, 1992.

In early 1994, Evans filed the present lawsuit alleging that GM infringed the ’636 patent by the manufacture and sale of cars having GM’s “LT1” and “L99” engines. GM counterclaimed for a declaration of invalidity and non-infringement. GM asserted that the ’636 patent was invalid because GM and its independent dealers had placed the patented invention on sale prior to the critical date with the introduction of its 1992 Corvette. Specifically, GM sent an “Order Guide” for the 1992 Corvette to its independent dealers in late April or early May, 1991 to be used for ordering the vehicle described in the Order Guide. At about the same time, GM sent its dealers a supplemental brochure that provided additional ordering information for the 1992 Corvette, specifically stating that the car had reverse flow engine cooling. A representative of GM testified that it expected the dealers would start ordering the vehicles as soon as the Order Guide was sent to them. A sales representative at a GM dealership also testified that it was the dealership’s common practice to order new cars and enter into agreements to sell new cars shortly after receiving the Guide. GM produced computer records documenting over 2000 orders placed by dealers around the country for the 1992 Corvette before the critical date. The orders, over 300 of which were placed on behalf of specific retail customers, were placed through a computer network and GM transmitted an acknowledgment back to the dealer after receiving the order. As a specific example, GM introduced evidence regarding a retail customer named Aram Najarian who visited a Corvette dealer in West Bloomfield, Michigan, in June, 1991. Mr. Najarian entered into a contract with a GM dealer on June 13, 1991 in which GM agreed to sell and

Mr. Najarian agreed to buy a Corvette with an LT1 engine. Although a firm price was not established at that time, Mr. Najarian was informed that the price would be up to \$2000 higher than the 1991 model and he placed a deposit on the car at that time. The order was transmitted to GM, and GM sent back an acknowledgment on June 14, 1991.

Evans asserted before the trial court that GM should not be allowed to invalidate the '636 patent because GM, in fact, stole the invention from Evans. Specifically, GM allegedly requested that Evans demonstrate its aqueous reverse flow cooling system at GM's test facility in the spring of 1989, and Evans alleges that GM stole the invention during this demonstration.

The district court granted summary judgment in favor of GM on September 30, 1996, because the record established that GM and its dealers placed the 1992 Corvette with the LT1 engine on sale prior to the critical date. The district court relied on the facts that Mr. Najarian entered into a contract with a GM dealer, the dealer agreed to sell and Mr. Najarian agreed to buy a 1992 Corvette, and Mr. Najarian paid a deposit and the dealer transmitted the order to GM. The court also noted that even an offer to sell will raise the on sale bar and that this transaction went beyond mere indefinite discussions about a possible sale. Turning to the policies underlying the on sale bar, the district court noted that John Evans claimed he reduced the invention to practice in 1986 but failed to file an application for some six years.

DISCUSSION

A person is not entitled to a patent if "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). . . .

I.

[The court held the order entered into by Najarian and Cauley Chevrolet on June 13, 1991 was an offer for sale that invalidates the '636 patent.]

II.

Although our analysis would normally be complete once we had concluded there was an invalidating offer for sale, Evans urges this court to create a new exception to the on sale bar. Specifically, Evans asks us to rule that an otherwise invalidating offer for sale does not invalidate a patent "where a third party surreptitiously steals an invention while it is a trade secret and then, unbeknownst to the inventor, allegedly puts the invention on sale [more than one year] before the inventor files a patent application covering the stolen invention."

Evans cites three Supreme Court cases and asserts that they state that prior use of an invention by one who misappropriates the invention cannot invalidate a patent. See *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19-20 (1829) ("[i]f before his application for a patent his invention should be pirated by another, or used without his consent; it can scarcely be supposed, that the legislature had within its contemplation such knowledge or use. . . . The use here referred to has always been understood to be a public use, and not a private or surreptitious use in fraud of the inventor."); *Shaw v. Cooper*, 32 U.S. (7 Pet.)

292, 319-20 (1833) (“But there may be cases, in which a knowledge of the invention may be surreptitiously obtained, and communicated to the public, that do not affect the right of the inventor. . . . If the right were asserted by him who fraudulently obtained it, perhaps no lapse of time could give it validity.”); *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 329 (1859) (affording immunity from suit to prior third party users of a patented invention but refusing to extend such immunity to those who received knowledge of the patented invention through fraud). Evans argues that these Supreme Court cases have never been expressly overruled and, in fact, the one time the Court of Customs and Patent Appeals addressed the issue it expressly left it open, stating:

We do not find it here necessary to decide whether a fraudulent use of an invention for more than two years [then the bar period] prior to an application for a patent therefor bars the issue of the patent upon such application. . . . It may be that . . . said Minerals Separation should have been held to be estopped to bring a public use proceeding. But even so, as to this we express no opinion. . . .

In re Martin, 22 C.C.P.A. 891 (CCPA 1935).

We, however, do not find any of these cases dispositive of the issue presented by this case. In *Pennock*, the Supreme Court actually invalidated the patents in suit under the public use bar, and in that case the use had been with the permission of the patentee, thereby rendering any statements regarding piracy mere dicta. Likewise, the statements relied on by Evans in *Shaw* are dicta, as there too the patent was invalidated because the innocent public had come to know and use the invention, although there was some evidence that the invention had first become known to the public by fraudulent means. The statutory on sale bar wasn’t even in issue in *Kendall*. Rather, the issue was whether the defendant had the right to continue to use the invention after the patent issued. *See also Eastman v. City of N.Y.*, 134 F. 844, 852-55 (2d Cir. 1904) (discussing whether “fraudulent, surreptitious, or piratical” use of an invention could raise the public use bar and rejecting statements in above Supreme Court cases as dicta).

We note as well that the one other court that has addressed this precise issue has rejected arguments similar to Evans’ arguments. *See Lorenz v. Colgate-Palmolive-Peet Co.*, 167 F.2d 423 (3d Cir. 1948). There, the court addressed the following question: “Was it the intention of Congress that public use by one who employs a process in breach of a fiduciary relationship, who tortiously appropriates it or who pirates it, should bar the inventor from the fruits of his monopoly?” 167 F.2d at 426. Lorenz had disclosed his invention to Colgate. Although Colgate told Lorenz the idea was rejected, it later made substantial commercial use of Lorenz’s invention and then sought to invalidate Lorenz’s patent based on this use. *Id.* at 424-25. After reviewing the Supreme Court and other relevant case law, the court rejected an exception to the statutory bar, stating:

The prior-public-use proviso . . . contains no qualification or exception which limits the nature of the public use. We think that Congress intended that if an inventor does not protect his discovery by an application for a patent within the period prescribed by the Act, and an intervening public use arises from any

source whatsoever, the inventor must be barred from a patent or from the fruits of his monopoly, if a patent has issued to him. There is not a single word in the statute which would tend to put an inventor, whose disclosures have been pirated, in any different position from one who has permitted the use of his process. . . . [I]solated instances of injustice may result if the law be strictly applied, but the inventor's remedy is sure. He is master of the situation and by prompt action [in filing a patent application] can protect himself fully and render the defense of prior public use impossible.

Id. at 429-30. Although this decision is not binding on this court, it is persuasive.

Even if we were to create an exception to the on sale bar such that third parties accused of misappropriating an invention could not invalidate a patent based upon sales by the guilty third party, GM correctly asserts that *Martin* squarely holds that activities of third parties uninvolved in the alleged misappropriation raise the statutory bar, even if those activities are instigated by the one who allegedly misappropriated the invention. In *Martin*, Martin's employer stole Martin's invention and filed an application on it and disclosed it to a third party. 74 F.2d at 952-53. After learning of his employer's activities, Martin filed his own application. After an interference was declared, the employer argued Martin's application was barred based on the activities of the third party. Martin conceded his invention had been in public use, but argued that the bar should not apply because the third party's use was "instigated by [his] employer and was a surreptitious and fraudulent public use against him." *Id.* at 953. After reviewing the Supreme Court and other relevant case law, the Court of Customs and Patent Appeals noted it had "been unable to find any authoritative decisions upon the question of whether a fraudulent public use of an invention . . . prior to the filing of an application . . . , or such public use of an invention instigated by fraud, bars the issuance of a patent. . . ." *Id.* at 955. Although the Court of Customs and Patent Appeals did not address that precise issue, the Court of Customs and Patent Appeals did hold that allowance of the application was barred because the third party's public use had been innocent, even though it had obtained the technology from the employer. *Id.*

As discussed below, this holding is dispositive here because, although Evans has charged GM with misappropriation, it has never contended that the independent dealers had any participation in or knowledge of the alleged theft; nor is there any indication that Mr. Najarian had such knowledge. Thus, the independent dealers are innocent users who put the invention on sale by placing orders for innocent retail customers like Najarian.

While such a result may not seem fair, Evans is not without recourse if GM in fact misappropriated his invention. Evans would have an appropriate remedy in state court for misappropriation of a trade secret. We note as well that the facts Evans alleges in support of its misappropriation claim demonstrate that Evans knew GM stole the invention at the very time it was allegedly stolen because during the demonstration GM employees allegedly told Mr. Evans they intended to steal the invention and a sealed room was unsealed during the night between the tests. Evans' patent rights would have nevertheless been protected if Mr. Evans had filed a patent application no more than one year from the date of the demonstration. This he did not do; instead Mr. Evans waited for more than two years after the demonstration and some six years after it was reduced to practice.

CONCLUSION

The '636 patent is invalid due to the pre-critical date contract entered into between the independent GM dealership and Mr. Najarian whereby the dealership offered to sell and Mr. Najarian agreed to buy a 1992 Corvette containing the LT1 engine. Even if GM misappropriated the idea behind the LT1 engine cooling system from Mr. Evans, the invention was nevertheless on sale and we decline to create the suggested new exception to the 102(b) bar which has no basis in the language of the statute. The trial court's decision is therefore affirmed.

Comments

1. ***Third-Party Use and the Public Interest.*** The issue of whether a third-party act can be a public use or on-sale event can be traced back to the 19th century. In *Pennock v. Dialogue*, 27 U.S. 1 (1829), Justice Story noted that an inventor would be barred from obtaining a patent if the inventor made or authorized any public use or sale of an embodiment of his invention (except possibly for purposes of experimentation) even one day before the inventor filed an application for a patent. But, in discussing the nature of the disclosure, Justice Story added: "But how known or used? If it were necessary, as it well might be, to employ others to assist in the original structure or use by the inventor himself; or if before his application for a patent his invention should be pirated by another, or used without his consent; it can scarcely be supposed, that the legislature had within its contemplation such knowledge or use." *Id.* at 19.

Pennock was codified in the 1836 Act, which prevented an inventor was receiving a patent on his invention if "at the time of his application" the invention was "in public use or on sale with consent or allowance." 5 Stat. 117. Three years later, the 1839 Act introduced a "grace period." As such, pre-application public use and on-sale activity did not preclude a patent from issuing "except on proof of abandonment of such invention to the public; or that such purchase, sale, or prior use has been for more than two years prior to such application for a patent." 5 Stat. 353. Presumably, a sale or use without the inventor's "consent or allowance" would not be a barring event under the 1836 Act. The 1839 Act eliminated any reference to "consent or allowance," but added a two-year grace period.

Subsequent to the 1839 Act, the Supreme Court has indicated that the statutory bar standards are the same, whether the use or sale is by the inventor or a third party acting without the inventor's consent or allowance. In *Andrews v. Hovey*, 123 U.S. 267 (1887), for example, the Court wrote:

It is very plain that under the act of 1836, if the thing patented had been in public use or on sale, with the consent or allowance of the applicant, for anytime, however short, prior to his application, the patent issued to him was invalid. Then came section 7 of the act of 1839, which was intended as an amelioration in favor of the inventor, in this respect, of the strict provisions of the act of 1836 [because it introduced a two-year grace period]. . . .

[But deleting the “consent or allowance” language,] [t]he evident intention of congress was to take away the right (which existed under the act of 1836) to obtain a patent after an invention had for a long period of time been in public use, without the consent or allowance of the inventor; it limited that period to two years, whether the inventor had or had not consented to or allowed the public use. The right of an inventor to obtain a patent was in this respect narrowed, and the rights of the public as against him were enlarged, by the act of 1839.

Id. at 274. Which approach is more consistent with the policies of patent law: A grace period or inventor consent? Whom are you trying to protect: the inventor, the public, or both? Which approach is more easily administered in terms of certainty? The Federal Circuit case law is consistent with *Andrews*. See *Zacharin v. U.S.*, 213 F.3d 1366, 1371 (Fed. Cir. 2000) (stating “it is of no consequence that the sale was made by a third party, not the inventor”).

2. *The Policy Behind Allowing Third-Party Activity to Defeat Patent Rights?*

Despite the 1839 Act, and the 1870 Act, which is consistent with the 1839 Act in this regard, the policy considerations identified in *Pennock*, such as the policy of not allowing undue extension of the patent term or public dedication by the inventor, arguably do not apply in the same way to third-party activity. Characterizing the case law that permitted third-party barring activity, William Robinson, the influential 19th-century treatise author, stated, “[t]his new position harmonizes with the tendency of modern judicial authority to discourage, as far as possible, any delay of the inventor in applying for a patent after his invention is complete, but is not consistent with the theory of dedication to the public, which always involves knowledge and consent” of the inventor. WILLIAM C. ROBINSON, *THE LAW OF PATENTS* 501-06 (1890).

Modern case law, however, has cited public dedication as a reason for allowing third-party barring activity. For example, in *General Electric v. United States*, 654 F.2d 55, 61 (Ct. Cl. 1981), the court stated, “Congress should be held to have concluded, at the least, that the policy against removing inventions from the public domain and the policy favoring early patent filing are of sufficient importance in and of themselves to invalidate a patent where the invention is sold by one other than the inventor or one under his control.” *Id.* at 62. And in *Baxter International, Inc. v. COBE Laboratories, Inc.*, 88 F.3d 1054 (Fed. Cir. 1996), Judge Lourie wrote that “the most applicable policy underlying the public use bar here is discouraging removal from the public domain of inventions that the public reasonably has come to believe are freely available.” In *Baxter*, Cullis invented a sealless centrifuge for separating blood into its components and obtained a patent. Dr. Jacques Suaudeau, a researcher at the NIH, was the alleged prior user. Dr. Suaudeau used a centrifuge that damaged platelets in the blood. According to his analysis, this damage was caused by the centrifuge’s rotating seals. Dr. Suaudeau consulted with his colleague at the NIH, Dr. Yoichiro Ito, who advised Suaudeau to use a sealless centrifuge designed by Dr. Ito himself. Suaudeau tested his centrifuge for as long as forty-three hours, all of which in his NIH laboratory. Baxter, the assignee, argued Suaudeau’s use of the centrifuge was not publicly known or

accessible. The court disagreed, and found Suaudeau engaged in “public use” under § 102(b).

One could understandably ask whether Suaudeau’s invention was in public use or whether the public came to believe that the invention was in the public domain. Moreover, did the court give insufficient weight to the section 102(b)’s other underlying policies such as prompt disclosure and providing the inventor with an economic/marketing trial period? In her dissent, Judge Newman wrote the majority created “a new and mischievous category of ‘secret’ prior art” that is “immune to the most painstaking documentary search.”

3. ***Stolen or Pirated Inventions.*** It seems odd to allow use or on sale activity resulting from theft to constitute a barring event. Is the public harmed in the absence of a statutory bar? The *Lorenz* court placed emphasis on the inventor, stating that “he is master of the situation,” and “by prompt action can protect himself fully and render the defense of prior public use impossible.” The prompt disclosure rationale is consistent with Professor Robinson’s understanding of third-party activity, noted in Comment 2, *supra*. But note that *Lorenz* did file a timely application, although it did not issue into a patent. (The reasons behind his abandonment are unclear.) Perhaps *Lorenz* is best read as a statutory interpretation case. Recall the court emphasized that Congress’ intent was that if an inventor does not protect himself by applying for a patent, and “an intervening public use arises from any source whatsoever, the inventor must be barred from a patent.” According to the court, “[t]here is not a single word in the statute which would tend to put an inventor, whose disclosures have been pirated, in any different position from one who has permitted the use of his process.” The *Evans* case involves another misappropriation — although more blatant — and reaches the same result. See also *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999) (stating “the statutory on sale bar is not subject to exceptions for sales made by third parties either innocently or fraudulently”).

COMPARATIVE PERSPECTIVE

Third-Party Activity in Europe and Japan

The European Patent Convention adopts an “absolute novelty” position, which means any public disclosure (except at an internationally recognized exhibition) made by the inventor is a bar to obtaining patent rights. There is no grace period for inventor disclosures. Article 55 of the EPC does provide for a grace period of six months for third-party disclosures that resulted from “an evident abuse in relation to the applicant.” Thus, theft or breach of contract or fiduciary duty would qualify as an “evident abuse” in this regard. Similarly, under Japanese patent law, a disclosure will not be prejudicial to patent rights if made “against the will” of the inventor. See Section 29 and 30 of the Japan Patent Act.

CHAPTER

6

Nonobviousness

INTRODUCTION

An invention must be nonobvious to be patentable. The nonobvious inquiry—set forth in § 103—asks whether the claimed invention would have been obvious to a person of ordinary skill in the art the time the claimed invention was made. The message behind an obviousness rejection is that the invention, although perhaps novel, is not different enough from the prior art, meaning in most cases that it provides an insufficient leap forward in the art.

The nonobviousness requirement is fundamental to the patent system and is an important policy tool. While both §§ 102 and 103 seek to guard the public domain, § 103 is a more aggressive sentry than § 102, because an obviousness inquiry allows for the combination of prior art references, and therefore demands more complex rules for determining when an invention satisfies § 103. As you work your way through this chapter, keep in mind that the obviousness requirement seeks to prevent the issuance of a patent that would withdraw “what is already known into the field of its monopoly and diminish[] the resources available to skillful men.”¹ Determining what is obvious (and what is not), however, is an inquiry that does not lend itself to certainty or objectivity. As a result, nonobviousness is frequently litigated, and, indeed, is the most common basis for invalidating patent rights.²

The notion that something more than novelty is required for patentability can be traced to *Hotchkiss v. Greenwood*, 52 U.S. 248 (1851), the first principal case in this chapter. The invention in *Hotchkiss* related to an old method of making doorknobs, but the only difference between the patented invention and the prior art was that the inventor substituted a clay or porcelain knob for a metallic knob. The invention was novel, but the Court nonetheless invalidated the patent because “there was an absence of that degree of skill and ingenuity, which constitute essential elements of every invention” . . . beyond that which is “possessed by an ordinary mechanic.” *Id.* at 266. Defining the requisite amount of “skill and ingenuity” is difficult and highly subjective.

1. *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1739 (2007) (quoting *Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950)).

2. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AM. INTELL. PROP. L.Q. 185 (1998) (finding that when asserted nonobviousness accounted for 42% of invalidity judgments at the appellate and trial levels, but also frequently failed as a defense 63.7% of the time).

Over the years, this ambiguity resulted in divergent applications of what became known as the “invention” requirement, which, according to one prominent patent lawyer, “left every judge practically scotfree to decide this often controlling factor according to his personal philosophy of what inventions should be patented, whether or not he had any competence to do so or any knowledge of the patent system as an operative socioeconomic force.”³ In an attempt to foster consistency and stability, the drafters of the 1952 Patent Act, by constructing § 103, sought to add greater clarity to the “invention” test and to provide a judge with well-defined parameters to work within when deciding whether an invention is obvious.⁴ Yet, as the Supreme Court noted in *Graham v. John Deere*, 383 U.S. 1 (1966), while § 103 was an improvement over the invention requirement, “[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context.” *Id.* at 17.

Hotchkiss and *Graham* are the two great cases of the 19th and 20th centuries, respectively, that stand for the proposition that something more than novelty is needed to obtain a patent. And their influence remains strong, as evidenced by the first significant 21st century obviousness case, *KSR v. Teleflex*, the principal case following *Graham*.

STATUTE: Conditions for patentability; non-obvious subject matter

35 U.S.C. § 103

A. THE HISTORICAL FOUNDATION OF § 103 AND THE NONOBVIOUSNESS REQUIREMENT

The *Hotchkiss* case is widely regarded as creating an additional patentability hurdle, above and beyond novelty and utility. This common law development predated § 103 by 100 years, yet exerted significant influence on the drafters of the 1952 patent code and continues to play an important role in the common law development of the nonobviousness inquiry.

3. Giles S. Rich, *The Vague Concept of “Invention” as Replaced by Section 103 of the Patent Act*, in NONOBVIOUSNESS: THE ULTIMATE CONDITION OF PATENTABILITY (J. Witherspoon ed., 1980), at 1:409.

4. See Giles S. Rich, *Laying the Ghost of the “Invention” Requirement*, in NONOBVIOUSNESS, *supra* note 3, at 1:508 (“The first policy decision underlying Section 103 was to cut loose altogether the century-old term ‘invention.’ So Section 103 speaks of a condition of *patentability* instead of ‘invention.’ The condition is unobviousness, but that is not all. The unobviousness is *as of a particular time* and *to a particular* legally fictitious, technical *person*, analogous to the ‘ordinary reasonable man’ so well known to courts as a legal concept. To protect the inventor from hindsight reasoning, the time is specified to be *the time when the invention was made*. To prevent the use of too high a standard—which would exclude inventors as a class and defeat the whole patent system—the invention must have been obvious at that time to ‘a person having ordinary skill in the art to which said subject matter (*i.e.*, the invention) pertains.’ But *that* is not all; *what* must have been obvious is ‘*the subject matter as a whole*.’ That, of course, is the invention as defined by each patent claim.”); P.J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. TRADEMARK OFF. SOC’Y 160, 181 (stating § 103 “is added to the statute for uniformity and definiteness . . . and with the view that an explicit statement in the statute may have some stabilizing effect”).

HOTCHKISS v. GREENWOOD**52 U.S. (11 How.) 248 (1851)**

Justice NELSON delivered the opinion of the court.

The suit was brought against the defendants for the alleged infringement of a patent for a new and useful improvement in making door and other knobs of all kinds of clay used in pottery, and of porcelain.

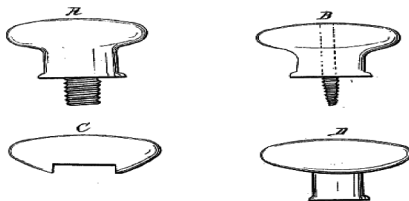
The improvement consists in making the knobs of clay or porcelain, and in fitting them for their application to doors, locks, and furniture, and various other uses to which they may be adapted; but more especially in this, that of having the cavity in the knob in which the screw or shank is inserted, and by which it is fastened, largest at the bottom and in the form of dovetail, or wedge reversed, and a screw formed therein by pouring in metal in a fused state; and, after referring to drawings [see below] of the article thus made, the patentees conclude as follows:

What we claim as our invention, and desire to secure by letters patent, is the manufacturing of knobs, as stated in the foregoing specifications, of potter's clay, or any kind of clay used in pottery, and shaped and finished by moulding, turning, burning, and glazing; and also of porcelain.

On the trial evidence was given on the part of the plaintiffs tending to prove the originality and usefulness of the invention, and also the infringement by the defendants; and on the part of the defendants, tending to show the want of originality; and that the mode of fastening the shank to the knob, as claimed by the plaintiffs, had been known and used before, and had been used and applied to the fastening of the shanks to metallic knobs.

And upon the evidence being closed, the counsel for the plaintiffs prayed the court to instruct the jury that, although the clay knob, in the form in which it was patented, may have been before known and used, and also the shank

*Hotchkiss, Davenport & Quincy,
Knob.
Nº 2,197. Patented July 29, 1841.*



*Witnesses:
Hudson & Gray*

*Inventor:
Davenport & Quincy*

and spindle by which it is attached may have been before known and used, yet if such shank and spindle had never before been attached in this mode to a knob of potter's clay, and it required skill and invention to attach the same to a knob of this description, so that they would be firmly united, and make a strong and substantial article, and which, when thus made, would become an article much better and cheaper than the knobs made of metal or other materials, the patent was valid, and the plaintiffs would be entitled to recover.

The court refused to give the instruction, and charged the jury that, if knobs of the same form and for the same purposes as that claimed by the patentees, made of metal or other material, had been before known and used; and if the spindle and shank, in the form used by them, had been before known and used, and had been attached to the metallic knob by means of a cavity in the form of dovetail and infusion of melted metal, the same as the mode claimed by the patentees, in the attachment of the shank and spindle to their knob; and the knob of clay was simply the substitution of one material for another, the spindle and shank being the same as before in common use, and also the mode of connecting them by dovetail to the knob the same as before in common use, and no more ingenuity or skill required to construct the knob in this way than that possessed by an ordinary mechanic acquainted with the business, the patent was invalid, and the plaintiffs were not entitled to a verdict.

This instruction, it is claimed, is erroneous, and one for which a new trial should be granted.

The instruction assumes, and, as was admitted on the argument, properly assumes, that knobs of metal, wood, &c., connected with a shank and spindle, in the mode and by the means used by the patentees in their manufacture, had been before known, and were in public use at the date of the patent; and hence the only novelty which could be claimed on their part was the adaptation of this old contrivance to knobs of potter's clay or porcelain; in other words, the novelty consisted in the substitution of the clay knob in the place of one made of metal or wood, as the case might be. And in order to appreciate still more clearly the extent of the novelty claimed, it is proper to add, that this knob of potter's clay is not new, and therefore constitutes no part of the discovery. If it was, a very different question would arise; as it might very well be urged, and successfully urged, that a knob of a new composition of matter, to which this old contrivance had been applied, and which resulted in a new and useful article, was the proper subject of a patent.

The novelty would consist in the new composition made practically useful for the purposes of life, by the means and contrivances mentioned. It would be a new manufacture, and none the less so, within the meaning of the patent law, because the means employed to adapt the new composition to a useful purpose was old, or well known.

But in the case before us, the knob is not new, nor the metallic shank and spindle, nor the dovetail form of the cavity in the knob, nor the means by which the metallic shank is securely fastened therein. All these were well known, and in common use; and the only thing new is the substitution of a knob of a different material from that heretofore used in connection with this arrangement.

Now it may very well be, that, by connecting the clay or porcelain knob with the metallic shank in this well-known mode, an article is produced better and cheaper than in the case of the metallic or wood knob; but this does not result from any new mechanical device or contrivance, but from the fact, that the

material of which the knob is composed happens to be better adapted to the purpose for which it is made. The improvement consists in the superiority of the material, and which is not new, over that previously employed in making the knob.

But this, of itself, can never be the subject of a patent. No one will pretend that a machine, made, in whole or in part, of materials better adapted to the purpose for which it is used than the materials of which the old one is constructed, and for that reason better and cheaper, can be distinguished from the old one; or, in the sense of the patent law, can entitle the manufacturer to a patent.

The difference is formal, and destitute of ingenuity or invention. It may afford evidence of judgment and skill in the selection and adaptation of the materials in the manufacture of the instrument for the purposes intended, but nothing more.

I remember having tried an action in the Circuit in the District of Connecticut some years since, brought upon a patent for an improvement in manufacturing buttons. The foundation of the button was wood, and the improvement consisted in covering the face with tin, and which was bent over the rim so as to be firmly secured to the wood. Holes were perforated in the centre, by which the button could be fastened to the garment. It was a cheap and useful article for common wear, and in a good deal of demand.

On the trial, the defendant produced a button, which had been taken off a coat on which it had been worn before the Revolution, made precisely in the same way, except the foundation was bone. The case was given up on the part of the plaintiff. Now the new article was better and cheaper than the old one; but I did not then suppose, nor do I now, that this could make any difference, unless it was the result of some new contrivance or arrangement in the manufacture. Certainly it could not, for the reason that the materials with which it was made were of a superior quality, or better adapted to the uses to which the article is applied.

It seemed to be supposed, on the argument, that this mode of fastening the shank to the clay knob produced a new and peculiar effect upon the article, beyond that produced when applied to the metallic knob, inasmuch as the fused metal by which the shank was fastened to the knob prevented the shank from acting immediately upon the knob, it being enclosed and firmly held by the metal; that for this reason the clay or porcelain knob was not so liable to crack or be broken, but was made firm and strong, and more durable.

This is doubtless true. But the peculiar effect thus referred to is not distinguishable from that which would exist in the case of the wood knob, or one of bone or ivory, or of other materials that might be mentioned.

Now if the foregoing view of the improvement claimed in this patent be correct, it is quite apparent that there was no error in the submission of the questions presented at the trial to the jury; for unless more ingenuity and skill in applying the old method of fastening the shank and the knob were required in the application of it to the clay or porcelain knob than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skilful mechanic, not that of the inventor.

We think, therefore, that the judgment is, and must be, affirmed.

Comments

1. **Hotchkiss and the “Invention” Requirement.** The *Hotchkiss* decision is viewed today as a foundational case in obviousness jurisprudence. Yet until the patent act of 1952 and the *Graham* decision in 1966, *Hotchkiss*’s esteemed status in patent law history was uncertain. This is largely because of the divergent interpretations engendered by the opinion. One school of interpretation led to the so-called “invention” requirement; in other words, to be patentable, there had to be an “invention,” a vague and malleable standard that judges could manipulate to mean whatever they wanted it to mean. Indeed, it had been called the “plaything of the judiciary.” See Giles S. Rich, *Why and How Section 103 Came to Be*, in *NONOBVIOUSNESS: THE ULTIMATE CONDITION OF PATENTABILITY* 1:208 (John Witherspoon ed., 1980). From 1940-1950, some members of the Supreme Court, relying on *Hotchkiss*, embraced the invention requirement to further what many in the patent community viewed as an anti-patent attitude. See, e.g., *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941) (holding to be patentable, an invention had to be the result of a “flash of genius”); *Great Atlantic Tea & Pacific Co. v. Supermarket Equipment Corp.*, 340 U.S. 147 (1950) (creating “synergism requirement”).
2. **Hotchkiss and the “Ordinary Mechanic.”** After *Great Atlantic* — viewed by some as reflecting the Court’s anti-patent attitude — a group of prominent patent professionals seized upon the “ordinary mechanic” language of *Hotchkiss* and sought to draft a “statutory substitute that would make more sense, would apply to all kinds of inventions, would restrict the court in their arbitrary, a priori judgments on patentability, and that, above all, would serve as a uniform standard of patentability.” Giles S. Rich, *Laying the Ghost of the “Invention” Requirement*, in *NONOBVIOUSNESS*, *supra*, at 1:508 (emphasis in original). Thus, § 103 was born. Section 103, in many ways, formed the heart of the 1952 act, and was a direct response to the “invention” requirement. The “ordinary mechanic” of *Hotchkiss* is the precursor to the “person having ordinary skill in the art” that today pervades patent law jurisprudence. By doing away with the “invention” test and requiring obviousness to be determined through the eyes of the skilled artisan, § 103 sought to foster greater stability and consistency. See P.J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. TRADEMARK OFF. SOC’Y 160, 181 (1993) (stating § 103 “is added to the statute for uniformity and definiteness . . . and with the view that an explicit statement in the statute may have some stabilizing effect”).

But § 103 received an inconsistent judicial reception. Some circuit courts viewed § 103 as a codification of the “requirement for invention,” even though it was clear the text of the statute omitted the word “invention.” Other circuits recognized that § 103 was drafted to “restore the law to what it had been 20 or 30 years earlier and . . . to change the slow but steady drift of judicial decisions that had been hostile to patents.” Giles S. Rich, *The Vague Concept of “Invention” as Replaced by Section 103 of the 1952 Patent Act*, in *NONOBVIOUSNESS*, *supra*, at 1:412.

In the light of this circuit conflict, the Supreme Court — 13 years after the 1952 patent act — decided to weigh in, which is the subject of Section B.

B. THE GRAHAM TEST

In 1965, the United States Supreme Court granted certiorari in *Graham v. John Deere* (as well as two companion cases) to consider the questions (1) “what effect the 1952 act had upon traditional statutory and judicial tests of patentability,” and (2) “what definitive tests are now required.” The *Graham* framework has been at the core of non-obviousness determinations to the present day. Importantly, *Graham* notes—in section II of the opinion—that the obviousness requirement flows directly from the IP clause of the Constitution, thus implying that § 103 embodies a constitutional requirement.

GRAHAM v. JOHN DEERE CO.

383 U.S. 1 (1966)

Justice CLARK delivered the opinion of the Court.

After a lapse of 15 years, the Court again focuses its attention on the patentability of inventions under the standard of Art. I, § 8, cl. 8, of the Constitution and under the conditions prescribed by the laws of the United States. Since our last expression on patent validity, *A. & P. Tea Co. v. Supermarket Equipment Corp.*, the Congress has for the first time expressly added a third statutory dimension to the two requirements of novelty and utility that had been the sole statutory test since the Patent Act of 1793. This is the test of obviousness, *i.e.*, whether “the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.” § 103 of the Patent Act of 1952.

The questions, involved in each of the companion cases before us, are what effect the 1952 Act had upon traditional statutory and judicial tests of patentability and what definitive tests are now required. We have concluded that the 1952 Act was intended to codify judicial precedents embracing the principle long ago announced by this Court in *Hotchkiss v. Greenwood*, and that, while the clear language of § 103 places emphasis on an inquiry into obviousness, the general level of innovation necessary to sustain patentability remains the same.

II.

At the outset it must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress “To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.” Art. I, § 8, cl. 8. The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the “useful arts.” It was written against the backdrop of the practices—eventually curtailed by the Statute of Monopolies—of the Crown in granting monopolies to court favorites

in goods or businesses which had long before been enjoyed by the public. The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must “promote the Progress of . . . useful Arts.” This is the standard expressed in the Constitution and it may not be ignored. And it is in this light that patent validity “requires reference to a standard written into the Constitution.” *Great A. & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. at 154 (concurring opinion).

Within the limits of the constitutional grant, the Congress may, of course, implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim. This is but a corollary to the grant to Congress of any Article I power. Within the scope established by the Constitution, Congress may set out conditions and tests for patentability. It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress.

III.

The difficulty of formulating conditions for patentability was heightened by the generality of the constitutional grant and the statutes implementing it, together with the underlying policy of the patent system that “the things which are worth to the public the embarrassment of an exclusive patent,” as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly. The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent.

This Court formulated a general condition of patentability in 1851 in *Hotchkiss v. Greenwood*. . . . *Hotchkiss*, by positing the condition that a patentable invention evidence more ingenuity and skill than that possessed by an ordinary mechanic acquainted with the business, merely distinguished between new and useful innovations that were capable of sustaining a patent and those that were not. The *Hotchkiss* test laid the cornerstone of the judicial evolution suggested by Jefferson and left to the courts by Congress. The language in the case, and in those which followed, gave birth to “invention” as a word of legal art signifying patentable inventions. Yet, as this Court has observed, “[t]he truth is, the word [‘invention’] cannot be defined in such manner as to afford any substantial aid in determining whether a particular device involves an exercise of the inventive faculty or not.” *McClain v. Ortmayer*, 141 U.S. 419, 427 (1891). Its use as a label brought about a large variety of opinions as to its meaning both in the Patent Office, in the courts, and at the bar. The *Hotchkiss* formulation, however, lies not in any label, but in its functional approach to questions of patentability. In practice, *Hotchkiss* has

required a comparison between the subject matter of the patent, or patent application, and the background skill of the calling. It has been from this comparison that patentability was in each case determined.

IV.

The 1952 Patent Act.

The pivotal section around which the present controversy centers is § 103. It provides:

§ 103. *Conditions for patentability; non-obvious subject matter*

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The section is cast in relatively unambiguous terms. Patentability is to depend, in addition to novelty and utility, upon the “non-obvious” nature of the “subject matter sought to be patented” to a person having ordinary skill in the pertinent art.

The first sentence of this section is strongly reminiscent of the language in *Hotchkiss*. Both formulations place emphasis on the pertinent art existing at the time the invention was made and both are implicitly tied to advances in that art. The major distinction is that Congress has emphasized “nonobviousness” as the operative test of the section, rather than the less definite “invention” language of *Hotchkiss* that Congress thought had led to “a large variety” of expressions in decisions and writings. In the title itself the Congress used the phrase “Conditions for patentability; *non-obvious subject matter*” (italics added), thus focusing upon “nonobviousness” rather than “invention.”

It is undisputed that this section was, for the first time, a statutory expression of an additional requirement for patentability, originally expressed in *Hotchkiss*. It also seems apparent that Congress intended by the last sentence of § 103 to abolish the test it believed this Court announced in the controversial phrase “flash of creative genius,” used in *Cuno Engineering Corp. v. Automatic Devices Corp.*

V.

While the ultimate question of patent validity is one of law, *A. & P. Tea Co. v. Supermarket Equipment Corp.*, the § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to

the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definiteness which Congress called for in the 1952 Act.

Although we conclude here that the inquiry which the Patent Office and the courts must make as to patentability must be beamed with greater intensity on the requirements of § 103, it bears repeating that we find no change in the general strictness with which the overall test is to be applied. We have been urged to find in § 103 a relaxed standard, supposedly a congressional reaction to the “increased standard” applied by this Court in its decisions over the last 20 or 30 years. The standard has remained invariable in this Court. Technology, however, has advanced, and with remarkable rapidity in the last 50 years. Moreover, the ambit of applicable art in given fields of science has widened by disciplines unheard of a half century ago. It is but an evenhanded application to require that those persons granted the benefit of a patent monopoly be charged with an awareness of these changed conditions. The same is true of the less technical, but still useful arts. He who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office.

VI.

Graham v. John Deere Co., an infringement suit by petitioners, presents a conflict between two Circuits over the validity of a single patent on a “Clamp for vibrating Shank Plows.” The invention, a combination of old mechanical elements, involves a device designed to absorb shock from plow shanks as they plow through rocky soil and thus to prevent damage to the plow. . . .

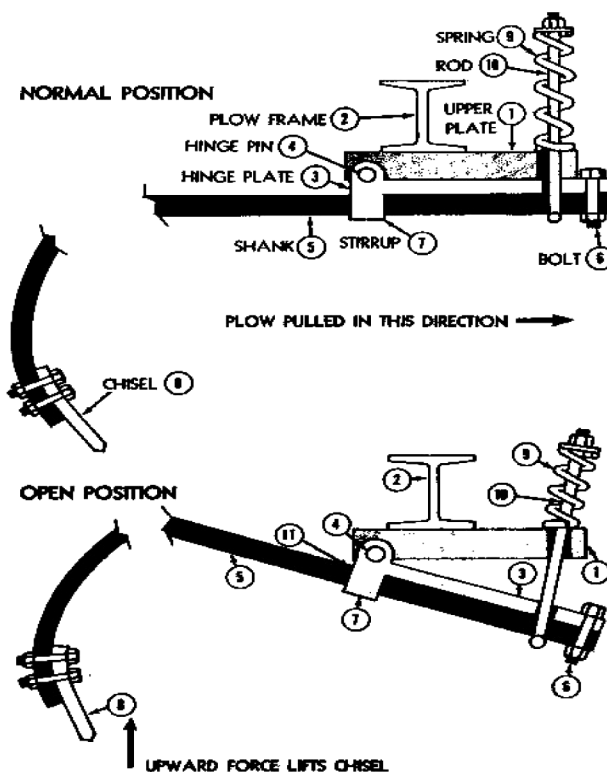
This patent, No. 2,627,798 (hereinafter called the ’798 patent) relates to a spring clamp which permits plow shanks to be pushed upward when they hit obstructions in the soil, and then springs the shanks back into normal position when the obstruction is passed over. The device, which we show diagrammatically in the accompanying sketches (See Fig. 1), is fixed to the plow frame as a unit. The mechanism around which the controversy center is basically a hinge. The top half of it, known as the upper plate (marked 1 in the sketches), is a heavy metal piece clamped to the plow frame (2) and is stationary relative to the plow frame. The lower half of the hinge, known as the hinge plate (3), is connected to the rear of the upper plate by a hinge pin (4) and rotates downward with respect to it. The shank (5), which is bolted to the forward end of the hinge plate (at 6), runs beneath the plate and parallel to it for about nine inches, passes through a stirrup (7), and then continues backward for several feet curving down toward the ground. The chisel (8), which does the actual plowing, is attached to the rear end of the shank. As the plow frame is

pulled forward, the chisel rips through the soil, thereby plowing it. In the normal position, the hinge plate and the shank are kept tight against the upper plate by a spring (9), which is atop the upper plate. A rod (10) runs through the center of the spring, extending down through holes in both plates and the shank. Its upper end is bolted to the top of the spring while its lower end is hooked against the underside of the shank.

When the chisel hits a rock or other obstruction in the soil, the obstruction forces the chisel and the rear portion of the shank to move upward. The shank is pivoted (at 11) against the rear of the hinge plate and pries open the hinge against the closing tendency of the spring. (See sketch labeled "Open Position," Fig. 1.) This closing tendency is caused by the fact that, as the hinge is opened, the connecting rod is pulled downward and the spring is compressed. When the obstruction is passed over, the upward force on the chisel disappears and the spring pulls the shank and hinge plate back into their original position. The lower, rear portion of the hinge plate is constructed in the form of a stirrup (7) which brackets the shank, passing around and beneath it. The shank fits loosely into the stirrup (permitting a slight up and down play). The stirrup is designed to prevent the shank from recoiling away from the hinge plate, and thus prevents excessive strain on the shank near its bolted connection. The stirrup also girds the shank, preventing it from fish-tailing from side to side.

In practical use, a number of spring-hinge-shank combinations are clamped to a plow frame, forming a set of ground-working chisels capable of

FIGURE 1

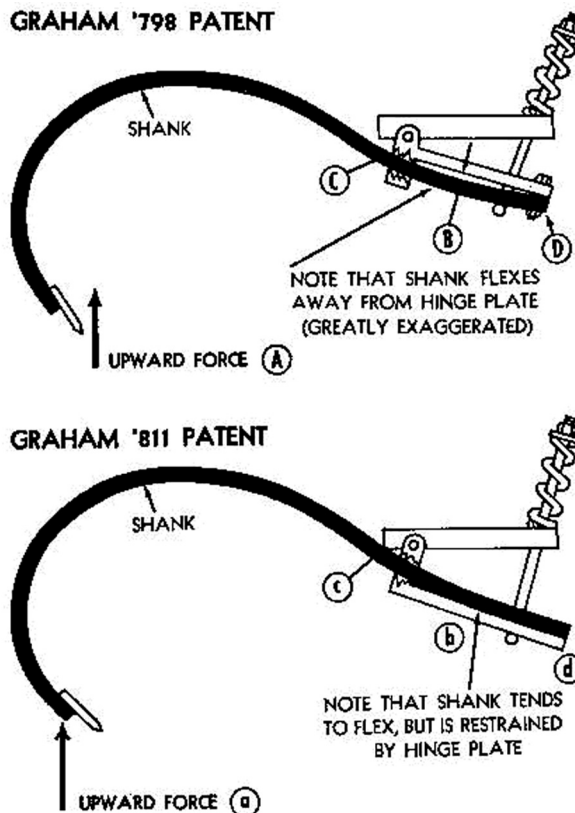


withstanding the shock of rocks and other obstructions in the soil without breaking the shanks. . . .

We confine our discussion to the prior patent of Graham, '811, and to the Glencoe clamp device, both among the references asserted by respondents. The Graham '811 and '798 patent devices are similar in all elements, save two: (1) the stirrup and the bolted connection of the shank to the hinge plate do not appear in '811; and (2) the position of the shank is reversed, being placed in patent '811 above the hinge plate, sandwiched between it and the upper plate. The shank is held in place by the spring rod which is hooked against the bottom of the hinge plate passing through a slot in the shank. Other differences are of no consequence to our examination. In practice the '811 patent arrangement permitted the shank to wobble or fishtail because it was not rigidly fixed to the hinge plate; moreover, as the hinge plate was below the shank, the latter caused wear on the upper plate, a member difficult to repair or replace. . . .

The contention is that this arrangement—which petitioners claim is not disclosed in the prior art—permits the shank to flex under stress for its entire length. As we have sketched (see sketch, 'Graham '798 Patent' in Fig. 2), when the chisel hits an obstruction the resultant force (A) pushes the rear of the shank upward and the shank pivots against the rear of the hinge plate at (C). The natural tendency is for that portion of the shank between the pivot point

FIGURE 2



and the bolted connection (i.e., between C and D) to bow downward and away from the hinge plate. The maximum distance (B) that the shank moves away from the plate is slight—for emphasis, greatly exaggerated in the sketches. This is so because of the strength of the shank and the short—nine inches or so—length of that portion of the shank between (C) and (D). On the contrary, in patent '811 (see sketch, “Graham '811 Patent” in Fig. 2), the pivot point is the upper plate at point (c); and while the tendency for the shank to bow between points (c) and (d) is the same as in '798, the shank is restricted because of the underlying hinge plate and cannot flex as freely. In practical effect, the shank flexes only between points (a) and (c), and not along the entire length of the shank, as in '798. Petitioners say that this difference in flex, though small, effectively absorbs the tremendous forces of the shock of obstructions whereas prior art arrangements failed. . . .

If free-flexing, as petitioners now argue, is the crucial difference above the prior art, then it appears evident that the desired result would be obtainable by not boxing the shank within the confines of the hinge. The only other effective place available in the arrangement was to attach it below the hinge plate and run it through a stirrup or bracket that would not disturb its flexing qualities. Certainly a person having ordinary skill in the prior art, given the fact that the flex in the shank could be utilized more effectively if allowed to run the entire length of the shank, would immediately see that the thing to do was what Graham did, i.e., invert the shank and the hinge plate.

UNITED STATES v. ADAMS

383 U.S. 39 (1966)

Justice CLARK delivered the opinion of the Court.

The United States seeks review of a judgment of the Court of Claims, holding valid and infringed a patent on a wet battery issued to Adams. This suit under 28 U.S.C. § 1498 (1964 ed.) was brought by Adams and others holding an interest in the patent against the Government charging both infringement and breach of an implied contract to pay compensation for the use of the invention. The Government challenged the validity of the patent, denied that it had been infringed or that any contract for its use had ever existed. The Trial Commissioner held that the patent was valid and infringed in part but that no contract, express or implied, had been established. The Court of Claims adopted these findings, initially reaching only the patent questions, but subsequently, on respondents' motion to amend the judgment, deciding the contract claims as well. The United States sought *certiorari* on the patent validity issue only. We granted the writ, along with the others, in order to settle the important issues of patentability. We affirm.

II.

The Patent in Issue and Its Background.

The patent under consideration, U.S. No. 2,322,210, was issued in 1943 upon an application filed in December 1941 by Adams. It relates to a non-rechargeable, as opposed to a storage, electrical battery. Stated simply, the

battery comprises two electrodes—one made of magnesium, the other of cuprous chloride—which are placed in a container. The electrolyte, or battery fluid, used may be either plain or salt water.

The specifications of the patent state that the object of the invention is to provide constant voltage and current without the use of acids, conventionally employed in storage batteries, and without the generation of dangerous fumes. Another object is “to provide a battery which is relatively light in weight with respect to capacity” and which “may be manufactured and distributed to the trade in a dry condition and rendered serviceable by merely filling the container with water.” Following the specifications, which also set out a specific embodiment of the invention, there appear 11 claims. Of these, principal reliance has been placed upon Claims 1 and 10, which read:

1. A battery comprising a liquid container, a magnesium electropositive electrode inside the container and having an exterior terminal, a fused cuprous chloride electronegative electrode, and a terminal connected with said electronegative electrode.
10. In a battery, the combination of a magnesium electropositive electrode, and an electronegative electrode comprising cuprous chloride fused with a carbon catalytic agent.

For several years prior to filing his application for the patent, Adams had worked in his home experimenting on the development of a wet battery. He found that when cuprous chloride and magnesium were used as electrodes in an electrolyte of either plain water or salt water an improved battery resulted.

The Adams invention was the first practical, water-activated, constant potential battery which could be fabricated and stored indefinitely without any fluid in its cells. It was activated within 30 minutes merely by adding water. Once activated, the battery continued to deliver electricity at a voltage which remained essentially constant regardless of the rate at which current was withdrawn. Furthermore, its capacity for generating current was exceptionally large in comparison to its size and weight. The battery was also quite efficient in that substantially its full capacity could be obtained over a wide range of currents. One disadvantage, however, was that once activated the battery could not be shut off; the chemical reactions in the battery continued even though current was not withdrawn. Nevertheless, these chemical reactions were highly exothermic, liberating large quantities of heat during operation. As a result, the battery performed with little effect on its voltage or current in very low temperatures. Relatively high temperatures would not damage the battery. Consequently, the battery was operable from 65° below zero Fahrenheit to 200° Fahrenheit.

Less than a month after filing for his patent, Adams brought his discovery to the attention of the Army and Navy. Arrangements were quickly made for demonstrations before the experts of the United States Army Signal Corps. The Signal Corps scientists who observed the demonstrations and who conducted further tests themselves did not believe the battery was workable. Almost a year later, in December 1942, Dr. George Vinal, an eminent government expert with the National Bureau of Standards, still expressed doubts. He felt that Adams was making “unusually large claims” for “high watt hour

output per unit weight,” and he found “far from convincing” the graphical data submitted by the inventor showing the battery’s constant voltage and capacity characteristics. He recommended, “Until the inventor can present more convincing data about the performance of his [battery] cell, I see no reason to consider it further.”

However, in November 1943, at the height of World War II, the Signal Corps concluded that the battery was feasible. The Government thereafter entered into contracts with various battery companies for its procurement. The battery was found adaptable to many uses. Indeed, by 1956 it was noted that “[t]here can be no doubt that the addition of water activated batteries to the family of power sources has brought about developments which would otherwise have been technically or economically impractical.”

Surprisingly, the Government did not notify Adams of its changed views nor of the use to which it was putting his device, despite his repeated requests. In 1955, upon examination of a battery produced for the Government by the Burgess Company, he first learned of the Government’s action. His request for compensation was denied in 1960, resulting in this suit.

III.

The Prior Art.

The basic idea of chemical generation of electricity is, of course, quite old. Batteries trace back to the epic discovery by the Italian scientist Volta in 1795, who found that when two dissimilar metals are placed in an electrically conductive fluid an electromotive force is set up and electricity generated. Essentially, the basic elements of a chemical battery are a pair of electrodes of different electrochemical properties and an electrolyte which is either a liquid (in “wet” batteries) or a moist paste of various substances (in the so-called “dry-cell” batteries). Various materials which may be employed as electrodes, various electrolyte possibilities and many combinations of these elements have been the object of considerable experiment for almost 175 years.

At trial, the Government introduced in evidence 24 patents and treatises as representing the art as it stood in 1938, the time of the Adams invention. Here, however, the Government has relied primarily upon only six of these references which we may summarize as follows.

The Niaudet treatise describes the Marie Davy cell invented in 1860 and De La Rue’s variations on it. The battery comprises a zinc anode and a silver chloride cathode. Although it seems to have been capable of working in an electrolyte of pure water, Niaudet says the battery was of “little interest” until De La Rue used a solution of ammonium chloride as an electrolyte. Niaudet also states that “[t]he capital advantage of this battery, as in all where zinc with sal ammoniac [ammonium chloride solution] is used, consists in the absence of any local or internal action as long as the electric circuit is open; in other words, this battery does not work upon itself.”

The Wood patent is relied upon by the Government as teaching the substitution of magnesium, as in the Adams patent, for zinc. Wood’s patent, issued in 1928, states: “It would seem that a relatively high voltage primary cell would be obtained by using . . . magnesium as the . . . [positive] electrode and I am aware that attempts have been made to develop such a cell. As far as

I am aware, however, these have all been unsuccessful, and it has been generally accepted that magnesium could not be commercially utilized as a primary cell electrode.” Wood recognized that the difficulty with magnesium electrodes is their susceptibility to chemical corrosion by the action of acid or ammonium chloride electrolytes. Wood’s solution to this problem was to use a “neutral electrolyte containing a strong soluble oxidizing agent adapted to reduce the rate of corrosion of the magnesium electrode on open circuit.” There is no indication of its use with cuprous chloride, nor was there any indication that a magnesium battery could be water-activated.

The Codd treatise is also cited as authority for the substitution of magnesium. However, Codd simply lists magnesium in an electromotive series table, a tabulation of electrochemical substances in descending order of their relative electropositivity. He also refers to magnesium in an example designed to show that various substances are more electropositive than others, but the discussion involves a cell containing an acid which would destroy magnesium within minutes. In short, Codd indicates, by inference, only that magnesium is a theoretically desirable electrode by virtue of its highly electropositive character. He does not teach that magnesium could be combined in a water-activated battery or that a battery using magnesium would have the properties of the Adams device. Nor does he suggest, as the Government indicates, that cuprous chloride could be substituted for silver chloride. He merely refers to the cuprous ion—a generic term which includes an infinite number of copper compounds—and in no way suggests that cuprous chloride could be employed in a battery.

The Government then cites the Wensky patent which was issued in Great Britain in 1891. The patent relates to the use of cuprous chloride as a depolarizing agent. The specifications of his patent disclose a battery comprising zinc and copper electrodes, the cuprous chloride being added as a salt in an electrolyte solution containing zinc chloride as well. While Wensky recognized that cuprous chloride could be used in a constant-current cell, there is no indication that he taught a water-activated system or that magnesium could be incorporated in his battery.

Finally, the Skrivanoff patent depended upon by the Government relates to a battery designed to give intermittent, as opposed to continuous, service. While the patent claims magnesium as an electrode, it specifies that the electrolyte to be used in conjunction with it must be a solution of “alcoline, chloro-chromate, or a permanganate strengthened with sulphuric acid.” The cathode was a copper or carbon electrode faced with a paste of “phosphoric acid, amorphous phosphorous, metallic copper in spangles, and cuprous chloride.” This paste is to be mixed with hot sulfuric acid before applying to the electrode. The Government’s expert testified in trial that he had no information as to whether the cathode, as placed in the battery, would, after having been mixed with the other chemicals prescribed, actually contain cuprous chloride. Furthermore, respondents’ expert testified, without contradiction, that he had attempted to assemble a battery made in accordance with Skrivanoff’s teachings, but was met first with a fire when he sought to make the cathode, and then with an explosion when he attempted to assemble the complete battery.

IV.

The Validity of the Patent.

The Government challenges the validity of the Adams patent on grounds of lack of novelty under 35 U.S.C. § 102(a) as well as obviousness under 35 U.S.C. § 103. As we have seen in *Graham v. John Deere Co.*, novelty and nonobviousness — as well as utility — are separate tests of patentability and all must be satisfied in a valid patent.

The Government concludes that wet batteries comprising a zinc anode and silver chloride cathode are old in the art; and that the prior art shows that magnesium may be substituted for zinc and cuprous chloride for silver chloride. Hence, it argues that the “combination of magnesium and cuprous chloride in the Adams battery was not patentable because it represented either no change or an insignificant change as compared to prior battery designs.” And, despite “the fact that, wholly unexpectedly, the battery showed certain valuable operating advantages over other batteries [these advantages] would certainly not justify a patent on the essentially old formula.”

There are several basic errors in the Government’s position. First, the fact that the Adams battery is water-activated sets his device apart from the prior art. It is true that Claims 1 and 10, do not mention a water electrolyte, but, as we have noted, a stated object of the invention was to provide a battery rendered serviceable by the mere addition of water. While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention. Taken together with the stated object of disclosing a water-activated cell, the lack of reference to any electrolyte in Claims 1 and 10 indicates that water alone could be used. Furthermore, of the 11 claims in issue, three of the narrower ones include references to specific electrolyte solutions comprising water and certain salts. The obvious implication from the absence of any mention of an electrolyte — a necessary element in any battery — in the other eight claims reinforces this conclusion. It is evident that respondents’ present reliance upon this feature was not the afterthought of an astute patent trial lawyer. In his first contact with the Government less than a month after the patent application was filed, Adams pointed out that “no acids, alkalines or any other liquid other than plain water is used in this cell. Water does not have to be distilled. . . .” The findings, approved and adopted by the Court of Claims, also fully support this conclusion.

Nor is *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327 (1945), apposite here. There the patentee had developed a rapidly drying printing ink. All that was needed to produce such an ink was a solvent which evaporated quickly upon heating. Knowing that the boiling point of a solvent is an indication of its rate of evaporation, the patentee merely made selections from a list of solvents and their boiling points. This was no more than “selecting the last piece to put into the last opening in a jig-saw puzzle.” 325 U.S., at 335. Indeed, the Government’s reliance upon *Sinclair & Carroll* points up the fallacy of the underlying premise of its case. The solvent in *Sinclair & Carroll* had no functional relation to the printing ink involved. It served only as an inert carrier. The choice of solvent was dictated by known, required properties. Here, however, the Adams battery is shown to embrace elements having

an interdependent functional relationship. It begs the question, and overlooks the holding of the Commissioner and the Court of Claims, to state merely that magnesium and cuprous chloride were individually known battery components. If such a combination is novel, the issue is whether bringing them together as taught by Adams was obvious in the light of the prior art.

We believe that the Court of Claims was correct in concluding that the Adams battery is novel. Skrivanoff disclosed the use of magnesium in an electrolyte completely different from that used in Adams. As we have mentioned, it is even open to doubt whether cuprous chloride was a functional element in Skrivanoff. In view of the unchallenged testimony that the Skrivanoff formulation was both dangerous and inoperable, it seems anomalous to suggest that it is an anticipation of Adams. An inoperable invention or one which fails to achieve its intended result does not negative novelty. That in 1880 Skrivanoff may have been able to convince a foreign patent examiner to issue a patent on his device has little significance in the light of the foregoing.

Nor is the Government's contention that the electrodes of Adams were mere substitutions of pre-existing battery designs supported by the prior art. If the use of magnesium for zinc and cuprous chloride for silver chloride were merely equivalent substitutions, it would follow that the resulting device—Adams'—would have equivalent operating characteristics. But it does not. The court below found, and the Government apparently admits, that the Adams battery "wholly unexpectedly" has shown "certain valuable operating advantages over other batteries" while those from which it is claimed to have been copied were long ago discarded. Moreover, most of the batteries relied upon by the Government were of a completely different type designed to give intermittent power and characterized by an absence of internal action when not in use. Some provided current at voltages which declined fairly proportionately with time. Others were so-called standard cells which, though producing a constant voltage, were of use principally for calibration or measurement purposes. Such cells cannot be used as sources of power. For these reasons we find no equivalency.

We conclude the Adams battery was also nonobvious. As we have seen, the operating characteristics of the Adams battery have been shown to have been unexpected and to have far surpassed then-existing wet batteries. Despite the fact that each of the elements of the Adams battery was well known in the prior art, to combine them as did Adams required that a person reasonably skilled in the prior art must ignore that (1) batteries which continued to operate on an open circuit and which heated in normal use were not practical; and (2) water-activated batteries were successful only when combined with electrolytes detrimental to the use of magnesium. These long-accepted factors, when taken together, would, we believe, deter any investigation into such a combination as is used by Adams. This is not to say that one who merely finds new uses for old inventions by shutting his eyes to their prior disadvantages thereby discovers a patentable innovation. We do say, however, that known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness.

Nor are these the only factors bearing on the question of obviousness. We have seen that at the time Adams perfected his invention noted experts expressed disbelief in it. Several of the same experts subsequently recognized the significance of the Adams invention, some even patenting improvements

on the same system. Fischbach *et al.*, U.S. Patent No. 2,636,060 (1953). Furthermore, in a crowded art replete with a century and a half of advancement, the Patent Office found not one reference to cite against the Adams application. Against the subsequently issued improvement patents to Fischbach, *supra*, and to Chubb, U.S. Reissue Patent No. 23,883 (1954), it found but three references prior to Adams — none of which are relied upon by the Government.

We conclude that the Adams patent is valid. The judgment of the Court of Claims is affirmed.

Comments

1. ***Obviousness Is a Legal Determination.*** The *Graham* Court explicitly stated that “the ultimate question of patent validity is one of law.” Just over 40 years later, the Court reaffirmed that while there are underlying factual considerations, “the ultimate judgment of obviousness is a legal determination.” *KSR Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1745 (2007) (citing *Graham*). Characterizing obviousness as a legal determination means that the ultimate decision under § 103 is more policy-laden in nature, particularly as it relates to how a *person having ordinary skill in the art* is constructed. See § C.2. See also the *Policy Perspective: Using § 103 as a Policy Tool* following the principal case of *Leapfrog Enterprises* in § C.1.
2. ***The Nonobviousness Test and Rules versus Standards.*** The *Graham* Court tracked the “relatively unambiguous terms” of § 103, noting there are several underlying factual determinations. These include: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) and the level of ordinary skill in the pertinent art. Once these facts are determined, the obviousness or nonobviousness of the subject matter is determined. It is important to remember, however, that § 103 is a standard, not a rule for determining obviousness. In fact, the Court compared the nonobviousness test to the reasonable person test in negligence law—the quintessential standard—stating the “difficulties” applying the § 103 inquiry “are comparable to those encountered daily by the courts in such frames of reference as negligence . . . and should be amenable to a case-by-case development.” The drafters “knew they were not making a *definition* but rather a *statement of policy*, a *specific approach* to a difficult problem.” Giles S. Rich, *The Vague Concept of “Invention” as Replaced by § 103 of the 1952 Patent Act*, 14 FED. CIRCUIT B.J. 147, 159 (2004-05) (taken from the Kettering Award Address, The Patent, Trademark, and Copyright Research Institute 144-45 (1964)) (emphasis in original).

Deciding whether to adopt a rule or standard is dependent on several factors and the nature of the legal regime in question. (A rules-based approach may be good for tax law, but ill-suited for constitutional law.) Rules and standards each have their respective strengths and weaknesses, and “[n]o sensible person supposes that rules are always superior to standards, or vice versa.” *MindGames, Inc. v. Western Pub. Co., Inc.*, 218 F.3d 652, 657 (7th Cir. 2000) (Posner, J.). As the *MindGames* court explains:

A rule singles out one or a few facts and makes it or them conclusive of legal liability; a standard permits consideration of all or at least most facts that are

relevant to the standard's rationale. A speed limit is a rule; negligence is a standard. Rules have the advantage of being definite and of limiting factual inquiry but the disadvantage of being inflexible, even arbitrary, and thus overinclusive, or of being underinclusive and thus opening up loopholes. . . . Standards are flexible, but vague and open-ended; they make business planning difficult, invite the sometimes unpredictable exercise of judicial discretion, and are more costly to adjudicate—and yet when based on lay intuition they may actually be more intelligible, and thus in a sense clearer and more precise, to the persons whose behavior they seek to guide than rules would be.

Id. The *Graham* Court expressly noted the unpredictability associated with applying the nonobviousness test, stating “[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context.” But establishing a nonobviousness standard (rather than a rule) is understandable because given the infinite variety and forms of invention, Congress could not enact a rule that would include or foresee when any given invention would satisfy the obviousness requirement.

Thus, § 103 can be seen as flexible, but also as establishing parameters for an obviousness determination. These parameters are defined by requiring the decisionmaker to engage in factual findings relating to “scope and content of the prior art,” “differences between the prior art and the claims at issue are to be ascertained” and “the level of ordinary skill in the pertinent art.” While these factual determinations do not unambiguously reveal what is and is not obvious, they do—contrary to the “requirement for invention” test—provide boundaries within which the § 103 decisionmaker must stay. This form of decisionmaking framework is common throughout the legal system. For instance, in discussing constitutional interpretation and the generality of constitutional clauses, Frederick Schauer writes:

[L]inguistically articulated rules . . . exclude[] wrong answers rather than point[] to right ones. . . . Since no clause can generate a uniquely correct answer, at least in the abstract rather than in the context of a specific question, the best view of the specific clauses is that they are merely less vague than the general clauses. The language of a clause, whether seemingly general or seemingly specific, establishes a boundary, or a frame, albeit a frame with fuzzy edges. Even though the language itself does not tell us what goes within the frame, it does tell us when we have gone outside it.

Frederick Schauer, *Easy Cases*, 58 S. CAL. L. REV. 399, 430 (1985). The rule versus standard debate applies to many areas of the law and has produced a rich literature. See, e.g., Daniel A. Crane, *Rules Versus Standards in Antitrust Adjudication*, 64 WASH. & LEE L. REV. 49 (2007); Edward Lee, *Rules and Standards for Cyberspace*, 77 NOTRE DAME L. REV. 1275 (2002); Thomas W. Merrill, *The Mead Doctrine: Rules and Standards, Meta-Rules and Meta-Standards*, 54 ADMIN. L. REV. 807 (2002); Clayton P. Gillette, *Rules, Standards, and Precautions in Payment Systems*, 82 VA. L. REV. 181 (1996); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992).

3. ***Graham and the Rejection of the “Requirement for Invention.”*** Consistent with § 103 and the intent of its drafters, the *Graham* Court rejected the confusing phrase “requirement for invention” as the operative test—what

Judge Learned Hand referred to as a “fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts.” *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir.1950) (Hand, J.). But the Court did not alter the objective level of creativity required to obtain a patent. Indeed, *Graham* recognized the similarities between *Hotchkiss* and § 103, stating the “first sentence of [§ 103] is strongly reminiscent of the language in *Hotchkiss*” and both are “implicitly tied to advances in that art.” The Court also appreciated the basis and motivation behind § 103, namely the emphasis on “‘nonobviousness’ as the operative test . . . rather than the less definite ‘invention’ language of *Hotchkiss* that Congress thought had led to ‘a large variety’ of expressions in decisions and writings.” According to the Court, patentability determinations by judges and examiners “must be beamed with greater intensity on the requirements of § 103.” For an excellent discussion of *Graham*, its history and influence, see John F. Duffy & Robert P. Merges, *The Story of Graham v. John Deere Company: Patent Law’s Evolving Standard of Creativity*, in *INTELLECTUAL PROPERTY STORIES* 108 (Jane C. Ginsburg & Rochelle Cooper Dreyfuss eds., 2006).

4. **Teaching Away.** An applicant or patentee has several arguments he can make to counter a finding or allegation of obviousness or simply to bolster the likelihood a court or examiner will find the claimed invention nonobviousness. Perhaps the strongest argument is that the prior art actually teaches away from the claimed invention or execution of the prior art resulted in a failure. The teaching away argument proved helpful to Adams. Recall the Court stated “that known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness.” The Federal Circuit has embraced the teaching away rationale. See *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003) (stating “[w]hile absolute certainty is not necessary to establish a reasonable expectation of success, there can be little better evidence negating an expectation of success than actual reports of failure”). And, after *KSR* (the principal case in Section C.1), evidence of teaching away will likely become more important.
5. **Suing the U.S. Government for Patent Infringement.** A patentee may sue the United States government for patent infringement. Under 28 U.S.C. § 1498—which is the only avenue to enforce U.S. government infringement—a patentee (like Adams) must bring suit in the Court of Federal Claims, not U.S. District Court. See *De Graffenried v. U.S.*, 29 Fed. Cl. 384, 391 (Fed. Cl. 1993) (stating “the government’s sole liability for the unauthorized use of a patented invention is set forth in 28 U.S.C. § 1498(a)”). Section 1498(a) provides, in relevant part:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

The courts have distinguished between Titles 28 and 35 in the context of patent infringement remedies. According to the Court of Federal Claims, while the “two titles are analogous, . . . Title 35 is premised on the notion that absent appropriate authorization, a private party generally cannot use a patented invention and is subject to injunction for any such unauthorized use,” whereas § 1498(a) “is founded on the premise that, although the government is obliged to pay a patent holder reasonable and entire compensation for use of his or her patent, the government can never be denied such use.” *De Graffenried, supra* at 391. Thus, injunctive relief is not available under § 1498, which means that, as a practical matter, the government can indirectly invoke a compulsory license. And in *Zoltek Corp. v. U.S.*, 442 F.3d 1345, 1352 (Fed. Cir. 2006), the Federal Circuit held that 5th Amendment takings jurisprudence does not apply to government infringing activity, noting a contrary result would read § 1498 “out of existence.” For more on the takings issue and patents, see *Adam Mossoff, Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689 (2007) (arguing that historically, courts treated patents as constitutionally protected private property interest subject to the Takings Clause).

6. **Flash of Genius Rejected.** One of the pre-1952 doctrines the drafters of § 103 rejected was the “flash of genius” test of *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941). The last sentence of § 103, which reads, “Patentability shall not be negated by the manner in which the invention was made,” specifically addressed *Cuno*. The *Graham* Court expressly adopted § 103’s approach when it wrote “[i]t . . . seems apparent that Congress intended by the last sentence of § 103 to abolish the test it believed this Court announced in the controversial phrase “flash of creative genius,” used in *Cuno*. This approach is consistent with Justice Story’s view of patentability, set forth in *Earle v. Sawyer*, 8 F. Cas. 254, 256 (C.C. Mass. 1825):

It is of no consequence, whether the thing be simple or complicated; whether it be by accident, or by long, laborious thought, or by an instantaneous flash of mind, that it is first done. The law looks to the fact, and not to the process by which it is accomplished. It gives the first inventor, or discoverer of the thing, the exclusive right, and asks nothing as to the mode or extent of the application of his genius to conceive or execute it.

C. APPLICATION OF THE GRAHAM TEST

Application of the *Graham* framework gets to the heart of an obviousness inquiry. In the principal case of *KSR v. Teleflex*, the Supreme Court—working within and building on *Graham*—identified several considerations that are relevant to an obviousness determination. In short, *KSR* explores how a court determines whether an invention is obvious. As you will recall from *Graham* and revisit in *KSR*, § 103 asks whether the claimed invention would have been obvious to a *person having ordinary skill in the art*, sometimes referred to as a

PHOSITA.* Who this person is and what is considered “ordinary skill” are addressed in the principal case of *Daiichi Sankyo* and the Comments that follow the case. Moreover, recall under § 102 an invention is anticipated if a *single* prior art reference discloses each and every limitation of the claimed invention; in contrast, references can be combined under § 103. But a non-obvious inquiry is also more restrictive than § 102 in that prior art must be *analogous* before it can be used under § 103. The doctrine of analogous art is a filter, although less so after *KSR*, sifting out references that are too far afield from the claimed invention. The issue of analogous art is discussed in *In re Icon Health & Fitness*.

1. Determining Obviousness (or Not)

An overwhelming majority of obviousness decisions involve more than one prior art reference. Since the mid-1980s the Federal Circuit and its predecessor, the CCPA, have required that before prior art references can be combined under § 103, the references must *teach, suggest* or *motivate* (TSM) a person of ordinary skill in the art to make the claimed invention. In other words, there had to be a reason to combine. Whether the TSM requirement is consistent with Supreme Court precedent was addressed in *KSR*, one of the most significant Supreme Court cases involving patent law in the past 50 years. Shortly after *KSR*, the Federal Circuit had an opportunity to apply the decision’s analysis in *Leapfrog*. Both *KSR* and *Leapfrog* are principal cases.

KSR INTERNATIONAL v. TELEFLEX, INC.

127 S. Ct. 1727 (2007)

Justice KENNEDY delivered the opinion of the Court.

Teleflex Incorporated and its subsidiary Technology Holding Company—both referred to here as Teleflex—sued KSR International Company for patent infringement. The patent at issue, United States Patent No. 6,237,565 B1, is entitled “Adjustable Pedal Assembly With Electronic Throttle Control.” The patentee is Steven J. Engelgau, and the patent is referred to as “the Engelgau patent.” Teleflex holds the exclusive license to the patent.

Claim 4 of the Engelgau patent describes a mechanism for combining an electronic sensor with an adjustable automobile pedal so the pedal’s position can be transmitted to a computer that controls the throttle in the vehicle’s engine. When Teleflex accused KSR of infringing the Engelgau patent by adding an electronic sensor to one of KSR’s previously designed pedals, KSR countered that claim 4 was invalid under the Patent Act, 35 U.S.C. § 103, because its subject matter was obvious.

Section 103 forbids issuance of a patent when “the differences between the subject matter sought to be patented and the prior art are such that the subject

* The acronym, PHOSITA, was coined by Cyril A. Soans in his article *Some Absurd Presumptions in Patent Cases*, 10 IDEA 433, 436 (1966). Soans referred to the person having ordinary skill in the art as “Mr. Phosita.”

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), the Court set out a framework for applying the statutory language of § 103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*, 11 How. 248 (1851), and its progeny. See 383 U.S., at 15-17. The analysis is objective:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Id., at 17-18.

While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

Seeking to resolve the question of obviousness with more uniformity and consistency, the Court of Appeals for the Federal Circuit has employed an approach referred to by the parties as the “teaching, suggestion, or motivation” test (TSM test), under which a patent claim is only proved obvious if “some motivation or suggestion to combine the prior art teachings” can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art. KSR challenges that test, or at least its application in this case. Because the Court of Appeals addressed the question of obviousness in a manner contrary to § 103 and our precedents, we granted certiorari. We now reverse.

I

A

In car engines without computer-controlled throttles, the accelerator pedal interacts with the throttle via cable or other mechanical link. The pedal arm acts as a lever rotating around a pivot point. In a cable-actuated throttle control the rotation caused by pushing down the pedal pulls a cable, which in turn pulls open valves in the carburetor or fuel injection unit. The wider the valves open, the more fuel and air are released, causing combustion to increase and the car to accelerate. When the driver takes his foot off the pedal, the opposite occurs as the cable is released and the valves slide closed.

In the 1990’s it became more common to install computers in cars to control engine operation. Computer-controlled throttles open and close valves in response to electronic signals, not through force transferred from the pedal by a mechanical link. Constant, delicate adjustments of air and fuel mixture are possible. The computer’s rapid processing of factors beyond the pedal’s position improves fuel efficiency and engine performance.

For a computer-controlled throttle to respond to a driver’s operation of the car, the computer must know what is happening with the pedal. A cable or mechanical link does not suffice for this purpose; at some point, an electronic

sensor is necessary to translate the mechanical operation into digital data the computer can understand.

Before discussing sensors further we turn to the mechanical design of the pedal itself. In the traditional design a pedal can be pushed down or released but cannot have its position in the footwell adjusted by sliding the pedal forward or back. As a result, a driver who wishes to be closer or farther from the pedal must either reposition himself in the driver's seat or move the seat in some way. In cars with deep footwells these are imperfect solutions for drivers of smaller stature. To solve the problem, inventors, beginning in the 1970's, designed pedals that could be adjusted to change their location in the footwell. Important for this case are two adjustable pedals disclosed in U.S. Patent Nos. 5,010,782 (filed July 28, 1989) (Asano) and 5,460,061 (filed Sept. 17, 1993) (Redding). The Asano patent reveals a support structure that houses the pedal so that even when the pedal location is adjusted relative to the driver, one of the pedal's pivot points stays fixed. The pedal is also designed so that the force necessary to push the pedal down is the same regardless of adjustments to its location. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

We return to sensors. Well before Engelgau applied for his challenged patent, some inventors had obtained patents involving electronic pedal sensors for computer-controlled throttles. These inventions, such as the device disclosed in U.S. Patent No. 5,241,936 (filed Sept. 9, 1991) ('936), taught that it was preferable to detect the pedal's position in the pedal assembly, not in the engine. The '936 patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. U.S. Patent No. 5,063,811 (filed July 9, 1990) (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, and to avoid grime and damage from the driver's foot, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad.

In addition to patents for pedals with integrated sensors inventors obtained patents for self-contained modular sensors. A modular sensor is designed independently of a given pedal so that it can be taken off the shelf and attached to mechanical pedals of various sorts, enabling the pedals to be used in automobiles with computer-controlled throttles. One such sensor was disclosed in U.S. Patent No. 5,385,068 (filed Dec. 18, 1992) ('068). In 1994, Chevrolet manufactured a line of trucks using modular sensors "attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates in operation." 298 F. Supp. 2d 581, 589 (E.D. Mich. 2003).

The prior art contained patents involving the placement of sensors on adjustable pedals as well. For example, U.S. Patent No. 5,819,593 (filed Aug. 17, 1995) (Rixon) discloses an adjustable pedal assembly with an electronic sensor for detecting the pedal's position. In the Rixon pedal the sensor is located in the pedal footpad. The Rixon pedal was known to suffer from wire chafing when the pedal was depressed and released.

This short account of pedal and sensor technology leads to the instant case.

B

KSR, a Canadian company, manufactures and supplies auto parts, including pedal systems. Ford Motor Company hired KSR in 1998 to supply an

adjustable pedal system for various lines of automobiles with cable-actuated throttle controls. KSR developed an adjustable mechanical pedal for Ford and obtained U.S. Patent No. 6,151,976 (filed July 16, 1999) ('976) for the design. In 2000, KSR was chosen by General Motors Corporation (GMC or GM) to supply adjustable pedal systems for Chevrolet and GMC light trucks that used engines with computer-controlled throttles. To make the '976 pedal compatible with the trucks, KSR merely took that design and added a modular sensor.

Teleflex is a rival to KSR in the design and manufacture of adjustable pedals. As noted, it is the exclusive licensee of the Engelgau patent. Engelgau filed the patent application on August 22, 2000 as a continuation of a previous application for U.S. Patent No. 6,109,241, which was filed on January 26, 1999. He has sworn he invented the patent's subject matter on February 14, 1998. The Engelgau patent discloses an adjustable electronic pedal described in the specification as a "simplified vehicle control pedal assembly that is less expensive, and which uses fewer parts and is easier to package within the vehicle." Engelgau, col. 2, lines 2-5. Claim 4 of the patent, at issue here, describes:

A vehicle control pedal apparatus [12] comprising:

- a support [18] adapted to be mounted to a vehicle structure [20];
- an adjustable pedal assembly [22] having a pedal arm [14] moveable in fore and aft directions with respect to said support [18];
- a pivot [24] for pivotally supporting said adjustable pedal assembly [22] with respect to said support [18] and defining a pivot axis [26]; and
- an electronic control [28] attached to said support [18] for controlling a vehicle system;

said apparatus [12] characterized by said electronic control [28] being responsive to said pivot [24] for providing a signal [32] that corresponds to pedal arm position as said pedal arm [14] pivots about said pivot axis [26] between rest and applied positions wherein the position of said pivot [24] remains constant while said pedal arm [14] moves in fore and aft directions with respect to said pivot [24].

Id., col. 6, lines 17-36.

We agree with the District Court that the claim discloses "a position-adjustable pedal assembly with an electronic pedal position sensor attached to the support member of the pedal assembly. Attaching the sensor to the support member allows the sensor to remain in a fixed position while the driver adjusts the pedal." 298 F. Supp. 2d, at 586-587.

Before issuing the Engelgau patent the U.S. Patent and Trademark Office (PTO) rejected one of the patent claims that was similar to, but broader than, the present claim 4. The claim did not include the requirement that the sensor be placed on a fixed pivot point. The PTO concluded the claim was an obvious combination of the prior art disclosed in Redding and Smith, explaining:

Since the prior art references are from the field of endeavor, the purpose disclosed . . . would have been recognized in the pertinent art of Redding. Therefore it would have been obvious . . . to provide the device of Redding with the . . . means attached to a support member as taught by Smith.

Id., at 595.

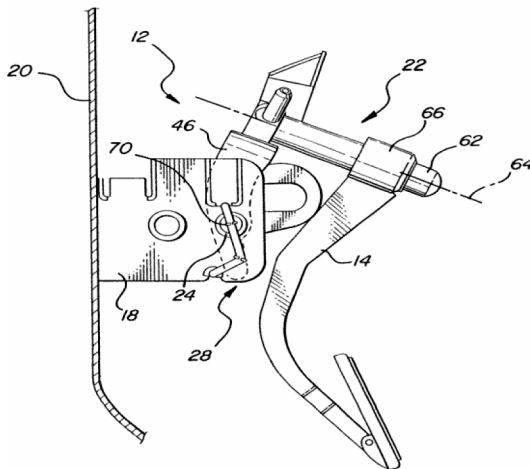
In other words Redding provided an example of an adjustable pedal and Smith explained how to mount a sensor on a pedal's support structure, and the rejected patent claim merely put these two teachings together.

Although the broader claim was rejected, claim 4 was later allowed because it included the limitation of a fixed pivot point, which distinguished the design from Redding's. *Ibid.* Engelgau had not included Asano among the prior art references, and Asano was not mentioned in the patent's prosecution. Thus, the PTO did not have before it an adjustable pedal with a fixed pivot point. The patent issued on May 29, 2001 and was assigned to Teleflex.

Upon learning of KSR's design for GM, Teleflex sent a warning letter informing KSR that its proposal would violate the Engelgau patent. "Teleflex believes that any supplier of a product that combines an adjustable pedal with an electronic throttle control necessarily employs technology covered by one or more" of Teleflex's patents. *Id.*, at 585. KSR refused to enter a royalty arrangement with Teleflex; so Teleflex sued for infringement, asserting KSR's pedal infringed the Engelgau patent and two other patents. *Ibid.* Teleflex later abandoned its claims regarding the other patents and dedicated the patents to the public. The remaining contention was that KSR's pedal system for GM infringed claim 4 of the Engelgau patent. Teleflex has not argued that the other three claims of the patent are infringed by KSR's pedal, nor has Teleflex argued that the mechanical adjustable pedal designed by KSR for Ford infringed any of its patents.

C

The District Court granted summary judgment in KSR's favor. After reviewing the pertinent history of pedal design, the scope of the Engelgau patent, and the relevant prior art, the court considered the validity of the contested claim. By direction of 35 U.S.C. § 282, an issued patent is presumed valid. The District Court applied *Graham*'s framework to determine whether under summary-judgment standards KSR had overcome the presumption and



demonstrated that claim 4 was obvious in light of the prior art in existence when the claimed subject matter was invented.

The District Court determined, in light of the expert testimony and the parties' stipulations, that the level of ordinary skill in pedal design was "an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) [and] familiarity with pedal control systems for vehicles." 298 F. Supp. 2d, at 590. The court then set forth the relevant prior art, including the patents and pedal designs described above.

Following *Graham's* direction, the court compared the teachings of the prior art to the claims of Engelgau. It found "little difference." 298 F. Supp. 2d, at 590. Asano taught everything contained in claim 4 except the use of a sensor to detect the pedal's position and transmit it to the computer controlling the throttle. That additional aspect was revealed in sources such as the '068 patent and the sensors used by Chevrolet.

Under the controlling cases from the Court of Appeals for the Federal Circuit, however, the District Court was not permitted to stop there. The court was required also to apply the TSM test. The District Court held KSR had satisfied the test. It reasoned (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to the wire chafing problems in Rixon, namely locating the sensor on the fixed structure of the pedal. This could lead to the combination of Asano, or a pedal like it, with a pedal position sensor.

The conclusion that the Engelgau design was obvious was supported, in the District Court's view, by the PTO's rejection of the broader version of claim 4. Had Engelgau included Asano in his patent application, it reasoned, the PTO would have found claim 4 to be an obvious combination of Asano and Smith, as it had found the broader version an obvious combination of Redding and Smith. As a final matter, the District Court held that the secondary factor of Teleflex's commercial success with pedals based on Engelgau's design did not alter its conclusion. The District Court granted summary judgment for KSR.

With principal reliance on the TSM test, the Court of Appeals reversed. It ruled the District Court had not been strict enough in applying the test, having failed to make "'finding[s] as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention' . . . to attach an electronic control to the support bracket of the Asano assembly." 119 Fed. Appx., at 288 (brackets in original) (quoting *In re Kotzab*, 217 F.3d 1365, 1371 (CA Fed. 2000)). The Court of Appeals held that the District Court was incorrect that the nature of the problem to be solved satisfied this requirement because unless the "prior art references address[ed] the precise problem that the patentee was trying to solve," the problem would not motivate an inventor to look at those references. 119 Fed. Appx., at 288.

Here, the Court of Appeals found, the Asano pedal was designed to solve the "'constant ratio problem'" —that is, to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted—whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. *Ibid.* As for Rixon, the court explained, that pedal suffered from the problem of wire chafing but was not designed to solve it. In the court's view Rixon did not teach anything helpful to Engelgau's purpose. Smith, in turn,

did not relate to adjustable pedals and did not “necessarily go to the issue of motivation to attach the electronic control on the support bracket of the pedal assembly.” *Ibid.* When the patents were interpreted in this way, the Court of Appeals held, they would not have led a person of ordinary skill to put a sensor on the sort of pedal described in Asano.

That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court’s view, because “[o]bvious to try” has long been held not to constitute obviousness.” *Id.*, at 289 (quoting *In re Deuel*, 51 F.3d 1552, 1559 (CA Fed. 1995)).

The Court of Appeals also faulted the District Court’s consideration of the PTO’s rejection of the broader version of claim 4. The District Court’s role, the Court of Appeals explained, was not to speculate regarding what the PTO might have done had the Engelgau patent mentioned Asano. Rather, the court held, the District Court was obliged first to presume that the issued patent was valid and then to render its own independent judgment of obviousness based on a review of the prior art. The fact that the PTO had rejected the broader version of claim 4, the Court of Appeals said, had no place in that analysis.

The Court of Appeals further held that genuine issues of material fact precluded summary judgment. Teleflex had proffered statements from one expert that claim 4 “was a simple, elegant, and novel combination of features,” 119 Fed. Appx., at 290, compared to Rixon, and from another expert that claim 4 was nonobvious because, unlike in Rixon, the sensor was mounted on the support bracket rather than the pedal itself. This evidence, the court concluded, sufficed to require a trial.

II

A

We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court’s engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, *Graham* recognized the need for “uniformity and definiteness.” 383 U.S., at 18. Yet the principles laid down in *Graham* reaffirmed the “functional approach” of *Hotchkiss*, 11 How. 248. See 383 U.S., at 12. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive. *Id.*, at 17.

Neither the enactment of § 103 nor the analysis in *Graham* disturbed this Court’s earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, the Court has held that a “patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men.” *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. Three cases decided after *Graham* illustrate the application of this doctrine.

In *United States v. Adams*, 383 U.S. 39, 40 (1966), a companion case to *Graham*, the Court considered the obviousness of a “wet battery” that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. 383 U.S., at 50-51. It nevertheless rejected the Government’s claim that Adams’s battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious. *Id.*, at 51-52. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams’s design was not obvious to those skilled in the art.

In *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969), the Court elaborated on this approach. The subject matter of the patent before the Court was a device combining two pre-existing elements: a radiant-heat burner and a paving machine. The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did the same. The two in combination did no more than they would in separate, sequential operation. *Id.*, at 60-62. In those circumstances, “while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented,” and the patent failed under § 103. *Id.*, at 62.

Finally, in *Sakraida v. AG Pro, Inc.*, 425 U.S. 273 (1976), the Court derived from the precedents the conclusion that when a patent “simply arranges old elements with each performing the same function it had been known to perform” and yields no more than one would expect from such an arrangement, the combination is obvious. *Id.*, at 282.

The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson’s-Black Rock* are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple

patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

B

When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. See *Application of Bergel*, 292 F.2d 955, 956-957 (1961). As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.

C

The flaws in the analysis of the Court of Appeals relate for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test. In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. *Ibid.* The primary purpose of Asano was solving the constant ratio problem; so, the court concluded, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. *Ibid.* Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, the design provided an obvious example of an adjustable pedal with a fixed pivot point; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve the constant ratio problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an automaton.

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U.S., at

36 (warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “guard against slipping into the use of hindsight” (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964))). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

We note the Court of Appeals has since elaborated a broader conception of the TSM test than was applied in the instant matter. See, e.g., *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (2006) (“Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense”); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (2006) (“There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine . . .”). Those decisions, of course, are not now before us and do not correct the errors of law made by the Court of Appeals in this case. The extent to which they may describe an analysis more consistent with our earlier precedents and our decision here is a matter for the Court of Appeals to consider in its future cases. What we hold is that the fundamental misunderstandings identified above led the Court of Appeals in this case to apply a test inconsistent with our patent law decisions.

III

When we apply the standards we have explained to the instant facts, claim 4 must be found obvious. We agree with and adopt the District Court’s recitation of the relevant prior art and its determination of the level of ordinary skill in the field. As did the District Court, we see little difference between the teachings of Asano and Smith and the adjustable electronic pedal disclosed in claim 4 of the Engलगau patent. A person having ordinary skill in the art could have combined Asano with a pedal position sensor in a fashion encompassed by claim 4, and would have seen the benefits of doing so.

A

Teleflex argues in passing that the Asano pedal cannot be combined with a sensor in the manner described by claim 4 because of the design of Asano’s pivot mechanisms. See Brief for Respondents 48-49, and n.17. Therefore, Teleflex reasons, even if adding a sensor to Asano was obvious, that does not establish that claim 4 encompasses obvious subject matter. This argument was not, however, raised before the District Court. There Teleflex was content to assert only that the problem motivating the invention claimed by the Engलगau patent would not lead to the solution of combining of Asano with a sensor. It is also unclear whether the current argument was raised before the Court of Appeals, where Teleflex advanced the nonspecific, conclusory contention that combining Asano with a sensor would not satisfy the limitations of claim 4. Teleflex’s own expert declarations, moreover, do not support the point Teleflex now raises. See Declaration of Clark J. Radcliffe, Ph.D.; Declaration of Timothy L. Andresen, at 208-210. The only statement in either declaration that might bear on the argument is found in the Radcliffe declaration:

“Asano . . . and Rixon . . . are complex mechanical linkage-based devices that are expensive to produce and assemble and difficult to package. It is exactly

these difficulties with prior art designs that [Engelgau] resolves. The use of an adjustable pedal with a single pivot reflecting pedal position combined with an electronic control mounted between the support and the adjustment assembly at that pivot was a simple, elegant, and novel combination of features in the Engelgau '565 patent."

Radcliffe Declaration at 206, ¶16.

Read in the context of the declaration as a whole this is best interpreted to mean that Asano could not be used to solve "[t]he problem addressed by Engelgau '565[:] to provide a less expensive, more quickly assembled, and smaller package adjustable pedal assembly with electronic control." *Id.*, at 205, ¶10.

The District Court found that combining Asano with a pivot-mounted pedal position sensor fell within the scope of claim 4. Given the significance of that finding to the District Court's judgment, it is apparent that Teleflex would have made clearer challenges to it if it intended to preserve this claim. In light of Teleflex's failure to raise the argument in a clear fashion, and the silence of the Court of Appeals on the issue, we take the District Court's conclusion on the point to be correct.

B

The District Court was correct to conclude that, as of the time Engelgau designed the subject matter in claim 4, it was obvious to a person of ordinary skill to combine Asano with a pivot-mounted pedal position sensor. There then existed a marketplace that created a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for achieving this advance. The Court of Appeals considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet truckline and disclosed in the '068 patent. The District Court employed this narrow inquiry as well, though it reached the correct result nevertheless. The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor.

In automotive design, as in many other fields, the interaction of multiple components means that changing one component often requires the others to be modified as well. Technological developments made it clear that engines using computer-controlled throttles would become standard. As a result, designers might have decided to design new pedals from scratch; but they also would have had reason to make pre-existing pedals work with the new engines. Indeed, upgrading its own pre-existing model led KSR to design the pedal now accused of infringing the Engelgau patent.

For a designer starting with Asano, the question was where to attach the sensor. The consequent legal question, then, is whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and Engelgau put it would have been obvious to a person of ordinary skill.

The '936 patent taught the utility of putting the sensor on the pedal device, not in the engine. Smith, in turn, explained to put the sensor not on the

pedal's footpad but instead on its support structure. And from the known wire-chafing problems of Rixon, and Smith's teaching that "the pedal assemblies must not precipitate any motion in the connecting wires," Smith, col. 1, lines 35-37, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor on a pivot, thereby designing an adjustable electronic pedal covered by claim 4.

Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Following similar steps to those just explained, a designer would learn from Smith to avoid sensor movement and would come, thereby, to Asano because Asano disclosed an adjustable pedal with a fixed pivot.

Teleflex indirectly argues that the prior art taught away from attaching a sensor to Asano because Asano in its view is bulky, complex, and expensive. The only evidence Teleflex marshals in support of this argument, however, is the Radcliffe declaration, which merely indicates that Asano would not have solved Engelgau's goal of making a small, simple, and inexpensive pedal. What the declaration does not indicate is that Asano was somehow so flawed that there was no reason to upgrade it, or pedals like it, to be compatible with modern engines. Indeed, Teleflex's own declarations refute this conclusion. Dr. Radcliffe states that Rixon suffered from the same bulk and complexity as did Asano. Teleflex's other expert, however, explained that Rixon was itself designed by adding a sensor to a pre-existing mechanical pedal. If Rixon's base pedal was not too flawed to upgrade, then Dr. Radcliffe's declaration does not show Asano was either. Teleflex may have made a plausible argument that Asano is inefficient as compared to Engelgau's preferred embodiment, but to judge Asano against Engelgau would be to engage in the very hindsight bias Teleflex rightly urges must be avoided. Accordingly, Teleflex has not shown anything in the prior art that taught away from the use of Asano.

Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious. Proper application of *Graham* and our other precedents to these facts therefore leads to the conclusion that claim 4 encompassed obvious subject matter. As a result, the claim fails to meet the requirement of § 103.

We need not reach the question whether the failure to disclose Asano during the prosecution of Engelgau voids the presumption of validity given to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished here.

IV

A separate ground the Court of Appeals gave for reversing the order for summary judgment was the existence of a dispute over an issue of material fact. We disagree with the Court of Appeals on this point as well. To the extent the court understood the *Graham* approach to exclude the possibility of summary judgment when an expert provides a conclusory affidavit addressing the question of obviousness, it misunderstood the role expert testimony plays

in the analysis. In considering summary judgment on that question the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U.S., at 17. Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate. Nothing in the declarations proffered by Teleflex prevented the District Court from reaching the careful conclusions underlying its order for summary judgment in this case.

* * *

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See U.S. Const., Art. I, § 8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* and codified in § 103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.

KSR provided convincing evidence that mounting a modular sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art. Its arguments, and the record, demonstrate that claim 4 of the Engelgau patent is obvious. In rejecting the District Court's rulings, the Court of Appeals analyzed the issue in a narrow, rigid manner inconsistent with § 103 and our precedents. The judgment of the Court of Appeals is reversed, and the case remanded for further proceedings consistent with this opinion.

Comments

1. ***Cumulative Innovation and § 103.*** In the concluding paragraphs of *KSR*, Justice Kennedy discussed the cumulative nature of innovation, how “advances, once part of our shared knowledge, define a new threshold from which innovation starts once more.” The aforementioned language is reminiscent of the 19th-century Supreme Court case of *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1883), wherein the Court wrote:

It was never the object of [patent] law[] to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures. Such an indiscriminate creation of exclusive privileges tends rather to obstruct than to stimulate invention. It creates a class of speculative schemers who make it their business to watch the advancing wave of improvement, and gather its foam in the form of patented monopolies, which enable them to lay a heavy tax upon the industry of the country, without contributing anything to the real advancement of the art. It embarrasses the

honest pursuit of business with fears and apprehensions of concealed liens and unknown liabilities to lawsuits and vexatious accountings for profits made in good faith.

Indeed, § 103 can be seen as embracing this language and the principle enunciated in *KSR*, that to reward patent rights to “the results of ordinary innovation” would “stifle, rather than promote, the progress of useful arts,” and therefore fail to advance the Constitutional mandate embodied in Article I, § 8, cl. 8. This language is reminiscent of the *Graham* Court’s assertion that the nonobviousness requirement is Constitutionally mandated. Moreover, some commentators have argued that the Supreme Court operates from a different premise than the Federal Circuit regarding how the two courts view the patent system. As Joseph Miller writes, the “Supreme Court differs with the Federal Circuit not merely over verbal formulae, but rather over a foundational premise for the patent system. . . . It is now plain that, for the Supreme Court, a wrongful patent grant is more harmful than a wrongful denial. For the Federal Circuit, by contrast, a wrongful patent denial is more harmful than a wrongful grant.” Joseph Scott Miller, *Remixing Obviousness*, 16 TEX. INTELL. PROP. L.J. — (forthcoming 2007).

2. **An “Expansive and Flexible Approach” to the Obviousness Inquiry.** *KSR* is a cautious opinion that recalibrates the obviousness inquiry, rather than offering a new and sweeping articulation of obviousness jurisprudence. The principal concern the Supreme Court expressed with the Federal Circuit’s TSM test was not the test itself, but the inflexible and formalistic manner in which the appeals court applied the test. As the Court stated, “[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis,” and “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” Yet, wrote the Court, “when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.” The Supreme Court stressed that it had consistently adopted an “expansive and flexible approach” to the obviousness inquiry and, interestingly, seemed to implicitly endorse the Federal Circuit’s *Dystar* and *Alza* opinions, both of which touted the flexibility built into the TSM test. In *Dystar*, for instance, the Federal Circuit wrote “[o]ur suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense.” 464 F.3d at 1367 (emphasis in original). And in *Alza*, the court pointed out “[w]e do not have a rigid test that requires an actual teaching to combine before concluding that one of ordinary skill in the art would know to combine references.” 464 F.3d 1291.*

In other cases, decided years before *Dystar* and *Alza*, the Federal Circuit stressed that in addition to prior art references, the source of the

*Both *Dystar* and *Alza* were decided after the Supreme Court granted certiorari in *KSR*. This fact was not lost on Justice Scalia, who during oral argument, stated “in the last year or so, after we granted cert in this case after these decades of thinking about [the nonobviousness doctrine, the Federal Circuit] suddenly decides to polish it up.” *KSR* Transcript of Oral Argument at 53; see also *id.* (setting forth Justice Breyer’s comment suggesting that, in its recent case law, the Federal Circuit “so quickly modified itself” after it had decades to elaborate a standard of obviousness).

motivation or suggestion may come (1) “from knowledge of those skilled in the art that certain references, or disclosures in the references, are known to be of special interest or importance in the particular field”; or (2) from the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem.” *Pro-Mold & Tool Company v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996). It is worth emphasizing again, *KSR* was not so much concerned about the TSM test as it was how the test has been applied. Although cases such as *Pro-Mold* were “on the books,” the *KSR* Court believed the Federal Circuit’s parochial application of TSM largely ignored the knowledge of the skilled artisan as well as many other considerations (as discussed in Comment 6) deemed important by *KSR*.

The prominent role played by the *Great Atlantic* case in *KSR* is also noteworthy. The Court stressed “the need for caution in granting a patent based on the combination of elements found in the prior art,” and, quoting from *Great Atlantic*, wrote “[f]or over a half century, the Court has held that a ‘patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men.’” *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 (1950). Thus, according to *KSR*, a combination of known elements is likely to be obvious if the elements do “no more than yield predictable results.” Similarly, in *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 60 (1969), discussed in *KSR*, the Court held a patent invalid because although the patentee’s combination of known elements lead to greater convenience in the operation of the invention, the combination “did not produce a ‘new’ or ‘different function.’” And recall in *Hotchkiss*, the Court noted that even if connecting the clay or porcelain knob to a metallic shank produced an article that is “better and cheaper than in the case of the metallic or wood knob, the knob of clay was simply the substitution of one material for another, . . . and no more ingenuity or skill [was] required to construct the knob in this way than that possessed by an ordinary mechanic acquainted with the business.” 52 U.S. at 265. In this regard, the TSM test seems inapplicable because the Court seems to imply a presumption of obviousness.

3. **What Is the Test for Obviousness?** The *Graham* factors, of course, provide the conceptual framework for an obviousness analysis, and the TSM test is viewed by the Federal Circuit as fitting comfortably within the fabric of *Graham*. The *KSR* Court rejected the rigid application of the TSM test (although not the test itself), yet did not provide a bright-line test for obviousness or a clear indication of what exactly its “expansive and flexible approach” has been “[t]hroughout [the] Court’s engagement with the question of obviousness.” Rather, the Court focused on broad themes such as predictability and the importance of the person having ordinary skill in the art (discussed in Comment 6 and Section C.2 below). For instance, the Court stated: (1) “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results”; (2) “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability”; (3) “a court must ask whether the improvement is more than the predictable use of prior art

elements according to their established functions”; and (4) “when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.”

With predictability as its theme, the Court offered a number of considerations that may be relevant to an obviousness inquiry. These considerations are captured in the following passages from the opinion (emphasis added):

[1] Often, it will be necessary for a court to look to *interrelated teachings of multiple patents*; the effects of *demands known to the design community or present in the marketplace*; and the *background knowledge possessed by a person having ordinary skill in the art*, all in order to determine whether there was an *apparent reason* to combine the known elements in the fashion claimed by the patent at issue.

[2] In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that *market demand, rather than scientific literature, will drive design trends*.

[3] [T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the *inferences and creative steps that a person of ordinary skill in the art would employ*.

[4] *[A]ny need or problem known in the field of endeavor* at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed. (This factor may pose a problem for entities also filing in European Patent Convention countries, because the EPC’s “inventive step” provision has been interpreted by many countries as a “problem and solution” approach. See the *Comparative Perspective* immediately following these Comments.)

[5] *[F]amiliar items may have obvious uses beyond their primary purposes*, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.

From these passages, a court, patent examiner, and patent counsel, looking through the eyes of the skilled artisan, would want to consider the following in determining whether there “was an apparent reason to combine the known elements in the fashion claimed by the patent at issue”:

- (1) interrelated teachings of the patents;
- (2) demands known to the design community and marketplace;
- (3) scientific literature and market demand;
- (4) background knowledge of the skilled artisan, as well as inferences and creative steps he would employ;
- (5) any need or problem known in the field of endeavor; and
- (6) uses of items beyond their primary purposes.

The Federal Circuit, through its common law powers, will have to develop and refine these factors into a § 103 analysis. The Supreme Court signaled that *Dystar* and *Alza* may be good starting points, noting that “[t]he extent to which [these cases] may describe an analysis more consistent with our earlier precedents and our decision here is a matter for the Court of Appeals to consider in its future cases.” On October 10, 2007, the PTO issued examination guidelines in the wake of *KSR*. The guidelines identified

seven “rationales,” including TSM, for supporting a § 103 rejection. See *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 In View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57529 (October 10, 2007). They include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” —choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention

For an extensive discussion of *KSR*, including links to commentary and briefs, see Dennis Crouch’s blog, Patently-O, at <http://www.patentlyo.com/>.

4. **“Reasonable Expectation of Success.”** Another consideration embraced by the Federal Circuit, but not mentioned in *KSR*, is the “reasonable expectation of success” requirement. This requirement usually goes hand-in-hand with TSM. In numerous cases, the Federal Circuit has not only required a motivation to combine references, but once combined, has asked whether a person of ordinary skill in the art would have a reasonable expectation of success. See *Dystar*, 464 F.3d at 1360. See also *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) (“Subsumed within the *Graham* factors is a subsidiary requirement articulated by this court that where, as here, all claim limitations are found in a number of prior art references, the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.”). The Federal Circuit has—post-*KSR*—reiterated the “reasonable expectation of success” prong. See *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) (holding patent-in-suit obvious because the prior art would have given rise to reasonable expectation of success for person having ordinary skill in the art).
5. **Hindsight and the Rationale of the TSM Test.** Just as historians caution us not to read history backward or to contemporize historical figures and decisions, so too with an obviousness determination. We must cast our minds back to the state of the art at the time the invention was made, and

prevent our current familiarity with the invention from biasing the § 103 analysis. The TSM test was created by the Federal Circuit and the Court of Customs and Patent Appeals to guard against the use of hindsight reasoning. The court views TSM as consistent with *Graham* and the Supreme Court's "recognition of 'the importance of guarding against hindsight.'" *Dystar*, 464 F.3d at 1361 (quoting *Graham*, 383 U.S. at 36). See *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (stating "the best defense against the subtle but powerful attraction of hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references").

But *KSR* viewed the hindsight rationale skeptically, criticizing the Federal Circuit for drawing "the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias." Interestingly, the Court did not elaborate a great deal on the hindsight issue even though it forms the basis for the TSM test. The Court simply wrote, "[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." *KSR* did not give the hindsight issue significant attention, or certainly, the attention it deserves. As noted above, the rationale for TSM was to guard against the 20-20 vision that accompanies hindsight. For interesting empirical studies relating to hindsight and obviousness determinations, see Lee Petherbridge & R. Polk Wagner, *The Federal Circuit and Patentability: An Empirical Assessment of the Law of Obviousness*, 85 TEX. L. REV. 2051 (2007); Christopher A. Cotropia, *Nonobviousness and the Federal Circuit: An Empirical Analysis of Recent Case Law*, 82 NOTRE DAME L. REV. 911 (2007); Gregory N. Mandel, *Patently Non-Obviousness: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1691 (2006); Gregory N. Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in KSR V. Teleflex*, 9 YALE J. L. & TECH. 1 (2007).

6. ***The Creative (and Resuscitated) PHOSITA***. As noted in the Comments following *Daichi*, the principal case in § C.2, of the criticisms commentators have levied against TSM, perhaps the most pronounced was the mechanical role assumed by the person having ordinary skill in the art. The *KSR* Court breathed new life into the PHOSITA, twice referring to the creativity of this skilled artisan. Recall, the Court stated a determination of obviousness should "take account of the inferences and creative steps that a person of ordinary skill in the art would employ," and that the "person of ordinary skill is also a person of ordinary creativity, not an automaton."

Indeed, two of the three appeals court errors identified by *KSR* related to the Federal Circuit's narrow conception of the skilled artisan. First, the Federal Circuit erred by focusing on the problem the patentee was trying to solve. The focus should not be on the patentee. Rather, the question is "whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." The second error was the Federal Circuit's assumption that a PHOSITA, confronted with a problem, will only consult the prior art designed to solve the same problem. According to the Court, "[c]ommon sense teaches . . . that

familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”

But the Court did not provide much guidance about how to construct the skilled artisan, and the Federal Circuit’s pronouncements in this regard are few and far between. Perhaps the appeals court will now devote more attention to this issue, given PHOSITA’s newfound star power.

7. **Obvious to Try.** The Federal Circuit has repeatedly held that “obvious to try” is not the standard under § 103. The court is concerned with a “shotgun” approach to invention without any guidance or indication from the prior art. As the court stated, in *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988):

“Obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. In others, what was “obvious to try” was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

See also Gillette Co. v. S.C. Johnson & Son, Inc., 919 F. 2d 720, 725 (Fed. Cir. 1990) (an obvious-to-try “situation exists when a general disclosure may pique the scientist’s curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued”).

Here, too, though, *KSR* held the Federal Circuit erred in rejecting the “obvious to try” standard because “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.”

It is not clear how much this approach differs from the Federal Circuit’s. *KSR* is concerned with “identified, predictable solutions” and “anticipated success.” The Federal Circuit is concerned with the prior art offering “guidance” and “direction” before obviousness is found. The Court’s mention of “design need and market pressure to solve a problem” seems similar to the secondary consideration “long-felt need.” That is, according to the Federal Circuit, the fact that there is a long-felt need in an industry and others in the industry have tried and failed to satisfy that need may imply nonobviousness. *See* Section D below and Comments following the principal case for a discussion of secondary considerations.

8. **A Greater Role for Expert Testimony and the PTO.** A more creative and nuanced PHOSITA may lead to a greater need for expert testimony because a court must construct the skilled artisan and judge obviousness through his eyes. Indeed, in *KSR*, the Court noted that in a summary

judgment context, “the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact.”

Moreover, the PTO, armed with a more flexible test, may have a greater and more challenging role. Because common knowledge of the PHOSITA (including inferences he would make), market demand, and demands known to the design community may be considered by the examiner, an already overburdened PTO will need to establish procedures to allow this type of evidence to be gathered. Indeed, *KSR* expressly stated, the obviousness “analysis should be made explicit,” citing *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006) (“To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.”). See also *In re Sang Su Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002) (stating the PTO’s “[c]onclusory statements” do not satisfy the agency’s obligation under the APA to provide a detailed explanation of its decision). While the district court has the ability to hear expert testimony, the examination process is an ex parte affair between the inventor and the examiner.” The PTO would have to exercise its rulemaking authority to accommodate the “expansive and flexible approach” to § 103. See *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004) (stating “the broadest of the [Patent] Office’s rulemaking powers is the power to ‘establish regulations, not inconsistent with law, which (A) shall govern the conduct of proceedings in the Office.’ 35 U.S.C. § 2(b)(2) (A) (2000). By this grant of power we understand Congress to have ‘delegated plenary authority over PTO practice, including interference proceedings,’ to the Office”). Cf. *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (stating although the PTO has rulemaking authority “to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO],’ the agency does not have substantive rulemaking authority”). Indeed, the agency’s obviousness guidelines, *supra* Comment 3, state that PTO “personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art.” *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 In View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57528 (October 10, 2007).).

COMPARATIVE PERSPECTIVE

Section 103’s European Counterpart — “Inventive Step”

The notion that something more than novelty is required for purposes of patentability is shared by several patent systems throughout the world. In Europe, it is called “inventive step,” and finds expression in Article 56 of the European Patent Convention:

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If

the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step.

The doctrines of nonobviousness and inventive step naturally have much in common, but there are also differences. Most notably, the Europeans and European Patent Office have adopted what is referred to as the “problem and solution approach” to Article 56. As Lionel Bently and Brad Sherman write:

[R]ather than asking whether an invention is obvious, the European Patent Office asks whether the solution that an invention provides to the problem being addressed would have been obvious to the person skilled in the art. In more positive terms, this means that for an invention to be patentable, the solution must *not* have been obvious to the person skilled in the art at the priority date of the invention in question.

LIONEL BENTLY & BRAD SHERMAN, *INTELLECTUAL PROPERTY LAW* 440-41 (Oxford 2001) (emphasis in original).

In § 3 of the U.K. Patent Act, “[a]n invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art.” The U.K. has developed a four-part obviousness test that resembles the U.S. approach:

The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being “known or used” and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.

Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59, 73-4. In *Haberman v. Jackal*, [1999] FSR 685, J. Laddie refined the analysis by adding several questions to the obviousness analysis, including (1) What was the problem which the patented development addressed; (2) How long had that problem existed; (3) How significant was the problem seen to be; and (4) How widely known was the problem and how many were likely to be seeking a solution. *Id.* at 699-701.

After *KSR*, the European problem and solution approach becomes problematic, because under *KSR* an applicant citing a problem opens himself up a § 103 rejection. Recall, the Court stated, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” During the European prosecution process, will applicants feel comfortable emphasizing the claimed invention solved a particular problem, knowing that the U.S. employs a broader scope of inquiry?

LEAPFROG ENTERPRISES, INC. v. FISHER-PRICE, INC.**485 F.3d 1157 (Fed. Cir. 2007)**

LOURIE, Circuit Judge.

Leapfrog Enterprises, Inc. (“Leapfrog”) appeals from the order of the United States District Court for the District of Delaware entering judgment of invalidity of claim 25 of Leapfrog’s U.S. Patent 5,813,861 (“the ’861 patent”) in favor of Fisher-Price, Inc. and Mattel, Inc. (collectively “Fisher-Price”). We affirm.

BACKGROUND

Leapfrog filed suit in October 2003, alleging that Fisher-Price’s Power-Touch product infringed claim 25 of the ’861 patent. Leapfrog amended the complaint to add Mattel, Inc. as a codefendant in September 2004. The ’861 patent relates to a learning device to help young children read phonetically. Claim 25 reads as follows:

An interactive learning device, comprising:

a housing including a plurality of switches;

a sound production device in communication with the switches and including a processor and a memory;

at least one depiction of a sequence of letters, each letter being associable with a switch; and

a reader configured to communicate the identity of the depiction to the processor, wherein selection of a depicted letter activates an associated switch to communicate with the processor, causing the sound production device to generate a signal corresponding to a sound associated with the selected letter, the sound being determined by a position of the letter in the sequence of letters.

’861 patent, col. 10 ll. 23-36.

In an April 7, 2005 Order, the trial court construed a number of terms from claim 25 of the patent. The court construed the phrase “selection of a depicted letter” to mean “choosing a particular depicted letter from the depicted sequence of letters by contacting or coming into proximity to that particular depicted letter.”

The accused PowerTouch device consists of a hinged plastic housing containing electronics and a speaker that opens to lie flat. When so opened, a user places a book made for use with the device in a rectangular recess in the housing. The books contain large, colorful pictures that also show words associated with the objects shown in those pictures. The user may select one of multiple modes of operation. In phonics mode, when the user touches one of the words on the page, the device pronounces the word, then pronounces each phoneme of the word in sequence, and finally pronounces the entire word again. The device relies on a grid of “crosspoints” located in the area underneath where the books are placed to detect the location on the page being touched by the user. The processor in the device may be programmed to associate a particular response with each crosspoint. Some of the words on the pages of the books are large enough that each letter of the word corresponds to a separate crosspoint. However, the phonics mode operates in the same manner for those words, with pronunciation of the word, the phonemes, and

the word again, regardless which letter the user touches because each letter has been associated with the same response in the device's programming.

The trial court issued its decision on March 30, 2006, finding claim 25 of the '861 patent . . . invalid as obvious. . . . The court concluded that claim 25 was invalid as obvious in view of the combination of U.S. Patent 3,748,748 to Bevan, the Texas Instruments Super Speak & Read ("SSR") device, and the knowledge of one of ordinary skill in the art as represented by the testimony of Fisher-Price's technical expert, Ronald Milner.

Leapfrog timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

B. Obviousness

"Obviousness is a question of law, reviewed de novo, based upon underlying factual questions which are reviewed for clear error following a bench trial." *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006).

Leapfrog argues that the district court engaged in improper hindsight in reaching its conclusion of obviousness by concluding that all of the limitations of the claim are found in the prior art. Leapfrog also argues that the court's finding that the Bevan device has the same functionality as claim 25 was clearly erroneous because the components of Bevan's device are mechanical, and thus different in structure and interrelation from the electronic components described in claim 25, and therefore cannot provide the same functionality. Leapfrog argues that there was inadequate evidence in the record to support a motivation to combine Bevan, the Texas Instruments SSR, and a reader to arrive at the invention of claim 25. Finally, Leapfrog argues that the district court did not properly consider the strong evidence of secondary considerations of nonobviousness.

In response, Fisher-Price argues that claim 25 is nothing more than the Bevan device, a toy that teaches reading based on the association of letters with their phonemic sounds, updated with modern electronics that were common by the time of the alleged invention. Fisher-Price also responds that particularized and specific motivations to combine need not be found in the prior art references themselves in the context of an improvement that arises from a desire to generally improve a known device (*e.g.*, to make the product smaller, lighter, or less expensive) using newer technology. Finally, Fisher-Price argues that the district court did give proper consideration to secondary considerations of nonobviousness, but simply concluded that those considerations were not sufficient to overcome the determination of obviousness based on primary considerations.

We agree with Fisher-Price that the district court correctly concluded that the subject matter of claim 25 of the '861 patent would have been obvious in view of the combination of Bevan, the SSR, and the knowledge of one of ordinary skill in the art. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. *See*

KSR Int'l Co. v. Teleflex Inc. (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). Thus, we bear in mind that the goal of the claim 25 device was to allow a child to press a switch associated with a single letter in a word and hear the sound of the letter as it is used in that word. In this way, the child would both associate the sound of the letter with the letter itself and be able to sound out the word one letter at a time to learn to read phonetically. Accommodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children’s learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years.

The Bevan patent was one of the pieces of prior art relied upon by the district court, and it describes an electro-mechanical learning toy. In the preferred embodiment of the Bevan device, a housing contains a phonograph record as a voice storage means, a speaker for playing sounds from the voice storage means, and an actuated electric motor to turn the record. Uniquely shaped puzzle pieces fit into correspondingly shaped openings in the top of the housing. Depressing the puzzle pieces in the openings causes the motor to turn the record and brings phonographic needles into contact with the portions of the record where the sounds associated with the puzzle pieces are stored so that they can be played through the speaker. In one embodiment, each puzzle piece is imprinted with one letter from a word, and pressing each puzzle piece produces the sound of a single letter in that word. Thus, although it relies on an electric motor and mechanical structures rather than a processor and related electronics, Bevan teaches an apparatus that achieves the goals described above of associating letters with their sounds and encouraging children to sound out words phonetically through a similar type of interaction. We therefore see no clear error in the district court’s finding that the Bevan device has the same method of operation, viewed as a whole, as claim 25 of Leapfrog’s ’861 patent.

A second piece of prior art relied upon by the district court was the Texas Instruments SSR. The SSR is a more modern type of prior art learning toy, constructed with electronic components, that has a slightly different mode of operation than Bevan. The SSR has a hinged plastic housing that opens to lie flat. Books for use with the toy fit into a recess in the housing. The housing contains switches that can detect when a child presses on different areas of the books’ pages. The housing also contains a processor, memory, and a speaker to produce sounds. In one mode of operation, the SSR allows the child to press the first letter of a word and hear the sound of that letter. The remainder of the letters in the word are grouped together and played together. For example, the child can press the letter “t” and hear the t phoneme and then press “ug” to hear all the sounds in the word “tug.” Similarly, the child can press the letter “b” and then “ug” to hear the sounds in “bug.” The SSR does not include a reader that allows the processor to automatically identify the inserted book. Instead, the user can press a triangle printed on the first page of the book, and the processor determines from the location of the triangle printed on the page which book is inserted. Similarly, the user can press a star on each page of the book, and the processor determines from the location of the star on the page which page of the book is being viewed. Thus, the SSR

provides a roadmap for one of ordinary skill in the art desiring to produce an electronics-based learning toy for children that allows the use of phonetic-based learning methods, including the association of individual letters with their phonemes.

We agree with the district court that one of ordinary skill in the art of children's learning toys would have found it obvious to combine the Bevan device with the SSR to update it using modern electronic components in order to gain the commonly understood benefits of such adaptation, such as decreased size, increased reliability, simplified operation, and reduced cost. While the SSR only permits generation of a sound corresponding to the first letter of a word, it does so using electronic means. The combination is thus the adaptation of an old idea or invention (Bevan) using newer technology that is commonly available and understood in the art (the SSR). We therefore also find no clear error in the finding of the district court that one of ordinary skill in the art could have utilized the electronics of the SSR device, with the method of operation taught by Bevan, to allow a child to press each individual letter in a word and hear the individual phonemes associated with each letter to sound out the words.

This combination of Bevan and the SSR lacks only the "reader" of claim 25 of the '861 patent. The district court found that readers were well-known in the art at the time of the invention. As there is ample evidence in the record to support that finding, we find no clear error in the court's determination. Furthermore, the reasons for adding a reader to the Bevan/SSR combination are the same as those for using readers in other children's toys — namely, providing an added benefit and simplified use of the toy for the child in order to increase its marketability. Leapfrog presents no evidence that the inclusion of a reader in this type of device was uniquely challenging or difficult for one of ordinary skill in the art. *See KSR*. Nor does Leapfrog present any evidence that the inclusion of a device commonly used in the field of electronics (a reader), and even in the narrower art of electronic children's toys, represented an unobvious step over the prior art. Our conclusion is further reinforced by testimony from the sole inventor at trial that he did not have a technical background, could not have actually built the prototype himself, and relied on the assistance of an electrical engineer and Sandia National Laboratory to build a prototype of his invention. . . .

In light of our review of the evidence and the lack of any clear error in the district court's factual findings, we agree with the district court's conclusion that claim 25 of the '861 is invalid as obvious in view of the combination of Bevan, the SSR device, and the knowledge of one of ordinary skill in the art concerning readers.

Comments

1. **Application of KSR.** The common sense of the skilled artisan was an important factor in *Leapfrog* and a direct result of *KSR*. Moreover, the court stressed the flexibility of the obviousness test. Citing *KSR* the Federal Circuit stated, "[a]n obviousness determination is not the result of a rigid

formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not.” This statement is a continuation of the theme stressed in *Dystar*. See 464 F.3d at 1367 (stating “[o]ur suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense”) (emphasis in original).

In *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1363 (Fed. Cir. 2007), the Federal Circuit, relying on *KSR*, reversed the district court’s finding of nonobviousness because the “inventors merely used routine research methods to prove what was already believed to be the case.” The court wrote:

While the inventors may have proved conclusively what was strongly suspected before—that umbilical cord blood is capable of hematopoietic reconstitution—and while their work may have significantly advanced the state of the science of hematopoietic transplantations by eliminating any doubt as to the presence of stem cells in cord blood, the mouse experiments and the conclusions drawn from them were not inventive in nature. Instead, the inventors merely used routine research methods to prove what was already believed to be the case. Scientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention. See *KSR*, 127 S. Ct. at 1732 (“Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress. . . .”)

2. **The Patentee’s “Burden.”** One of the lessons of *Leapfrog* is that the patentee should be prepared to present expert testimony on nonobviousness. The Bevan/SSR combination was missing only the “reader” limitation of claim 25. In the face of “ample evidence” that a reader was well-known in the art, and why a reader has special applicability to the claimed invention, Leapfrog did not present “any evidence that the inclusion of a device commonly used in the field of electronics (a reader), and even in the narrower art of electronic children’s toys, represented an unobvious step over the prior art.”

POLICY PERSPECTIVE *Using § 103 as a Policy Tool*

Within the parameters established by § 103, there resides a significant subjective component. As the *Graham* Court observed, “[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context.” This subjectivity, however, allows § 103 to be used as a policy instrument to further the constitutional goal of promoting the progress of the useful arts. In this regard, the nonobviousness inquiry can be viewed as serving a “gatekeeper function,” suggesting

§ 103 has a policy richness that is absent from § 102 and many other Title 35 statutory sections.

Some commentators see in § 103 fertile ground to further important functions of the patent system based on costs and uncertainty of invention. For instance, in an influential article, Edmund Kitch — concerned about over-rewarding inventive activity — suggested § 103 should reward patents for those innovations that would not have been developed “absent the protection of a patent.” See Edmund W. Kitch, *Graham v. John Deere: New Standards for Patents*, 1966 SUP. CT. REV. 293, 301. Kitch is concerned with costs of invention, but lack of invention is not only a function of high costs, but also lack of value in the invented item. Once the market signals value, the idea in waiting may “be discovered more or less simultaneously by a number of those who can exploit it.” WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 304 (2003). In addition (and related) to costs, uncertainty plays an important role in invention, particularly if tackling uncertainty is a costly endeavor. Robert Merges, whose work builds on Kitch’s insights, has argued that the nonobviousness requirement should act “as a legal rule that influences behavior” and “encourage[] researchers to pursue projects whose success appears highly uncertain at the outset.” See Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 BERKELEY HIGH TECH. L.J. 1, 2 (1992). See also Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 609, 610-14 (1962). Thus, Merges views § 103 as a tool to focus on those inventors who need the inducement of the patent system the most — to develop and disclose innovations whose success is rife with early-stage uncertainty. As Landes and Posner note, “[u]ncertainty implies the likelihood of failure en route to success. Those failures are costly, and since the costs are incurred before the successful invention can be patented and marketed, they are additional costs that the inventor must recover in the revenues generated by his patent.” LANDES & POSNER, *ECONOMIC STRUCTURE*, *supra* at 304.

Lastly, Dan Burk and Mark Lemley have advocated using the flexibility inherent in constructing the level of skill in the art possessed by a PHOSITA as a “policy lever” to tailor § 103 (and other statutory sections) to the needs of divergent industries. See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1648-52 (2003). It is indeed somewhat surprising that there very few judicial opinions that offer a detailed analysis of level of ordinary skill in the art, but this may all change in the light of *KSR*.

2. Constructing the Person Having Ordinary Skill in the Art

The person having ordinary skill in art is one of the cynosures of the American patent system and is valued, particularly after *KSR*, for his knowledge of his technical field and the underlying assumptions and technical problems present in his technological community. How the PHOSITA is constructed and his level of skill in the art as determined by the court can greatly affect

validity determinations and, as noted in the prior *Perspective* — *Using § 103 as a Policy Tool* — can be a valuable policy tool for courts.

DAIICHI SANKYO CO., LTD. v. APOTEX, INC.

84 U.S.P.Q.2d 1285 (Fed. Cir. 2007)

ARCHER, Senior Circuit Judge.

Apotex, Inc. and Apotex Corp. (collectively “Apotex”) appeal the judgment of the United States District Court for the District of New Jersey that Apotex infringes U.S. Pat. No. 5,401,741 (“the ’741 patent”) and that the ’741 patent is not invalid. Because the invention of the ’741 patent would have been obvious in view of the prior art, we reverse.

I

The ’741 patent is drawn to a method for treating bacterial ear infections by topically administering the antibiotic ofloxacin into the ear. Claim 1 is representative and states “[a] method for treating otopathy which comprises the topical otic administration of an amount of ofloxacin or a salt thereof effective to treat otopathy in a pharmaceutically acceptable carrier to the area affected with otopathy.” ’741 Patent, col. 6 ll. 36-39.

Apotex [sought] approval to manufacture a generic ofloxacin ear drop [by filing an Abbreviated New Drug Application or ANDA]. Following receipt of the ANDA, Daiichi, owner of the ’741 patent, sued Apotex for infringement. [F]ollowing a bench trial, the court concluded that the ’741 patent was not invalid. . . . Apotex appeals, and we have jurisdiction pursuant to 28 U.S.C. 1295(a)(1).

II

Obviousness is a question of law based on underlying questions of fact. Thus, we review the ultimate determination of obviousness by a district court *de novo* and the underlying factual inquiries for clear error.

The underlying factual inquiries in an obviousness analysis include: “(1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness.” *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999). In this case, we begin our analysis with the question of the level of ordinary skill in the prior art.

The district court concluded that the ordinary person skilled in the art pertaining to the ’741 patent “would have a medical degree, experience treating patients with ear infections, and knowledge of the pharmacology and use of antibiotics. This person would be . . . a pediatrician or general practitioner — those doctors who are often the ‘first line of defense’ in treating ear infections and who, by virtue of their medical training, possess basic pharmacological knowledge.” *Daiichi Pharm. Co. v. Apotex, Inc.*, 380 F. Supp. 2d 478, 485 (D.N.J. 2005) (“Claim Construction Order”). Apotex argues that the district court clearly erred in this determination and that one having ordinary skill in the relevant art is properly defined as “a person engaged in developing new pharmaceuticals, formulations and treatment methods, or a specialist in

ear treatments such as an otologist, otolaryngologist, or otorhinolaryngologist who also has training in pharmaceutical formulations.”

“Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Envntl. Designs, Ltd. v. Union Oil Co.*, 713 F. 2d 693, 696 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.3d 1376, 1381-82 (Fed. Cir. 1983)). These factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art.

In making its determination regarding the level of skill in the art, the district court noted that the parties had provided “little more than conclusory arguments concerning this issue in their briefs.” As a result, the court looked to other decisions involving patents for a method of treating a physical condition for guidance. Only one case cited by the district court is binding on us, *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 347 F.3d 1367 (Fed. Cir. 2003). The district court was correct that in that case we affirmed the trial court’s conclusion that a person having ordinary skill in the relevant art was a person having a medical degree, experience treating patients with osteoporosis, and knowledge of the pharmacology and usage of biphosphonates—the compounds at issue in *Merck*. However, in *Merck* the level of skill in the art was not disputed by the parties. Thus, we simply accepted the district court’s finding. That clearly is not the case before us. Therefore, the district court’s reliance on the level of skill in the art stated in *Merck* was improper.

The art involved in the ’741 patent is the creation of a compound to treat ear infections without damaging a patient’s hearing. The inventors of the ’741 patent were specialists in drug and ear treatments—not general practitioners or pediatricians. At the time of the invention, Inventor Sato was a university professor specializing in otorhinolaryngology; Inventor Handa was a clinical development department manager at Daiichi, where he was involved with new drug development and clinical trials; and Inventor Kitahara was a research scientist at Daiichi engaged in the research and development of antibiotics. Additionally, others working in the same field as the inventors of the ’741 patent were of the same skill level. See Daiichi Material for [C]onference on Development, Nov. 11, 1987 (stating that “there are many voices among medical persons concerned with otorhinolaryngology for demanding development of an otic solution making use of [ofloxacin]”).

Further, the problem the invention of the ’741 patent was trying to solve was to create a topical antibiotic compound to treat ear infections (otopathy) that did not have damage to the ear as a side effect. ’741 Patent, col. 1 ll. 23-34. Indeed, most of the written description details the inventors’ testing ofloxacin on guinea pigs and their findings that ototoxicity did not result from the use of their compound. Such animal testing is traditionally outside the realm of a general practitioner or pediatrician. Finally, while a general practitioner or pediatrician could (and would) prescribe the invention of the ’741 patent to treat ear infections, he would not have the training or knowledge to develop the claimed compound absent some specialty training such as that possessed by the ’741 patent’s inventors. Accordingly, the level of ordinary skill in the art of the ’741 patent is that of a person engaged in devel-

oping pharmaceutical formulations and treatment methods for the ear or a specialist in ear treatments such as an otologist, otolaryngologist, or otorhinolaryngologist who also has training in pharmaceutical formulations. Thus, the district court clearly erred in finding otherwise.

Comments

1. **Level of Skill Matters.** In *Daiichi*, the level of ordinary skill in the art was determinative on the issue of obviousness. According to the court, the PHOSITA was not a pediatrician or general practitioner as the district court found, but rather, “a person engaged in developing pharmaceutical formulations and treatment methods for the ear or a specialist in ear treatments such as an otologist, otolaryngologist, or otorhinolaryngologist who also has training in pharmaceutical formulations.” The court cited the six *Environmental Designs* factors used for measuring level of skill in the art, but of those six, emphasized the inventors’ level of skill in the art as well as others working in the field and the problem the ’741 patent addressed. As the next Comment reveals, whether it was proper to rely so heavily on the inventors’ skill level is questionable.
2. **PHOSITA’s New Lease on Life.** Prior to the Supreme Court’s decision in *KSR v. Teleflex* decision, the Federal Circuit adopted what has been characterized as a mechanical application of the PHOSITA, relegating the artisan to a relatively unimportant and unimaginative player in the patent system. The PHOSITA, according to the Federal Circuit, is “presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights, it makes no difference which.” *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). The Federal Circuit has noted that a PHOSITA is not the inventor or any particular expert or handyman, but rather a hypothetical person, which renders immaterial the subjective motivations of inventors. See *Kimberly-Clark Corp. v. Johnson & Johnson, Co.*, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (“The inventor, for purposes of legal reasoning, has been replaced, as some courts have discovered, by the statutory hypothetical “person of ordinary skill in the art” who has been provided by 35 U.S.C. § 103. Since that date, there has been no need to presume that the inventor knows anything about the prior art.”).

This construction of the PHOSITA has been criticized by commentators. As Rebecca Eisenberg states, the Federal Circuit:

has all but ignored the statutory directive that judgments of nonobviousness be made from the perspective of PHOSITA. Today, PHOSITA sits on the sidelines of obviousness analysis. Courts consult PHOSITA on the scope, content and meaning of prior art references but not on the ultimate question of whether the invention would have been obvious at the time it was made in light of the prior art. The resulting analysis excludes from consideration the judgment, intuition and tacit knowledge of ordinary practitioners in the field that cannot be documented in the written record. The written record understates the technological know-how that active practitioners bring to bear

upon a problem, particularly in fields of industrial technology that offer few incentives to publish.

Rebecca A. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 888 (2004). *See also* ROGER SCHECHTER & JOHN R. THOMAS, *PRINCIPLES OF PATENT LAW* 161 (2d ed. 2004) (stating “[i]n most fields, practitioners are seldom such dullards as to require detailed step-by-step instructions to accomplish basic tasks. Yet here, and in other cases, the Federal Circuit seems to state that an invention would not have been obvious unless its precise recipe existed in the prior art.”).

The Supreme Court, in *KSR*, rejected the Federal Circuit’s view of the PHOSITA and breathed new life into the skilled artisan. The Court stated a determination of obviousness should “take account of the inferences and creative steps that a person of ordinary skill in the art would employ,” and that the “person of ordinary skill is also a person of ordinary creativity, not an automaton.” A prominent role for the PHOSITA is understandable given that a § 103 obviousness determination is a question of law, based on whether a person having ordinary skill in the art, to which the claimed invention pertains, would have found the claimed invention obvious. Thus, constructing a PHOSITA is of crucial importance; indeed, this artisan of ordinary skill is one of the cynosures of the patent system, playing a prominent role in determining not only obviousness, but, for example, sufficiency of disclosure and claim interpretation.

3. ***The Artisan Abroad.*** The skilled artisan is also a central feature of the U.K.’s obviousness analysis. Section 3 of the U.K. Patent Act states: “An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art.” In the well-known *Windsurfing* case, the Court of Appeals elaborated on the role of the skilled artisan by noting that the question of inventive step:

has to be answered, not by looking with the benefit of hindsight at what is known now and what was known at the priority date and asking whether the former flows naturally and obviously from the latter, but by hypothesizing what would have been obvious at the priority date to a person skilled in the art to which the patent in suit relates, who is assumed to have access to what was known of the art in the United Kingdom immediately before the priority date.

The hypothetical Skilled Man is, no doubt, (together with his cousins the Reasonable Man and the Officious Bystander) a useful concept as setting a standard and, in the instant case, as providing the touchstone by which the question of obviousness may be judged by the equally hypothetical Juror; but he must not be allowed to obscure the nature of the inquiry which the words of the statute require, and one cannot help feeling that his image may lead to confusion if one seeks to attribute to him human qualities either of constitutional idleness or of perception beyond the knowledge and skill in the field in which he is hypothetically supposed to operate. It is accepted by the appellants that the question of whether the alleged invention was obvious has to be answered objectively by reference to whether, at the material time (that is, immediately, prior to the priority date), the allegedly inventive step or concept would have been obvious to a skilled addressee.

Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59, 71.

3. Available Prior Art and the Analogous Art Doctrine

Only “analogous” prior art can be used for a § 103 inquiry. Unlike § 102, which does not have an analogous art component, the courts have required art for an obviousness inquiry to come from “the same field of endeavor” as the claimed invention or be “reasonably pertinent to the particular problem with which the inventor is involved.” The latter prong of the analogous arts doctrine has arguably been broadened by *KSR*, a point we take up in the Comments after *Icon Health*.

IN RE ICON HEALTH AND FITNESS, INC.

496 F.3d 1374 (Fed. Cir. 2007)

PROST, Circuit Judge.

ICON Health & Fitness, Inc. (“Icon”) appeals from a decision by the Board of Patent Appeals and Interferences (“Board”) during reexamination of Icon’s U.S. Patent No. 5,676,624 (“the ’624 patent”). Finding no error in the Board’s decision, we affirm its decision holding Icon’s claims unpatentable as obvious.

BACKGROUND

Icon owns the ’624 patent, issued October 14, 1997, and sought reexamination by the Patent and Trademark Office (“PTO”). The ’624 patent claims a treadmill with a folding base, allowing the base to swivel into an upright storage position. Claim 1, from which all other claims on appeal depend, recites:

1. A treadmill comprising:

a gas spring connected between the tread base and the upright structure to assist in stably retaining said tread base in said second position relative to said upright structure with said tread base in said second position.

(emphasis added).

The present dispute involves only the final limitation, requiring a gas spring “to assist in stably retaining” the tread base in the upright position. On reexamination, the examiner rejected Icon’s claims as obvious under 35 U.S.C. § 103, based on the combination of an advertisement by Damark International, Inc. (“Damark”) and U.S. Patent No. 4,370,766 to Teague, Jr. (“Teague”).

Damark consists of an advertisement for a folding treadmill; Icon does not challenge the Board’s finding that Damark demonstrates all claim elements other than the gas spring. The present inquiry, therefore, focuses on Teague’s disclosure of gas springs and the applicability of Teague to Icon’s invention. Teague describes a bed that folds up into a cabinet or recess. It purports to improve on prior art counterbalancing mechanisms by using a novel dual-action spring rather than the prior single-action springs. Single-action springs

provide a force pushing the bed closed at all times. Teague's dual-action spring, on the other hand, reverses its force as the mechanism passes a neutral position; the neutral position in Teague occurs when the center of gravity of the bed aligns vertically with the pivot point. As the bed moves past the neutral position to the closed position, the mechanism opposes continued motion. The bed moves into the closed position under the pull of gravity. When fully closed, therefore, the mechanism in Teague provides an opening force, but not one sufficient to counteract the force of gravity. Essentially, Teague's dual-action spring partially supports the weight of the bed in both the closed and open positions. This provides the benefit of reducing the force required to open the bed from the closed position, while still reducing the force required to lift the bed from the open position.

The Board affirmed the examiner's determination that the combination of Teague and Damark rendered claim 1 obvious. First, the Board rejected Icon's argument that Teague does not provide analogous art. Specifically, because Teague and the current application both address the need to stably retain a folding mechanism, the Board found Teague reasonably pertinent to the current application. Further, it found that discussion of a lifting force in the present application paralleled Teague's mechanism for creating a lifting force.

DISCUSSION

Although based on determinations of underlying facts, which we review for substantial evidence, the ultimate conclusion of obviousness is a legal question, which we review de novo. Underlying facts include the scope and content of the prior art, the level of ordinary skill in the art at the time of the invention, objective evidence of nonobviousness, and differences between the prior art and the claimed subject matter. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). The Board's determination that a prior art reference is analogous art also presents an issue of fact, reviewed for substantial evidence.

II

A

Icon disputes the Board's conclusion that one skilled in the art would have found it obvious to combine the teachings of Teague and Damark. As the first of its two major arguments on appeal, Icon argues that Teague falls outside the "treadmill art" and addresses a different problem than the present application, removing it from the relevant prior art. We agree that, describing a folding bed, Teague comes from a different field than Icon's application. We disagree, however, that Teague addresses a different problem.

If reasonably pertinent to the problem addressed by Icon, Teague may serve as analogous art. *Paulsen*, 30 F.3d at 1481. "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F. 2d 656, 659 (Fed. Cir. 1992). In other words, "familiar items may have obvious uses beyond their primary purposes." *KSR Int'l Co. v. Teleflex, Inc.*, — U.S. —, —, 127 S. Ct. 1727, 1742. We there-

fore have concluded, for example, that an inventor considering a hinge and latch mechanism for portable computers would naturally look to references employing other “housings, hinges, latches, springs, etc.,” which in that case came from areas such as “a desktop telephone directory, a piano lid, a kitchen cabinet, a washing machine cabinet, a wooden furniture cabinet, or a two-part housing for storing audio cassettes.” *Paulsen*, 30 F.3d at 1481-82.

Icon’s invention provides a treadmill with a folding mechanism and a means for retaining that mechanism in the folded position. The application specifically discusses the gas spring as part of a “lift assistance assembly . . . to apply a force or torque urging the tread base” towards the closed position. 624 patent, col. 15, ll. 3-5. Nothing about Icon’s folding mechanism requires any particular focus on treadmills; it generally addresses problems of supporting the weight of such a mechanism and providing a stable resting position. Analogous art to Icon’s application, when considering the folding mechanism and gas spring limitation, may come from any area describing hinges, springs, latches, counterweights, or other similar mechanisms—such as the folding bed in *Teague*. Accordingly, we conclude that substantial evidence supports the Board’s finding that *Teague* provides analogous art.

B

Several factors support the Board’s conclusion of obviousness. When analyzing Icon’s application, we consider a variety of sources that may have led one skilled in the art to combine the teachings of *Damark* and *Teague*. Indeed, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 127 S. Ct. at 1742.

First, *Teague* discusses prior art, single-action coil springs that always push the bed towards the closed position. As *Teague* recites, in those beds, “the coil springs also exert forces holding the bed in the fully closed position.” *Teague*, col. 1, ll. 51-55. Such springs, in this application, would produce a force always urging the tread base towards the closed position—exactly the type of mechanism that Icon argues its claims require. While the passage concerns coil springs rather than gas springs, *Teague* explicitly discusses the interchangeability of gas springs and coil springs. *Teague*, col. 3, ll. 61-65. Therefore, *Teague* provides an example of a mechanism clearly satisfying Icon’s claim limitation.

Next, Icon’s application discusses the gas spring in connection with a “lift assistance assembly.” ’624 patent, col. 15, ll. 3-25. Similarly, *Teague* is directed at a “counterbalancing mechanism,” intended to support the weight of a bed as it opens and closes. *Teague*, col. 1, ll. 5-34. One skilled in the art would naturally look to prior art addressing the same problem as the invention at hand, and in this case would find an appropriate solution. Indeed, while perhaps not dispositive of the issue, the finding that *Teague*, by addressing a similar problem, provides analogous art to Icon’s application goes a long way towards demonstrating a reason to combine the two references. Because Icon’s broad claims read on embodiments addressing that problem as described by *Teague*, the prior art here indicates a reason to incorporate its teachings.

Finally, *Teague* provides a mechanism such that the bed “has two stable rest positions.” *Teague*, col. 1, ll. 35-38. It describes, “as the center of gravity of the

bed passes over the pivot axis . . . gravity tends to hold the bed in its fully closed position.” Teague, col. 1, ll. 47-51. When folding the treadmill described in Icon’s application, “[t]he tread base 434 is rotated until the center of gravity 440 is displaced clockwise past the vertical 446 a distance 448 selected to stably retain the tread base 434 in the second position.” ’624 patent, col. 12, ll. 29-32. The striking similarity between Icon’s application and Teague clearly illustrates the similarity of problems they address and solutions to that problem, further supporting the idea that one skilled in the art would combine Teague with Damark.

The aforementioned connections between Teague and Icon’s application provide a sufficient basis to conclude that one skilled in the art would combine the teachings of Teague and Damark. . . .

Comments

1. **KSR and the Analogous Arts Doctrine.** Under Federal Circuit law, there are two distinct tests for defining the scope of analogous art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004) (finding toothbrush art analogous to Bigio’s hairbrush).

In *KSR*, the Supreme Court expressly stated the Federal Circuit erred “by holding that courts and patent examiners should look only to the problem the patentee was trying to solve.” According to the Court, the Federal Circuit “failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent’s subject matter.” Are these statements consistent with the analogous art doctrine expressed in *In re Bigio*, above? It is arguable that *KSR* expanded the scope of the analogous arts doctrine. In *Icon Health*, the principal case, the court, quoting *KSR*, stated “familiar items may have obvious uses beyond their primary purposes,” and that “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 127 S. Ct. at 1742. And the PTO’s obviousness guidelines—citing *KSR*—provide, “prior art that is in a field of endeavor other than that of the applicant, or solves a problem which is different from that which the applicant was trying to solve, may also be considered for the purposes of 35 U.S.C. 103.” *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57527-8 (October 10, 2007).

But even prior to *KSR*, the Federal Circuit noted, “[a] reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his problem.” *In re Clay*, 966 F. 2d 656, 659 (Fed. Cir. 1992). In short, “familiar items may have obvious uses beyond their primary purposes.” *KSR*, 127 S. Ct. at 1742. For example, *In re Paulsen*, 30 F.3d 1475 (Fed. Cir. 1994), cited by *Icon Health*, involved prior art that was not within the same field of endeavor of the claimed invention. In *Paulsen*, the patent related to a portable computer contained within a compact metal

case. An important feature of the invention was the “claim shell” design. This configuration connected the display of the computer to the computer’s midsection by a hinge assembly, which in turn allowed for the display to move from a closed position to an open position. In other words, the patent claimed the design of a “laptop” computer. During a reexamination, the PTO rejected the claims under § 103 in the light of references directed to hinges and latches as used in a desktop telephone directory, a piano lid, a kitchen cabinet, a washing machine cabinet, a wooden furniture cabinet, or a two-part housing for storing audiocassettes. The Federal Circuit, in affirming the PTO, rejected the applicant’s argument that the prior art was non-analogous. The court agreed that the prior art was not in the same field of endeavor as computers, but the “problems encountered by the inventors of the ’456 patent were problems that were not unique to portable computers.” *Id.* at 1482.

They concerned how to connect and secure the computer’s display housing to the computer while meeting certain size constraints and functional requirements. The prior art cited by the examiner discloses various means of connecting a cover (or lid) to a device so that the cover is free to swing radially along the connection axis, as well as means of securing the cover in an open or closed position. We agree with the Board that given the nature of the problems confronted by the inventors, one of ordinary skill in the art “would have consulted the mechanical arts for housings, hinges, latches, springs, etc.”

Id.

2. **What Constitutes Prior Art Under § 103?** Section 103 refers to the differences between the claimed invention and the “prior art.” The source of prior art for § 103 purposes comes from § 102. This sounds confusing, but think of § 102 as having a dual function, defining both (1) novelty (as well as priority and statutory bars) and (2) what constitutes prior art. Regarding the former, both §§ 102 and 103 can be seen as guarding the public domain, but § 103 is more aggressive, preventing a patent from issuing on “concepts within the public grasp, or so obvious that they readily could be.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989).

Regarding the latter, § 102(a) prior art comprises patents and printed publications anywhere in the world, and public knowledge and use in the United States. (Of course, to constitute *prior* art, this information must be available before the date of invention.) Once identified, prior art can be used to defeat novelty under § 102 or be used to prove obviousness under § 103. A considerable majority of prior art used for obviousness is based on § 102(a). See *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1305 (Fed. Cir. 2006) (“‘Prior art’ in the obviousness context includes the material identified in section 102(a).”); *In re Mulder*, 716 F. 2d 1542, 1545 (Fed. Cir. 1983) (“[P]rinted publication . . . is prior art under [section] 102(a), . . . , and thus also ‘prior art’ under [section] 103.”). Prior art and activity under the § 102 (b) on-sale and public-use bars and § 102(e) patent disclosures and (g) inventive activity can also serve as prior art for purposes of obviousness under § 103. See *LaBounty Mfg. v. Int’l Trade Comm’n*, 958 F.2d 1066, 1071 (Fed. Cir. 1992) (“Section 102(b) may create a bar to patentability . . . in conjunction with [§ 103], if the claimed invention would have been obvious from the on-sale device in conjunction with the prior art.”); *Netscape*

Communications Corp. v. Konrad, 295 F.3d 1315, 1321 (Fed. Cir. 2002) (stating a “device used in public includes every limitation of the later claimed invention, or by obviousness if the differences between the claimed invention and the device used would have been obvious to one of ordinary skill in the art”); *Hazeltine Research, Inc. v. Brenner*, 382 U.S. 252 (1965) (§§ 102(e)/103); *In re Bass*, 474 F.2d 1276 (CCPA 1973) (§§ 102(g)/103).

3. **Differences Between § 102 and § 103.** You may recall there is no analogous arts doctrine for the novelty requirement. Any single prior art reference that discloses each limitation of the claimed invention is sufficient under the novelty inquiry. What is different about section 103? Because 103 references by definition do not disclose each limitation and can be combined, it becomes more difficult for inventors through searching to fully appreciate the full scope of the prior art. Thus, patent law requires the art to be “analogous” to ease the inventor’s burden. Thus, the analogous arts doctrine “more closely approximates the reality of the circumstances surrounding the making of an invention by only presuming knowledge by the inventor of prior art in the field of his endeavor and in analogous arts.” *In re Wood*, 599 F. 2d 1032, 1036 (CCPA 1979).

D. SECONDARY CONSIDERATIONS

Recall in *Graham*, the Supreme Court stated “[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” 383 U.S. at 17-18. Among these considerations, commercial success is the most commonly asserted, but, as the *Iron Grip* case reveals, all of them are relevant to a nonobviousness determination.

IRON GRIP BARBELL COMPANY, INC. v. USA SPORTS, INC.

392 F.3d 1317 (Fed. Cir. 2004)

DYK, Circuit Judge.

Iron Grip Barbell Company (“Iron Grip”) appeals from the judgment of the United States District Court for the Central District of California. The district court found claims 1 to 3 and 6 to 8 of Iron Grip’s patent, U.S. Patent No. 6,436,015 (“the ’015 patent”), to be invalid as obvious. We affirm.

BACKGROUND

Iron Grip is a manufacturer of weight plates used with fitness equipment such as barbells and is the assignee of the ’015 patent. Claim 1 of the ’015 patent claims:

A weight plate for physical fitness including: a plate body formed with a central throughbore and . . . further *formed with solely a triad of spaced apart elongated*

handle openings disposed generally equiangularly . . . , said openings having respective outboard edges cooperating with said plate *to define a triad of integral handle elements for grasping* by a single hand to effect transport of said weight plate.

Id. col. 4, ll. 24-35 (emphasis added).

Typically, a barbell consists of a rigid bar and removable weight plates attached on both ends. Traditional weight plates had a single hole in the center for attachment to the barbell. A key problem with traditional single-hole weight plates was that they were difficult to grasp and transport. Iron Grip's '015 patent addresses this defect of traditional weight plates by disclosing a weight plate with three elongated openings near the periphery of the plate that function effectively as handles.

During the prosecution of the '015 patent, Iron Grip disclosed prior art showing, *inter alia*, weight plates with one elongated grip, U.S. Patent No. 4,199,140 ("the '140 patent"), and two elongated grips, U.S. Patent No. 5,137,502 ("the '502 patent"). The examiner further considered other prior art including barbell weight plates with four openings. U.S. Patent No. 4,618,142. After multiple rejections on grounds of obviousness, the '015 patent eventually issued on Aug. 20, 2002.

USA Sports, Inc. ("USA Sports") is a competing manufacturer of weight plates. It also manufactures a three-grip plate. In May of 2002, Iron Grip sued USA Sports in the district court for infringement of an unrelated patent, and subsequently amended its complaint to state an action for infringement of claims 1-3 and 6-8 of the '015 patent. USA Sports defended on the basis that the asserted claims in the '015 patent were invalid as obvious in light of the prior art. . . . Upon motion for reconsideration, the district court held that the contested claims in the '015 patent were obvious. The district court held that "it would have been obvious to a layman to combine the prior art," and invalidated claims 1-3 and 6-8 of the '015 patent. Iron Grip appeals.

* * *

In determining obviousness, we employ the four-part test set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). This test requires us to examine (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) the objective evidence of nonobviousness. *Id.*

[T]he issue of the '015 patent's obviousness arises because the prior art showed one, two and four elongated handles on weight plates. A single elongated handle on a weight plate was disclosed by the '140 patent. Two elongated handles on a weight plate was disclosed by the '502 patent. Four elongated handles on a weight plate was disclosed by U.S. Design Patent No. 406, 183 ("the '183 patent"). Reproductions of the two and four grip weight plates in the prior art, and Iron Grip's three-grip weight plate, appear below.

DISCUSSION

I

[The court applied the first three *Graham* factors and held that] [b]ecause the claimed invention falls within a range disclosed in the prior art, and the patentee has not shown that the prior art taught away from the invention or new

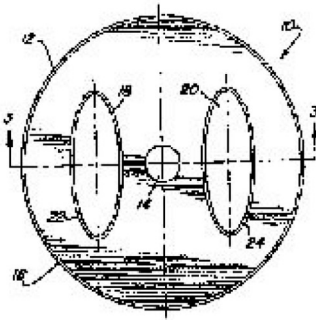


Fig. 1. The '502 patent's two-grip plate.

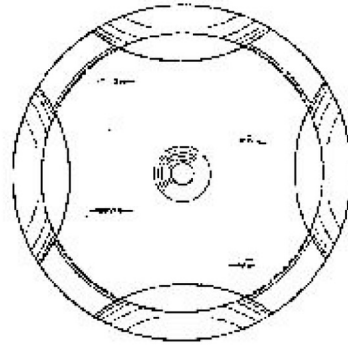


Fig. 2. The '183 patent's four-grip plate.

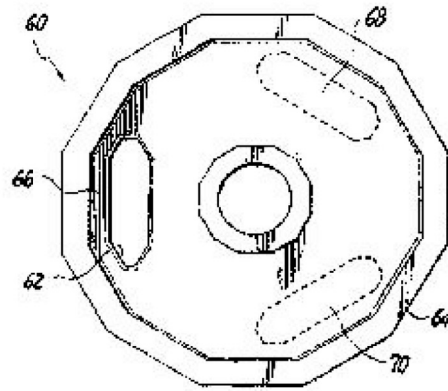
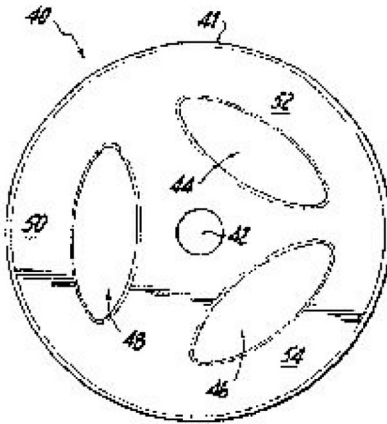


Fig. 3. The '015 patent's three-grip plates.

and unexpected results from a three elongated grip weight plate as compared to those in the prior art, we conclude that the claims are obvious absent substantial evidence of pertinent secondary factors supporting patentability.

III

We now consider whether the patentee has demonstrated secondary evidence of nonobviousness. We have previously held that in “determining the question of obviousness, inquiry should always be made into whatever objective evidence of nonobviousness there may be.” *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984). The district court’s opinion here did not consider the patentee’s claimed evidence. “Our precedents . . . establish that failure to cite secondary considerations, alone, is not reversible error.” *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 668 (Fed. Cir. 2000). “Where the evidence of record is unchallenged as to secondary considerations ignored by the decision maker, this court may, as a matter of law, consider this objective evidence in reviewing the ultimate conclusion of obviousness/nonobviousness entered by the trial court” without the need for a remand. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 307 (Fed. Cir. 1985). Because in considering this

record evidence, we conclude that it does not show the existence of relevant secondary factors to support patentability, we affirm the district court.

This court has previously identified, *inter alia*, commercial success, satisfaction of a long-felt need, and copying to be relevant factors in this inquiry. Iron Grip has not made a showing of commercial success. Our cases make clear that a “nexus must be established between the merits of the claimed invention and evidence of commercial success before that evidence may become relevant to the issue of obviousness.” *Solder Removal Co. v. USITC*, 582 F.2d 628, 637 (1978). Ordinarily, this nexus may be inferred when “the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent.” *Demaco*, 851 F.2d at 1392.

The only evidence of marketplace success that Iron Grip proffers is that six retail competitors offered three-grip plates, and three of those competitors have entered into license agreements with respect to the '015 patent. Iron Grip does not explain the terms of the licenses nor the circumstances under which they were granted, except to concede that two were taken in settlement of litigation. Our cases specifically require affirmative evidence of nexus where the evidence of commercial success presented is a license, because it is often “cheaper to take licenses than to defend infringement suits.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 908 (Fed. Cir. 1985). Thus we held in *In re GPAC Inc.*, 57 F.3d 1573 (Fed. Cir. 1995), that licenses “may constitute evidence of nonobviousness; however, only little weight can be attributed to such evidence if the patentee does not demonstrate a nexus between the merits of the invention and the licenses of record.” *Id.* at 1580. Without a showing of nexus, “the mere existence of . . . licenses is insufficient to overcome the conclusion of obviousness” when there is a strong *prima facie* case of obviousness. *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1358 (Fed. Cir. 2000). There is no such evidence of a nexus here; hence the existence of licenses is of little significance.⁴

Iron Grip places significant emphasis on the fact that, before it filed for the '015 patent, there was no three-grip plate being offered in the retail market. It argues that the absence of such a three-grip plate in light of the prior art speaks to the nonobviousness of its invention. However, Iron Grip has presented no evidence of a long-felt need for three-grip weight plates or the failure of others. Absent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness.

Iron Grip also argues that USA Sports has copied its invention and this is objective evidence of nonobviousness. Our cases do establish that copying by a competitor may be a relevant consideration in the secondary factor analysis. *Vandenberg*, 740 F.2d at 1567. Not every competing product that arguably falls within the scope of a patent is evidence of copying. Otherwise every infringement suit would automatically confirm the nonobviousness of the patent. Rather, copying requires the replication of a specific product. This may be demonstrated either through internal documents; direct evidence such as

4. Whatever little significance the licenses may have is clearly outweighed by the strong evidence of obviousness found in the prior art. *Ruiz*, 234 F.3d at 668; *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1131 (Fed. Cir. 2000).

disassembling a patented prototype, photographing its features, and using the photograph as a blueprint to build a virtually identical replica; or access to, and substantial similarity to, the patented product (as opposed to the patent). The evidence of copying offered by Iron Grip is that USA Sports abandoned a one-grip plate and produced a three-grip plate after the '015 patent issued, despite receiving assurance from Iron Grip that a one-grip plate would not infringe Iron Grip's patent. This does not establish that USA Sports engaged in copying.

Since Iron Grip has not presented evidence of commercial success, satisfaction of a long-felt need, or copying, we conclude that there is no objective evidence to rebut the strong showing of obviousness based on the prior art.

Comments

1. ***Commercial Success as Proof of Nonobviousness.*** Commercial success of an invention—the most commonly asserted secondary consideration—is relevant to nonobviousness because it assumes that if the invention were obvious, competitors of the inventor would have produced the invention given its significant consumer demand. See *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005) (“Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.”). At the same time, if an invention does not enjoy commercial success, it does not necessarily follow that the invention is obvious.

A patent product's success in the market, however, may be the result of factors that have very little to do with the product's technical quality. In fact, there are many products on the market that prompt consumer attention and devotion because of aggressive advertising or clever marketing. For this reason, a party asserting commercial success must link up its technical innovation with the ultimate purchase. In other words, there must be a nexus or causal relationship between the commercial success of the product and the technical merits of the claimed invention. See *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) (stating “[e]vidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success” and “[t]hus, if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant”).

2. ***Additional Thoughts on Commercial Success.*** The Federal Circuit's receptivity of secondary considerations was particularly pronounced in the early 1980s, soon after the court's creation and its mandate to strengthen patent rights was fresh. See, e.g., *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983) (stating “evidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art”); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) (stating that secondary considerations can “often

serve as insurance against the insidious attraction of the siren hindsight when confronted with a difficult task of evaluating the prior art”). The court’s emphasis on commercial success has prompted some commentators to express doubts about the value of commercial success. For example, Robert Merges offered a thorough criticism of the commercial success doctrine, stating that it “is a poor indicator of patentability because it is indirect; it depends for its effectiveness on a long chain of inferences, and the links in the chain are often subject to doubt.” Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 838-39 (1988). But Edmund Kitch has noted that using success in the marketplace as an indicator of patentability allows for greater “security in the investment process necessary to maximize the value of the patent.” Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 283 (1977).

3. **Long-Felt Need and Failure of Others.** A patentee may also argue that his invention is not obvious because he developed what was considered a long-felt need in the industry, a solution competitors unsuccessfully were trying to develop as well. As Judge Easterbrook wrote, “If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence . . . of the state of knowledge.” *In re Mahurkar Patent Litigation*, 831 F. Supp. 1354, 1377-78 (N.D. Ill. 1993), *aff’d*, 71 F.3d 1573 (Fed. Cir. 1995). Yet, as with commercial success, there is a counterargument. For example, competitors of the patentee may have had different R&D priorities, decided to spend precious research dollars on other projects or not at all, or were simply content with the existing state of affairs.
4. **Licensing/Acquiescence.** Yet another secondary consideration relates to the patentee’s assertion that his patent is not obvious because he enjoyed a successful licensing strategy. In other words, a party’s willingness to license his patent is an implicit admission of nonobviousness. Why would a competitor pay a royalty on an invalid patent? Well, as any business person knows, litigation is quite expensive and results in high opportunity costs. Thus, it is oftentimes rational from a business perspective for a competitor to license a patent—even if he doubts its validity—rather than challenge its validity in court. As the defendant, in a patent litigation suit responded when asked why he settled, “It was a nuisance lawsuit, and it was the most efficient decision to settle it for a minimal amount.” N.Y. Times, Business Section (Dec. 25, 2004).

CHAPTER

7

Enforcing Patent Rights

INTRODUCTION

A patent owner has numerous rights. The most fundamental right is found in § 154 of the patent code, which provides the patent owner with the “right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”¹ In addition, § 271 states “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.” Reverse engineering, independent creation, and lack of intent are not defenses to patent infringement.²

The patent grant—a potentially powerful economic tool—confers a *right to exclude*; it does not give the patentee a right to make, use, or sell the patented invention. Patent rights and the accompanying right to exclude do not exist at common law; rather, the right to exclude flows from positive

1. Section 154 continues to provide “if the invention is a process,” the patentee is granted “the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.”

2. See *Blair v. Westinghouse Elec. Corp.*, 291 F. Supp. 664, 670 (D.D.C. 1968) (stating “[i]t is, of course, elementary, that an infringement may be entirely inadvertent and unintentional and without knowledge of the patent. In this respect the law of patents is entirely different from the law of copyright”). Patent infringement has been characterized as a strict liability regime because an alleged infringer may be enjoined despite not having prior notice (from the patentee) of infringing activity. See *Am. Med. Sys. v. Med. Eng’g. Corp.*, 6 F.3d 1523, 1534-39 (Fed. Cir. 1993) (affirming permanent injunction even though defendant was put on notice three months after infringing activity); Mark A. Lemley, *Should Patent Infringement Require Proof of Copying*, 105 MICH. L. REV. 1525, 1525 (2007) (stating “[p]atent infringement is a strict liability offense”). Cf. Roger D. Blair & Thomas F. Cotter, *Strict Liability and Its Alternatives in Patent Law*, 17 BERKELEY TECH. L.J. 799 (2002) (arguing that patent law is best conceived as a modified strict liability regime).

Importantly, however, a patentee will not be able to recover damages until the alleged infringer has actual or constructive notice, and then damages will be available only for subsequent infringing activity. See 35 U.S.C. § 287(a). See also *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996) (stating “the statute defines that “[a patentee] is entitled to damages from the time when it either began marking its product in compliance with section 287(a) [constructive notice,] or when it actually notified [the accused infringer] of its infringement, whichever was earlier”). But process patent holders are an exception to the notice requirement because of the practical difficulty of marking process inventions. See *American Medical Systems, Inc. v. Medical Engineering Corp.*, 6 F.3d 1523 (Fed. Cir. 1993). Marking and § 287 are discussed in Chapter 9.

law—a sovereign act.³ In other words, “[t]he government is not granting the common-law right to make, use and vend, but it is granting the incident of exclusive ownership of that common-law right.”⁴

With this in mind, it follows that one may obtain a patent on an invention and still infringe a preexisting patent. Consider the following example: Inventor 1 obtains a patent on a chair and claims a seat portion, a back portion, and four legs. Subsequently, Inventor 2 invents and secures a patent on a chair having a seat portion, a back portion *that reclines* and four legs. Although Inventor 2 received a patent (say, because the reclining feature in combination with the other features were novel and not obvious), he cannot practice his claimed invention because it would infringe Inventor 1’s patent. Infringement exists here because Inventor 2’s chair has all of the limitations of Inventor 1’s patent claim (i.e., a seat portion, a back portion, and four legs). While the reclining feature may have allowed Inventor 2 to patent his chair, this feature does not save Inventor 2 from infringement. By the same token, Inventor 1 cannot practice Inventor 2’s claimed invention. As the Supreme Court recognized in *Smith v. Nichols*,⁵

[A] new idea may be ingrafted upon an old invention, be distinct from the conception which preceded it, and be an improvement. In such case it is patentable. The prior patentee cannot use it without the consent of the improver, and the latter cannot use the original invention without the consent of the former.⁶

Patents such as these are sometimes referred to as “blocking patents.”⁷ But there is a way out of this congestion. Assuming Inventor 2’s invention is an improvement over Inventor 1’s with greater commercial potential, each party has the motivation to enter into a cross-licensing agreement permitting each to practice their respective claimed inventions.⁸ Matters become more complex when multiple parties and patent rights are involved, leading to large-scale cross-licensing or pooling arrangements.⁹ These private ordering

3. See JOHN BARKER WAITE, *PATENT LAW 1* (Princeton University Press 1920) (“The Common Law does not recognize any right of ownership in an invention,” and, thus, an inventor’s “only right . . . is by virtue of statutes.”).

4. *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 36 (1923). See also 1 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS*, §§ 24-30 (1890) (discussing relationship between natural rights and patent rights).

5. 88 U.S. 112 (1874).

6. *Id.* at 118-19.

7. A similar situation would exist if an improver developed a new use of a patented product. For example, Inventor 1 patents a composition of matter that is used for shining shoes. Inventor 2 subsequently discovers that Inventor 1’s patent composition can be used to treat burns. Inventor 2 can obtain a patent on the new use, but must still obtain a license from Inventor 1 to make or use the composition. Likewise, Inventor 1 must obtain a license from Inventor 2 if the former wants to use his patented composition to treat burns. Importantly, a patentee of a product or composition patent can exclude others from any use of the product or composition even if the patentee did not envision or disclose the use.

8. For a good discussion of blocking patents, see Robert P. Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75 (1994).

9. Cross-licensing and pooling arrangements have been defined as “agreements of two or more owners of different items of intellectual property to license one another or third parties.” ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (Department of Justice and Federal Trade Commission, April 6, 1995). An early example of a cross-license: in the early part of the 20th century Standard Oil Company and The Texas Company cross-licensed each other in an agreement that came to be known as the “Patent Club.” See PAUL H. GIDDENS, *STANDARD OIL COMPANY: OIL PIONEER OF THE MIDDLE WEST* 258 (1955).

responses are common in cumulative technology industries such as telecommunications and information technology,¹⁰ and are consistent with patent law's disseminative function. And, as noted by the Department of Justice and Federal Trade Commission IP-Antitrust Guidelines, while pooling and cross-licensing arrangements may have anticompetitive effects, they may also "provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation."¹¹

A patent is enforceable from the date it issues¹² and is presumed valid under 35 U.S.C. § 282. A party challenging the validity of a patent, therefore, has the burden of proving invalidity by clear and convincing evidence. Patent law is exclusively federal; thus, a patentee may enforce his patent rights only by filing suit in federal district court.¹³ Litigation may also commence when a potential infringer takes the initiative and files a declaratory judgment action (a "DJ") in district court alleging either, or both, patent invalidity and non-infringement.¹⁴ In either case, the Court of Appeals for the Federal Circuit, with rare exception, has exclusive appellate jurisdiction.¹⁵ And, as in other

10. Cumulative technology is usually contrasted to discrete technology. According to Robert Merges and Richard Nelson, discrete technologies do "not point the way to wide ranging subsequent technical advances" and "do not typically incorporate a large number of interrelated components; they stand more or less alone" and "tend not to comprise integral components of some larger product or system." Examples include chemicals and pharmaceuticals where the patent is on a specific compound that did not form part of a larger product. In contrast, cumulative technologies "build on and interact with many other features of existing technology" . . . and "[i]n many cases the technology in question defines a complex system with many components, subcomponents and parts, and technical advance may proceed on a number of different fronts at once." Robert P. Merges & Richard R. Nelson, *On Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 881 (1990). Some commentators have suggested the pharmaceutical and biotechnology industries are becoming more cumulative in nature. See Testimony of Richard C. Levin, FTC/DOJ Hearings on Competition and Intellectual Property Law (Washington D.C. February 6, 2002) (stating "with the widespread use of patented research tools and the attendant need for cross-licensing, the pharmaceutical and biotechnology industries are moving closer to the cumulative technology paradigm"). The phrase "complex technology" has also been used to describe a product or process "comprised of numerous, separately patentable elements." Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 11 (NBER Working Paper No. W7552, May 2004).

11. Antitrust Guidelines for the Licensing of Intellectual Property § 5.5 (Department of Justice and Federal Trade Commission, April 6, 1995).

12. There is one notable exception. For applications filed on or after November 29, 2000, the patent applicant enjoys provisional rights beginning on the date the application is published and ending on the date the patent issues. But enforcement is only available upon issuance of the patent application. Thus, the remedy is retroactive; no injunction is available during the period of time between publication and issuance. See 35 U.S.C. § 154(d).

13. See 28 U.S.C. § 1338(a): "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases."

14. See Declaratory Judgment Act, 28 U.S.C. §§ 2201-2. Declaratory judgment actions are discussed in Chapter 8, § A.3.

15. See 28 U.S.C. § 1295(a): "The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction (1) of an appeal from a final decision of a district court of the United States, . . . if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title." Section 1338 states, in relevant part, that "district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents." Importantly, regional circuits may hear cases with patent law issues if the patent issue is raised in a counterclaim. See *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 539 U.S. 826 (2002). The Federal Circuit's jurisdiction is explored in Section D, *infra*.

areas of the law, the Supreme Court has jurisdiction to hear Federal Circuit appeals, if it so chooses.

Recent empirical scholarship on patent litigation suggests that only about 1% of patents are ever litigated.¹⁶ Of this small percentage, 5% of the cases go to trial,¹⁷ an additional 6-9% are resolved on the merits through summary judgment,¹⁸ and the remaining are resolved through some form of settlement.¹⁹ One of the more prominent incentives driving settlement is the high cost of patent litigation. One survey showed that median costs for litigation with less than \$1 million at risk, litigation fees, inclusive of all costs, were \$767,000; with \$1-25 million at risk, the fees rose to \$2,645,000; and when more than \$25 million is at stake, litigation expenses approached \$4.5 million.²⁰ Moreover, patent litigation has risen dramatically over the past 20 years,²¹ with patents in some industries much more likely to be litigated than in other industries.²²

16. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. L. Rev. 1495, 1501 (2001). Some scholars have suggested that the small number of patents being litigated is because “[m]any patents are not worth enforcing—either because the inventions they cover turn out to be worthless, or because even if the invention has economic value the patent does not.” John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 GEO. L.J. 435, 436 (2004). Of course, many patents are licensed (or subject to cross-licensing) agreements, can be used to intimidate competitors, or be useful in attractive capital investment. See Shubha Ghosh & Jay Kesan, *What Do Patents Purchase? In Search of Optimal Ignorance in the Patent Office*, 40 HOUS. L. REV. 1219 (2004). But see Lemley, *Rational Ignorance*, *supra* (estimating only 3.5% of patents are licensed for a royalty).

17. Jean O. Lanjouw & Mark Schankerman, *Protecting Intellectual Property Rights: Are Small Firms Handicapped?*, 47 J.L. & ECON. 45 (2004); Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237 (2006). Paul Janicke’s empirical work on patent litigation shows that in 2006, 3.1% of patent cases went to trial (2.2 jury trial and 0.9 bench trial). Paul Janicke, *Patent Litigation Remedies: Some Statistical Observations* (2007) at http://www.patstats.org/editors_page.rev6.html.

18. See Janicke, *Patent Litigation Remedies*, *supra* note 17 (in 2006, 7% of patent cases were resolved through summary judgment).

19. See Kesan & Ball, *How Are Patent Cases Resolved*, *supra* note 17; Janicke, *Patent Litigation Remedies*, *supra* note 17, (showing in 2006, 86.5% of patent cases were settled, which includes consent judgments, voluntary dismissals, and dismissals stating settlement or “other dismissals”). These figures, of course, only tell part of the picture. In testimony on patent reform before the House Subcommittee on Courts, the Internet, and Intellectual Property, an Apple Computer representative stated: “[F]or every lawsuit that goes to final judgment, there is 25 more that don’t go to final judgment, that get adjudicated or settled ahead of time, and for every one of those, there’s 25 [cease and desist] letters that were written that never made it to a lawsuit at all.” H.R. Rep. 109-11, pt. 1, at 122 (2005).

20. AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, REPORT OF THE ECONOMIC SURVEY I-90-1 (2007).

21. See Jean O. Lanjouw & Mark Schankerman, *Protecting Intellectual Property Rights: Are Small Firms Handicapped?*, 47 J.L. & ECON. 45 (2004) (noting an “almost 10-fold” increase in patent litigation over the past two decades); Joseph P. Cook, *On Understanding the Increase in Patent Litigation*, 9 AM. L. & ECON. REV. 48, 48 (2007) (stating “[f]or the last 20 years, patent litigation in the United States has been steadily increasing. In the last 10 years, the number of patent cases filed in US federal courts has approximately doubled”). But a recent study conducted by PricewaterhouseCoopers found that after increasing from 1991 (1,171 patent cases filed) to 2004 (3,074 cases), patent litigation filings decreased from 2004 to 2005, when 2,720 cases were filed. This decrease represents the first decline in 16 years. The report suggests that several factors influenced the reduction in patent cases, including greater use of ADR, high litigations fees, recent Supreme Court rulings, and reduced damage awards.

22. See John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 GEO. L.J. 435, 471-75 (2004) (finding “patents on medical devices, computer-related inventions, software, electronics, and mechanics are significantly more likely to be litigated than the average of all patents. By contrast, chemistry, automotive, and semiconductor patents are significantly less likely to be litigated”). See also Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & ECON. 463 (1995) (finding biotechnology patents more likely to be litigated than other forms of technology).

In a patent infringement suit, a patentee asserts that the patent *claims* are infringed, not the commercial embodiment of the claimed invention or what is set forth in the specification. As first explored in Chapter 2, patent claims are the touchstone of patent protection, and it is the claims that set forth the patentee's proprietary boundaries. Thus, a crucial and oftentimes determinative aspect of patent litigation is ascertaining what the claim language in question means. The process whereby a court determines the precise meaning of patent claim language is called *claim construction* or *claim interpretation*. Construing the claims is always the first step in an infringement (and validity) analysis. (Claim interpretation is covered in Section A, below.) The second step is determining whether the accused product infringes the patent claim(s) at issue, an expansive topic this is explored in Sections B-F, below.

The causes of action for patent infringement can be divided into two categories: (1) *direct infringement*; and (2) *indirect infringement*. Under the theory of direct infringement, the patentee brings an action against a defendant who himself is committing acts (*e.g.*, making a product or practicing a process) that infringe one or more patent claims. Direct patent infringement comprises both (1) literal infringement; and (2) non-literal infringement, commonly referred to as the *doctrine of equivalents* (or "DOE"). Literal infringement is straightforward and occurs when every limitation recited in the claim is found in the accused device. Recall the chair example above, but replace Inventor 2 with Competitor, who instead of filing a patent application on an improvement, makes and uses a competing chair having a seat portion, a back portion and four legs. Competitor literally infringes Inventor 1's patent claim, because Competitor practices each and every limitation set forth in Inventor 1's claim. Sometimes patent professionals would say that Inventor 1's claim "reads on" Competitor's product. Literal infringement is discussed in Section B.1.

The common law doctrine of equivalents comes into play when there is no literal infringement, and allows liability when an accused infringing device (or process) is an "equivalent" to the claimed invention. Returning to the chair example, let's say Inventor 1 claims a chair frame made of titanium and having a seat portion, a back portion, and four legs. But now Competitor makes a chair having a seat portion, a back portion, four legs, and a chair frame made of aluminum. There is no literal infringement because Competitor's product does not have each and every limitation of Inventor 1's claim, but Competitor may still infringe under the DOE if it is determined that aluminum is an "equivalent" to titanium. How that determination is made, and the analytical structure of the DOE are explored in Section B.2, below.

There are four important limitations on the DOE: (1) *prosecution history estoppel*; (2) the *public dedication* rule; (3) *all-limitations/specific exclusion* rule; and (4) *prior art*. Prosecution History Estoppel ("PHE") precludes a patent owner in an infringement proceeding from obtaining broader claim scope than the issued claims (as construed), when the original claims in the application would have encompassed the equivalent at issue and where the claim was narrowed to exclude the equivalent, which was foreseeable at the time of such narrowing. For instance, Inventor initially claims three legs as part of his invention. The patent examiner rejects the application because there is prior art that discloses a chair having three legs. In response, Inventor amends the claim by deleting "three legs" and adding "four legs." The patent issues. When Inventor tries to enforce his patent against Competitor's three-legged chair,

Competitor can invoke the doctrine of prosecution history estoppel and argue, successfully, that Inventor surrendered “three legs” to obtain a patent and, therefore, the DOE cannot extend the claim scope to capture three legs. A chair with three legs was certainly foreseeable at the time Inventor amended his claim; in fact, PHE would apply even if Inventor did not initially claim three legs as long as a three-legged chair was foreseeable at the time Patentee narrowed his claim through amendment. The PHE and its relationship with the DOE will become clearer as you read the principal cases of *Festo Corp. (Festo VIII)* and *Cross Medical* and the accompanying text in Section B.3.a, below.

The *public dedication rule* holds that subject matter disclosed in the specification, but not claimed is dedicated to the public domain. So, assume Inventor claims a chair having a seat portion *made of cotton*, a back portion and four legs, but the specification reveals to a PHOSITA that the chair can be made of either cotton or wool. Competitor makes a chair with every limitation in Inventor’s claim, but instead of cotton, uses wool. The public dedication rule can be used by Competitor during litigation to argue that Inventor dedicated wool to the public domain because Inventor, while expressly disclosing both wool and cotton in the specification, only claimed cotton. This doctrine is explored in the principal case of *Johnston Associates* and accompanying text in Section B.3.b, below.

The *all-limitations rule* demands that each limitation of a patent claim is material to defining the scope of the patented invention and must not be vitiated or rendered meaningless. Thus, for there to be infringement under the DOE an equivalent of each claim limitation must be found in the accused device. In other words, the DOE is applied to each limitation, not to the invention as a whole. The related *specific exclusion rule*, a corollary to the all-limitations rule, holds that the DOE is unavailable to capture subject matter that the claim specifically excludes. The reasoning behind this rule is that by defining a claim in a way that specifically excludes certain subject matter, the patentee implicitly disclaimed the subject matter and is therefore prevented from invoking the DOE. See the principal case of *SciMed Life Systems* and accompanying text in Section B.3.c, below.

The role of *prior art* as a limitation on the DOE is straightforward. Claim coverage under the DOE cannot extend to include subject matter that forms part of the prior art. The reason is claims that read on the prior art do not satisfy the patentability requirements, and therefore, the PTO would never have issued the patent. See the principal case of *Wilson Sport Goods* and accompanying text in Section B.3.d, below.

COMPARATIVE PERSPECTIVE *Enforcing Patents in Europe*

While it is common to refer to patents that issue from the European Patent Office (“EPO”) as “European Patents,” there is no such thing as a European patent that provides a unitary right in all member states of the European Patent Convention (“EPC”) or European Union. While the EPC contains substantive laws relating to patentability, these laws are almost exclusively applicable to the process of obtaining patent rights.

A patent issuing from the EPO eventually becomes a bundle of individual national patents based on the countries designated by the applicant. Thus, while the process of obtaining rights is centralized, enforcement is a matter of national law. As Article 64(3) of the EPC states, “[a]ny infringement of a European patent shall be dealt with by national law.” This disparate enforcement structure is of particular concern within the European patent community and beyond. As noted in a report produced by the EPO in 2006, the present enforcement structure:

Is a *fragmentation of the European market*, as it is impossible to ensure that a European patent yields a uniform level of protection throughout all states. The disparities between the national systems as regards the litigation of European patents are thus prejudicial to the free movement of goods in Europe and counteract progress towards the creation of an environment conducive to free competition.

Assessment of the Impact of the European Patent Litigation Agreement (EPLA) on Litigation of European Patents (EPO 2006), para. 8 (emphasis in original).

There have been two noteworthy responses to these concerns. First, the idea of a community wide patent was first raised at the Luxembourg Community Patent Convention in 1975, which would create a unitary patent right within the European Union. Although this idea sounds attractive, it has been mired in difficulty from the very beginning, despite several attempts to revisit the proposal. The principal failure to adopt a community patent regime relates to difficulties on a common language(s) for the patent and the fact that the role of national patent offices would be diminished. Under the current system, once a patent is granted by the EPO, the patent must be translated in an official language of each designated country (i.e., country where the patentee wants protection). If translation is not forthcoming within a prescribed time frame, the patent “shall be deemed to be void ab initio in that State.” EPC Article 65. As Laurent Manderieux explains, until recently there was no effective EU consensus on the community patent because:

Several countries want their language to be an official one for patents, and at the same time, if too many translations are compulsory, operators would find no cost advantage over the present system, and thus they would show no interest in the new system. Also several states have reservations on how to establish an EU-wide jurisdiction which could decide on questions regarding an EU-wide patent right.

Laurent Manderieux, *Europe’s IP Architecture*, in *THE HANDBOOK OF EUROPEAN INTELLECTUAL PROPERTY MANAGEMENT* 3-10 (Jolly & Philpott eds., 2007). To address the language concern, the EPC member states have proposed the London Agreement of 2000, which would require EPC states to waive their requirement for translation into the state’s national language. In 2007, France endorsed the London Agreement, thus leading to its ratification.

Second, and independent of the community patent, Europeans have begun debating what is referred to as the European Patent Litigation Agreement (“EPLA”), which would commit the signatory countries of the

European Patent Convention to an integrated judicial system, including a centralized appellate court with competencies similar to the Federal Circuit in the United States. (The EPLA also envisions numerous Courts of First Instance.) The rulings of the centralized patent court would have binding effect on all member states. It may very well be that the Europeans will soon have both a community patent and a revised enforcement structure along the lines of the EPLA.

For more on the EPLA, see <http://patlaw-reform.european-patent-office.org/epla/index.en.php>. For a helpful discussion on the community patent and the EPLA, see Anthony Arnall & Robin Jacob, *European Patent Litigation: Out of the Impasse*, 29 EURO. INTEL. PROP. REV. 209 (June 2007). For a short treatment on the design and history of the European patent system, see Laurent Manderieux, *Europe's IP Architecture*, in THE HANDBOOK OF EUROPEAN INTELLECTUAL PROPERTY MANAGEMENT 3-10 (Jolly & Philpott eds., 2007).

A. CLAIM INTERPRETATION

Throughout the history of American patent law there has been an ever-increasing emphasis on claim language as the measure of exclusive rights. It is common to hear patent professionals speak of claims as defining the “metes and bounds” of the patentee’s property right or “the claim is the name of the game.”²³ Claim interpretation—which precedes a determination of validity and infringement—is the most important part of patent litigation because “to decide what the claims mean is nearly always to decide the case.”²⁴ Indeed, after claims are construed, it is not uncommon for the parties to settle the litigation or, if settlement is not reached, the case is increasingly resolved by summary judgment.²⁵

Once we understand the significance of claim construction, questions such as who interprets claim language and the interpretive methodologies employed become very important. The *Markman* case directly addresses the question of *who*: judge or jury. The Supreme Court, based on historical and functional considerations, held claim interpretation is solely for the judge. In *Phillips*, the principal case following *Markman*, the Federal Circuit addressed interpretive methodology and set forth what can be characterized as an in-

23. Giles S. Rich, *Extent of the Protection and Interpretation of Claims—American Perspectives*, 21 INT’L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990).

24. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 989 (Fed. Cir. 1995) (Mayer, J., concurring). See also *Lucas Aerospace, Ltd. v. Unison Indus., L.P.*, 890 F. Supp. 329, 332 n.3 (D. Del. 1995) (“[C]laim construction more often than not determines the outcome on infringement.”); Linda Greenhouse, *Ruling Curbs Jury’s Role on Patents*, N.Y. TIMES, Apr. 24, 1996, at D1 (“Once you have construed the scope of the claim, that’s the end of the game.”) (quoting patent attorney, Bo Pasternack of Choate, Hall & Stewart).

25. For a study of settlement rates in patent litigation, see Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved: An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L.Q. 247 (2006); Paul Janicke, *Patent Litigation Remedies: Some Statistical Observations* (2007) at http://www.patstats.org/editors_page.rev6.html. With respect to the increase in summary judgment grants, see John R. Allison & Mark A. Lemley, *The (Unnoticed) Demise of the Doctrine of Equivalents*, 59 STAN. L. REV. 955 (2007).

terpretive road map. The court established a hierarchy of evidence, including what is referred to as “intrinsic evidence”—such as claim language, the specification, prosecution history—and various forms of “extrinsic evidence,” which include, for example, expert testimony, dictionaries, technical treatises. The last principal case in the claim interpretation section is *Unique Concepts*, which explores the relationship among the various types of intrinsic evidence.

1. The Judge as Interpreter of Claim Language

The principal case of *Markman v. Westview Instruments, Inc.* is arguably the most well-known case in patent law because its holding gave birth to the *Markman* hearing, a staple of almost every patent litigation. (The *Markman* hearing is discussed in Comment 1 immediately following *Markman*.) The Supreme Court was asked in *Markman* to address whether the act of interpreting claims—claim interpretation—is a matter for the jury as of right or for the court. The Supreme Court affirmed the Federal Circuit and held claim interpretation is solely for the judge. But the Supreme Court did not directly address what standard of review the Federal Circuit should use when reviewing district court claim interpretations, nor did the Court directly rule on whether claim interpretation is a question of law, fact, or both—although the Federal Circuit held claim interpretation is a question of law to be reviewed *de novo*. 52 F.3d 967, 979, 983-84 (Fed. Cir. 1995) (*Markman I*). The Supreme Court’s treatment, or lack thereof, of the standard of review prompted the Federal Circuit to sit en banc to resolve this issue. See Comment 2 following *Markman* for a discussion of the Federal Circuit’s en banc ruling and underlying policy considerations.

MARKMAN v. WESTVIEW INSTRUMENTS, INC. (MARKMAN II)

517 U.S. 370 (1996)

Justice SOUTER delivered the opinion of the Court.

The question here is whether the interpretation of a so-called patent claim, the portion of the patent document that defines the scope of the patentee’s rights, is a matter of law reserved entirely for the court, or subject to a Seventh Amendment guarantee that a jury will determine the meaning of any disputed term of art about which expert testimony is offered. We hold that the construction of a patent, including terms of art within its claim, is exclusively within the province of the court.

* * *

III

[The Court initially applied its 7th Amendment “historical test” to determine whether a right to a jury trial on the issue claim interpretation “existed under the English common law when the Amendment was adopted.” This test did not yield a definitive answer, forcing the Court to look “elsewhere” to answer the question presented.]

Since evidence of common law practice at the time of the Framing does not entail application of the Seventh Amendment's jury guarantee to the construction of the claim document, we must look elsewhere to characterize this determination of meaning in order to allocate it as between court or jury. We accordingly consult existing precedent and consider both the relative interpretive skills of judges and juries and the statutory policies that ought to be furthered by the allocation.

A

The two elements of a simple patent case, construing the patent and determining whether infringement occurred, were characterized by the former patent practitioner, Justice Curtis. "The first is a question of law, to be determined by the court, construing the letters-patent, and the description of the invention and specification of claim annexed to them. The second is a question of fact, to be submitted to a jury." *Winans v. Denmead*, 15 How., at 338.

In arguing for a different allocation of responsibility for the first question, Markman relies primarily on two cases, *Bischoff v. Wethered*, 19 L. Ed. 829 (1870), and *Tucker v. Spalding*, 20 L. Ed. 515 (1872). These are said to show that evidence of the meaning of patent terms was offered to 19th-century juries, and thus to imply that the meaning of a documentary term was a jury issue whenever it was subject to evidentiary proof. That is not what Markman's cases show, however. . . . [N]either *Bischoff* nor *Tucker* indicates that juries resolved the meaning of terms of art in construing a patent, and neither case undercuts Justice Curtis's authority.

B

Where history and precedent provide no clear answers, functional considerations also play their part in the choice between judge and jury to define terms of art. We said in *Miller v. Fenton*, 474 U.S. 104 (1985), that when an issue "falls somewhere between a pristine legal standard and a simple historical fact, the fact/law distinction at times has turned on a determination that, as a matter of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question." So it turns out here, for judges, not juries, are the better suited to find the acquired meaning of patent terms.

The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis. Patent construction in particular "is a special occupation, requiring, like all others, special training and practice. The judge, from his training and discipline, is more likely to give a proper interpretation to such instruments than a jury; and he is, therefore, more likely to be right, in performing such a duty, than a jury can be expected to be." *Parker v. Hulme*, 18 F. Cas., at 1140. Such was the understanding nearly a century and a half ago, and there is no reason to weigh the respective strengths of judge and jury differently in relation to the modern claim; quite the contrary, for "the claims of patents have become highly technical in many respects as the result of special doctrines relating to the proper form and scope of claims that have been developed by the courts and the Patent Office." Woodward, *Definiteness and Particularity in Patent Claims*, 46 MICH. L. REV. 755, 765 (1948).

Markman would trump these considerations with his argument that a jury should decide a question of meaning peculiar to a trade or profession simply because the question is a subject of testimony requiring credibility determinations, which are the jury's forte. It is, of course, true that credibility judgments have to be made about the experts who testify in patent cases, and in theory there could be a case in which a simple credibility judgment would suffice to choose between experts whose testimony was equally consistent with a patent's internal logic. But our own experience with document construction leaves us doubtful that trial courts will run into many cases like that. In the main, we expect, any credibility determinations will be subsumed within the necessarily sophisticated analysis of the whole document, required by the standard construction rule that a term can be defined only in a way that comports with the instrument as a whole. Thus, in these cases a jury's capabilities to evaluate demeanor, to sense the "mainsprings of human conduct," or to reflect community standards, are much less significant than a trained ability to evaluate the testimony in relation to the overall structure of the patent. The decisionmaker vested with the task of construing the patent is in the better position to ascertain whether an expert's proposed definition fully comports with the specification and claims and so will preserve the patent's internal coherence. We accordingly think there is sufficient reason to treat construction of terms of art like many other responsibilities that we cede to a judge in the normal course of trial, notwithstanding its evidentiary underpinnings.

C

Finally, we see the importance of uniformity in the treatment of a given patent as an independent reason to allocate all issues of construction to the court. As we noted in *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938), "[t]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public." Otherwise, a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field," *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942), and "[t]he public [would] be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights." *Merrill v. Yeomans*, 94 U.S. 568, 573 (1877). It was just for the sake of such desirable uniformity that Congress created the Court of Appeals for the Federal Circuit as an exclusive appellate court for patent cases, observing that increased uniformity would "strengthen the United States patent system in such a way as to foster technological growth and industrial innovation." H.R. Rep. No. 97-312, pp. 20-23 (1981).

Uniformity would, however, be ill served by submitting issues of document construction to juries. Making them jury issues would not, to be sure, necessarily leave evidentiary questions of meaning wide open in every new court in which a patent might be litigated, for principles of issue preclusion would ordinarily foster uniformity. Cf. *Blonder Tongue Laboratories, Inc. v. University of Ill. Foundation*, 402 U.S. 313 (1971). But whereas issue preclusion could not be asserted against new and independent infringement defendants even within a given jurisdiction, treating interpretive issues as purely legal will promote (though it will not guarantee) intrajurisdictional certainty through the appli-

cation of *stare decisis* on those questions not yet subject to interjurisdictional uniformity under the authority of the single appeals court.

* * *

Accordingly, we hold that the interpretation of the word “inventory” in this case is an issue for the judge, not the jury, and affirm the decision of the Court of Appeals for the Federal Circuit.

Comments

1. *The Markman Hearing.* The Supreme Court’s *Markman* decision and subsequent Federal Circuit case law led to the creation of what eventually became known as the *Markman* hearing, a procedural device employed by district court judges designed to determine the meaning of the claim language at issue. District court judges have broad discretion in how they structure the hearing, and are faced with common procedural questions. For instance, (1) when during the trial should the court construe the patent claim? (2) what input may the court properly receive to help in claim construction? and (3) how may the court use this input? See *Elf Atochem North America, Inc. v. Libbey-Owens-Ford Co., Inc.*, 894 F. Supp. 844, 850 (D. Del. 1995) (“The ‘obligation’ created by the Federal Circuit to instruct the jury on the meaning of the words used by an inventor in a claim basically leaves a district court with three options. The court can attempt to resolve these disputes on the paper record. Second, the court can hold a trial to resolve the disputes. Finally, the court can wait until trial and attempt to resolve claim disputes the evening before the jury must be instructed.”). Most courts opt to hold a pre-trial *Markman* hearing, typically followed by the “winning” party filing summary judgment motions on validity and/or infringement.

It has been several years since the *Markman* decision, and courts have developed established structures for *Markman* hearings, particularly in jurisdictions that have crowded patent dockets (e.g., C.D. and N.D. California). For example, the Northern District of California (and several other jurisdictions) has adopted special local rules for patent cases, which, in effect, impose more detailed pleading and disclosure rules than are generally mandated by the Federal Rules of Civil Procedure.

2. *Standard of Appellate Review and Claim Interpretation.* The grant of certiorari in *Markman* focused on the Seventh Amendment right to a jury trial in the context of claim construction. While the Court held that claim construction is “is an issue for the judge, not the jury,” the Court did not expressly discuss the proper standard of review of district court judge claim interpretations, or rule whether an interpretive analysis is one of fact, law, or a mixture thereof.

But, in what turned out to be controversial dicta, the Court characterized claim construction as a “mongrel practice” that “falls somewhere between a pristine legal standard and a simple historical fact.” 517 U.S. at 378, 388. This dicta is noteworthy because the categorization of claim construction as one of law and/or fact may determine whether a claim construction ruling is reviewed *de novo* (as a legal question), for clear error

(as fact finding in a bench trial), or some mixed review. Failure to expressly address the issue of standard of review prompted a minority of Federal Circuit judges, sympathetic to a more deferential standard of review, to assert that de novo review was not endorsed by the Supreme Court, and claim interpretation is a mixed question of law and fact. *See, e.g., Fromson v. Anitec Printing Plates, Inc.*, 132 F.3d 1437 (Fed. Cir. 1997). Other judges disagreed, and continued to stress that claim interpretation is a question of law subject to de novo review. *See, e.g., Phonometrics, Inc. v. N. Telecom, Inc.*, 133 F.3d 1359 (Fed. Cir. 1998).

This intra-circuit conflict led to *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998), an en banc decision that unequivocally held claim construction is “a purely legal question” that is reviewed “de novo on appeal including any allegedly fact based questions relating to claim construction.”

One could argue that *Cybor* is understandable if the predominant policy consideration is uniformity. Consider the following hypothetical litigation scenario:

The '123 patent is owned by patentee A. A files a patent infringement suit in the Northern District of Ohio asserting that defendant B is infringing the '123 patent. Shortly thereafter, patentee A files another patent infringement action in the Northern District of California claiming that defendant C is infringing the '123 patent. Each district court judge—allowing and relying on expert testimony—interpret the same claim language differently. These divergent interpretations lead to the '123 patent being held invalid by the Ohio judge, and not invalid by the California judge.

Employing a standard of review that is more deferential than de novo, it is entirely plausible that the Federal Circuit would affirm both district court interpretations, resulting in disuniformity.

But uniformity in claim representation is only one policy objective; certainty is another, particularly *early* certainty. An appellate standard of review that is more deferential would most likely lead to greater affirmance rates of district court claim construction rulings. A higher affirmance rate will likely inject certainty earlier in the process, and arguably promote more settlement activity. In his *Cybor* dissent, Judge Rader wrote “this court’s enthusiastic assertion of its unfettered review authority has the potential to undercut the benefits of *Markman I*,” namely “early certainty about the meaning of a patent claim,” which, “in turn, would prompt early settlement of many, if not most, patent suits.” 138 F.3d at 1475. Indeed, the *de novo* review standard has resulted in a relatively high reversal rate of district court claim constructions. *See* Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?* 9 LEWIS & CLARK L. REV. 231, 247 (2005) (noting the high reversal rate for claim construction rulings); Christian A. Chu, *Empirical Analysis of the Federal Circuit’s Claim Construction Trends*, 16 BERKELEY TECH. L.J. 1075, 1100 (2001) (asserting in the context of claim construction, “the promises of pre-trial predictability and expedient patent litigation seem to remain a tantalizing dream”). Moreover, there is the question of institutional competence and relative exposure to and time spent with evidentiary sources. *See* Hon. Patti Saris, *The Past, Present and Future of the Federal Circuit*, 54 CASE W. RES. L. REV.

671, 679 (2004) (stating “there should be more deference given to the interpretation of the trial judge who had the opportunity to see, hear, and look at evidence”).

There are also procedural devices available to district court judges that would foster uniformity. For instance, the doctrine of issue preclusion, when available, addresses, at least partially, the uniformity issue at the district level. *See TM Patents v. IBM Corp.*, 72 F. Supp. 2d 370 (S.D.N.Y. 1999) (applying issue preclusion against plaintiff-patentee); *Abbott Labs v. Day*, 110 F. Supp. 2d 667 (N.D. Ill. 2000) (same). But some district courts have refused to apply issue preclusion against plaintiff-patentees based on finality concerns. *See, e.g., Graco Children’s Products, Inc. v. Regalo Int’l*, 77 F. Supp. 2d 660 (E.D. Pa. 1999) (issue preclusion does not apply to patentee because case settled and, therefore, not appealed); *Kollmorgen Corp. v. Yaskawa Elec. Corp.*, 147 F. Supp. 2d 464, 468 (W.D. Va. 2002) (stating “[a]s more than forty percent of all Markman Orders are reversed by the Federal Circuit, logic dictates that for these claim constructions to have a preclusive effect, the litigants must first have an opportunity to seek Federal Circuit review”).

Lastly, Federal Circuit could apply *stare decisis* as a basis for adopting the prior claim construction. But thus far there is no Federal Circuit decision that has employed the doctrine of *stare decisis* to claim interpretation, despite the Supreme Court’s acknowledgement of the doctrine’s applicability:

[W]hereas issue preclusion could not be asserted against new and independent infringement defendants even within a given jurisdiction, treating interpretive issues as purely legal will promote . . . intrajurisdictional certainty through the application of *stare decisis* on those questions not yet subject to interjurisdictional uniformity under the authority of the single appeals court.

Markman, 517 U.S. at 391. *See also Cybor*, 138 F.3d at 1479 (Newman, J., dissenting) (stating “[t]he promise of uniformity and finality, flowing from decisions of national effect, is a failed promise if we are not bound by *stare decisis* in our own claim interpretation”). While *stare decisis* may foster uniformity, it is not without problems. Most notably it denies a new defendant his day in court, although this concern is more pronounced in the issue preclusion context. *See Texas Instruments v. Linear Tech. Corp.*, 182 F. Supp. 2d 580, 585-89 (E.D. Tex. 2002) (rejecting applicability of *stare decisis* in context of claim construction).

3. **Are Cybor’s Days Numbered?** The Federal Circuit has begun to openly question the wisdom of *Cybor*. For instance, in a petition for rehearing (ultimately denied) in *Amgen v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039 (Fed. Cir. 2006), six dissenting and concurring opinions were filed revealing the internal division relating to *Cybor* and the court’s standard of review for claim construction. Judge Michel wrote:

I have come to believe that reconsideration is appropriate and revision may be advisable. In my view, four practical problems have emerged under the *Markman-Cybor* regime: (1) a steadily high reversal rate; (2) a lack of predictability about appellate outcomes, which may confound trial judges and discourage settlements; (3) loss of the comparative advantage often enjoyed by the district judges who heard or read all of the evidence and may have

spent more time on the claim constructions than we ever could on appeal; and (4) inundation of our court with the minutia of construing numerous disputed claim terms (in multiple claims and patents) in nearly every patent case.

Id. at 1040. Revisit the appropriateness of *Cybor* after reading the *Phillips* case below, which adopted a context-specific and strongly fact-dependent approach to claim interpretation. Ask yourself if characterizing claim interpretation as a question of law subject to *de novo* review is consistent with this approach.

4. **Interlocutory Appeal.** Given the high reversal rate of district court claim constructions, and accompanying waste of judicial resources and significant private legal costs, perhaps there should be an interlocutory route to review claim constructions. A central question in this regard is whether a claim construction ruling is a final judgment because appeals can only be entertained from final judgments. See Craig Allen Nard, *Process Considerations in the Age of Markman and Mantras*, 2001 U. ILL. L. REV. 101 (exploring interlocutory review of district court claim constructions). The Federal Circuit — “in its discretion” — may grant interlocutory review, but has thus far refused. See *Cybor*, 138 F.3d at 1479 (Newman, J., dissenting) (stating “Although the district courts have extended themselves, and so-called ‘*Markman*’ hearings’ are common, this has not been accompanied by interlocutory review of the trial judge’s claim interpretation. The Federal Circuit has thus far declined all such certified questions”). Practically, interlocutory review would greatly increase the Federal Circuit’s patent docket or there are doctrinal reasons at play.

For their part, trial judges may be more inclined to dispose of cases on summary judgment. As then district court (now circuit court) judge, Kent Jordan, stated upon ruling in favor of defendant’s motion for summary judgment of non-infringement, “[i]t may be cold comfort, but at least [patentee] now has the prospect of obtaining a definitive ruling on the disputed claim construction without first having to incur the considerable expense of a full trial on the merits. Should the Federal Circuit alter the claim construction on appeal, the parties may then proceed to trial, confident that they have the correct claim construction in hand.” *Chimie v. PPG Industries, Inc.*, 303 F. Supp. 2d 502, 509 (D. Del. 2004). See also Kimberly A. Moore, *Are District Court Judges Equipped to Decide Patent Cases*, 15 HARV. J.L. & TECH. 1, 33 (2001) (asserting “[s]ummary judgment on the issue of infringement will likely increase after *Markman*”); William F. Lee & Anita K. Krug, *Still Adjusting to Markman: A Prescription for the Timing of Claim Construction Hearings*, 13 HARV. J.L. & TECH. 55, 59 (1999) (stating an “expected result of *Markman* has been an increase in the number of motions for summary judgment and partial summary judgment on matters of claim construction and infringement”).

2. Interpretive Methodologies and Sources of Evidence

What interpretive tools a district court judge can or should use when interpreting claim language is one of the more controversial questions in patent law. In developing this area of the law, the Federal Circuit has signaled a receptiveness to both “intrinsic evidence” (e.g., the claim, specification, and prosecution history) and certain forms of “extrinsic evidence” (e.g., diction-

aries and technical treatises, and much less so, expert testimony). While there is an unmistakable preference for intrinsic evidence, questions remain regarding the relationship between intrinsic and extrinsic evidence, when it is proper to engage extrinsic evidence, and what distinctions, if any, exist among its various forms. The en banc case of *Phillips v. AWH* addresses the relationship between intrinsic and extrinsic evidence, and sets out an interpretive road map with an emphasis on context. Yet the court surprisingly offered little navigational guidance beyond what was already established law.

In addition to the intrinsic/extrinsic divide, there is a hierarchy within intrinsic evidence itself, with one school of interpretation placing a great deal of emphasis on the claim and the notice function of patent law. Another interpretive school, while not denying the importance of the claim, is more willing to consider all three forms of intrinsic evidence to discern claim meaning. The majority and dissent in the classic *Unique Concepts* case explore these two schools of thought.

PHILLIPS v. AWH CORP.

415 F.3d 1303 (Fed. Cir. 2005) (en banc)

BRYSON, Circuit Judge.

Edward H. Phillips invented modular, steel-shell panels that can be welded together to form vandalism-resistant walls. The panels are especially useful in building prisons because they are load-bearing and impact-resistant, while also insulating against fire and noise. Mr. Phillips obtained a patent on the invention, U.S. Patent No. 4,677,798 (“the ’798 patent”), and he subsequently entered into an arrangement with AWH Corporation, Hopeman Brothers, Inc., and Lofton Corporation (collectively “AWH”) to market and sell the panels. That arrangement ended in 1990. In 1991, however, Mr. Phillips received a sales brochure from AWH that suggested to him that AWH was continuing to use his trade secrets and patented technology without his consent. In a series of letters in 1991 and 1992, Mr. Phillips accused AWH of patent infringement. Correspondence between the parties regarding the matter ceased after that time.

In February 1997, Mr. Phillips brought suit in the United States District Court for the District of Colorado charging AWH with infringement of claims 1, 21, 22, 24, 25, and 26 of the ’798 patent. The district court focused on the language of claim 1, which recites “further means disposed inside the shell for increasing its load bearing capacity comprising internal steel baffles extending inwardly from the steel shell walls.” The court interpreted that language as “a means . . . for performing a specified function,” subject to 35 U.S.C. § 112, paragraph 6, which provides that such a claim “shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” Looking to the specification of the ’798 patent, the court noted that “every textual reference in the Specification and its diagrams show baffle deployment at an angle other than 90 to the wall faces” and that “placement of the baffles at such angles creates an intermediate interlocking, but not solid, internal barrier.” The district court therefore ruled that, for purposes of the ’798 patent, a baffle must “extend inward from the steel shell walls at an oblique or acute angle to the wall face” and must form part of an

interlocking barrier in the interior of the wall module. Because Mr. Phillips could not prove infringement under that claim construction, the district court granted summary judgment of noninfringement.

A panel of this court affirmed on both issues. As to the patent infringement claims, the panel was divided. The majority sustained the district court's summary judgment of noninfringement, although on different grounds. The dissenting judge would have reversed the summary judgment of noninfringement.

* * *

This court agreed to rehear the appeal en banc and vacated the judgment of the panel. [W]e reverse the portion of the court's judgment addressed to the issue of infringement.

I

Claim 1 of the '798 patent is representative of the asserted claims with respect to the use of the term "baffles." It recites:

Building modules adapted to fit together for construction of fire, sound and impact resistant security barriers and rooms for use in securing records and persons, comprising in combination, an outer shell . . . , sealant means . . . and further means disposed inside the shell for increasing its load bearing capacity comprising internal steel baffles extending inwardly from the steel shell walls.

* * *

II

The first paragraph of section 112 of the Patent Act, 35 U.S.C. § 112, states that the specification

shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same. . . .

The second paragraph of section 112 provides that the specification

shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Those two paragraphs of section 112 frame the issue of claim interpretation for us. The second paragraph requires us to look to the language of the claims to determine what "the applicant regards as his invention." On the other hand, the first paragraph requires that the specification describe the invention set forth in the claims. The principal question that this case presents to us is the extent to which we should resort to and rely on a patent's specification in seeking to ascertain the proper scope of its claims.

This is hardly a new question. The role of the specification in claim construction has been an issue in patent law decisions in this country for nearly two centuries. We addressed the relationship between the specification and the claims at some length in our en banc opinion in *Markman v. Westview Instruments, Inc.* We again summarized the applicable principles in *Vitronics Corp. v. Conception, Inc.*, and more recently in *Innova/Pure Water, Inc. v. Safari*

Water Filtration Systems, Inc. What we said in those cases bears restating, for the basic principles of claim construction outlined there are still applicable, and we reaffirm them today. We have also previously considered the use of dictionaries in claim construction. What we have said in that regard requires clarification.

A

It is a “bedrock principle” of patent law that “the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Innova*, 381 F.3d at 1115. That principle has been recognized since at least 1836, when Congress first required that the specification include a portion in which the inventor “shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.” Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119. In the following years, the Supreme Court made clear that the claims are “of primary importance, in the effort to ascertain precisely what it is that is patented.” *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876). Because the patentee is required to “define precisely what his invention is,” the Court explained, it is “unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.” *White v. Dunbar*, 119 U.S. 47, 52 (1886).

We have frequently stated that the words of a claim “are generally given their ordinary and customary meaning.” *Vitronics*, 90 F.3d at 1582. We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. That starting point is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art.

Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. This court explained that point well in *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998):

It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor’s words that are used to describe the invention—the inventor’s lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

B

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim

construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Innova*, 381 F.3d at 1116. Those sources include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.*

1

Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms. To begin with, the context in which a term is used in the asserted claim can be highly instructive. To take a simple example, the claim in this case refers to “steel baffles,” which strongly implies that the term “baffles” does not inherently mean objects made of steel.

Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term. Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.

2

The claims, of course, do not stand alone. Rather, they are part of “a fully integrated written instrument,” *Markman*, 52 F.3d at 978, consisting principally of a specification that concludes with the claims. For that reason, claims “must be read in view of the specification, of which they are a part.” *Id.* at 979. As we stated in *Vitronics*, the specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” 90 F.3d at 1582.

This court and its predecessors have long emphasized the importance of the specification in claim construction. In *Autogiro Co. of America v. United States*, 384 F.2d 391, 397-98 (Ct. Cl. 1967), the Court of Claims characterized the specification as “a concordance for the claims,” based on the statutory requirement that the specification “describe the manner and process of making and using” the patented invention. The Court of Customs and Patent Appeals made a similar point.

Shortly after the creation of this court, Judge Rich wrote that “[t]he descriptive part of the specification aids in ascertaining the scope and meaning of the claims inasmuch as the words of the claims must be based on the

description. The specification is, thus, the primary basis for construing the claims.” *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985).

The importance of the specification in claim construction derives from its statutory role. The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in “full, clear, concise, and exact terms.” 35 U.S.C. § 112, para. 1. In light of the statutory directive that the inventor provide a “full” and “exact” description of the claimed invention, the specification necessarily informs the proper construction of the claims. In *Renishaw*, this court summarized that point succinctly:

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.

158 F.3d at 1250.

Consistent with that general principle, our cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs. In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.

The pertinence of the specification to claim construction is reinforced by the manner in which a patent is issued. The Patent and Trademark Office (“PTO”) determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction “in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must “conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.” 37 C.F.R. § 1.75(d)(1). It is therefore entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims.

3

In addition to consulting the specification, we have held that a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which we have designated as part of the “intrinsic evidence,” consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.

Furthermore, like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent. Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes. Nonetheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

C

Although we have emphasized the importance of intrinsic evidence in claim construction, we have also authorized district courts to rely on extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980, citing *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 546 (1870). However, while extrinsic evidence “can shed useful light on the relevant art,” we have explained that it is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004).

Within the class of extrinsic evidence, the court has observed that dictionaries and treatises can be useful in claim construction. We have especially noted the help that technical dictionaries may provide to a court “to better understand the underlying technology” and the way in which one of skill in the art might use the claim terms. Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention. Such evidence, we have held, may be considered if the court deems it helpful in determining “the true meaning of language used in the patent claims.” *Markman*, 52 F.3d at 980.

We have also held that extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field. See *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998). However, conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony “that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.” *Key Pharms.*, 161 F.3d at 716.

We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms, for several reasons. First, extrinsic evidence by definition is not part of the patent

and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning. Second, while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent. Third, extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence. The effect of that bias can be exacerbated if the expert is not one of skill in the relevant art or if the expert's opinion is offered in a form that is not subject to cross-examination. Fourth, there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question. In the course of litigation, each party will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff. Finally, undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the "indisputable public records consisting of the claims, the specification and the prosecution history," thereby undermining the public notice function of patents. *Southwall Techs.*, 54 F.3d at 1578.

In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence. Nonetheless, because extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence. In exercising that discretion, and in weighing all the evidence bearing on claim construction, the court should keep in mind the flaws inherent in each type of evidence and assess that evidence accordingly.

III

Although the principles outlined above have been articulated on numerous occasions, some of this court's cases have suggested a somewhat different approach to claim construction, in which the court has given greater emphasis to dictionary definitions of claim terms and has assigned a less prominent role to the specification and the prosecution history. The leading case in this line is *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002). . . . [*Texas Digital*] placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and prosecution history. While the court noted that the specification must be consulted in every case, it suggested a methodology for claim interpretation in which the specification should be consulted only after a determination is made, whether based on a dictionary, treatise, or other source, as to the ordinary meaning or meanings of the claim term in dispute. Even then, recourse to the specification is limited to determining whether the specification excludes one of the meanings derived from the dictionary, whether the presumption in favor of the dictionary definition of the claim term has been overcome by "an explicit

definition of the term different from its ordinary meaning,” or whether the inventor “has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.” 308 F.3d at 1204. In effect, the *Texas Digital* approach limits the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term if the specification requires the court to conclude that fewer than all the dictionary definitions apply, or if the specification contains a sufficiently specific alternative definition or disavowal. See, e.g., *Texas Digital*, 308 F.3d at 1202 (“unless compelled otherwise, a court will give a claim term the full range of its ordinary meaning”). That approach, in our view, improperly restricts the role of the specification in claim construction.

Assigning such a limited role to the specification, and in particular requiring that any definition of claim language in the specification be express, is inconsistent with our rulings that the specification is “the single best guide to the meaning of a disputed term,” and that the specification “acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” *Vitronics*, 90 F.3d at 1582.

The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. Properly viewed, the “ordinary meaning” of a claim term is its meaning to the ordinary artisan after reading the entire patent. Yet heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification. The patent system is based on the proposition that claims cover only the invented subject matter. As the Supreme Court has stated, “[i]t seems to us that nothing can be more just and fair, both to the patentee and the public, than that the former should understand, and correctly describe, just what he has invented, and for what he claims a patent.” *Merrill v. Yeomans*, 94 U.S. at 573-74. The use of a dictionary definition can conflict with that directive because the patent applicant did not create the dictionary to describe the invention. Thus, there may be a disconnect between the patentee’s responsibility to describe and claim his invention, and the dictionary editors’ objective of aggregating all possible definitions for particular words. . . .

[W]e do not intend to preclude the appropriate use of dictionaries. Dictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words and have been used both by our court and the Supreme Court in claim interpretation. A dictionary definition has the value of being an unbiased source “accessible to the public in advance of litigation.” *Vitronics*, 90 F.3d at 1585. As we said in *Vitronics*, judges are free to consult dictionaries and technical treatises

at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.

Id. at 1584 n.6.

We also acknowledge that the purpose underlying the *Texas Digital* line of cases—to avoid the danger of reading limitations from the specification into the claim—is sound. Moreover, we recognize that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice. However, the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court's focus remains on understanding how a person of ordinary skill in the art would understand the claim terms. For instance, although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment. That is not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.

To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent.

In the end, there will still remain some cases in which it will be hard to determine whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature. While that task may present difficulties in some cases, we nonetheless believe that attempting to resolve that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification.

In *Vitronics*, this court grappled with the same problem and set forth guidelines for reaching the correct claim construction and not imposing improper limitations on claims. The underlying goal of our decision in *Vitronics* was to increase the likelihood that a court will comprehend how a person of ordinary skill in the art would understand the claim terms. In that process, we recognized that there is no magic formula or catechism for conducting claim construction. Nor is the court barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence. For example, a judge who encounters a claim term while reading a patent might consult a general purpose or specialized dic-

tionary to begin to understand the meaning of the term, before reviewing the remainder of the patent to determine how the patentee has used the term. The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law. In *Vitronics*, we did not attempt to provide a rigid algorithm for claim construction, but simply attempted to explain why, in general, certain types of evidence are more valuable than others. Today, we adhere to that approach and reaffirm the approach to claim construction outlined in that case, in *Markman*, and in *Innova*. We now turn to the application of those principles to the case at bar.

IV

A

The critical language of claim 1 of the '798 patent—"further means disposed inside the shell for increasing its load bearing capacity comprising internal steel baffles extending inwardly from the steel shell walls"—imposes three clear requirements with respect to the baffles. First, the baffles must be made of steel. Second, they must be part of the load-bearing means for the wall section. Third, they must be pointed inward from the walls. Both parties, stipulating to a dictionary definition, also conceded that the term "baffles" refers to objects that check, impede, or obstruct the flow of something. The intrinsic evidence confirms that a person of skill in the art would understand that the term "baffles," as used in the '798 patent, would have that generic meaning.

The other claims of the '798 patent specify particular functions to be served by the baffles. For example, dependent claim 2 states that the baffles may be "oriented with the panel sections disposed at angles for deflecting projectiles such as bullets able to penetrate the steel plates." The inclusion of such a specific limitation on the term "baffles" in claim 2 makes it likely that the patentee did not contemplate that the term "baffles" already contained that limitation. See *Dow Chem. Co. v. United States*, 226 F.3d 1334, 1341-42 (Fed. Cir. 2000) (concluding that an independent claim should be given broader scope than a dependent claim to avoid rendering the dependent claim redundant). Independent claim 17 further supports that proposition. It states that baffles are placed "projecting inwardly from the outer shell at angles tending to deflect projectiles that penetrate the outer shell." That limitation would be unnecessary if persons of skill in the art understood that the baffles inherently served such a function. See *TurboCare*, 264 F.3d at 1123 (claim terms should not be read to contain a limitation "where another claim restricts the invention in exactly the [same] manner"). Dependent claim 6 provides an additional requirement for the baffles, stating that "the internal baffles of both outer panel sections overlap and interlock at angles providing deflector panels extending from one end of the module to the other." If the baffles recited in claim 1 were inherently placed at specific angles, or interlocked to form an intermediate barrier, claim 6 would be redundant.

The specification further supports the conclusion that persons of ordinary skill in the art would understand the baffles recited in the '798 patent to be load-bearing objects that serve to check, impede, or obstruct flow. At several

points, the specification discusses positioning the baffles so as to deflect projectiles. *See* '798 patent, col. 2, ll. 13-15; *id.*, col. 5, ll. 17-19. The patent states that one advantage of the invention over the prior art is that "[t]here have not been effective ways of dealing with these powerful impact weapons with inexpensive housing." *Id.*, col. 3, ll. 28-30. While that statement makes clear the invention envisions baffles that serve that function, it does not imply that in order to qualify as baffles within the meaning of the claims, the internal support structures must serve the projectile-deflecting function in all the embodiments of all the claims. The specification must teach and enable all the claims, and the section of the written description discussing the use of baffles to deflect projectiles serves that purpose for claims 2, 6, 17, and 23, which specifically claim baffles that deflect projectiles.

The specification discusses several other purposes served by the baffles. For example, the baffles are described as providing structural support. The patent states that one way to increase load-bearing capacity is to use "at least in part inwardly directed steel baffles 15, 16." '798 patent, col. 4, ll. 14-15. The baffle 16 is described as a "strengthening triangular baffle." *Id.*, col. 4, line 37. Importantly, Figures 4 and 6 do not show the baffles as part of an "intermediate interlocking, but not solid, internal barrier." In those figures, the baffle 16 simply provides structural support for one of the walls, as depicted below:

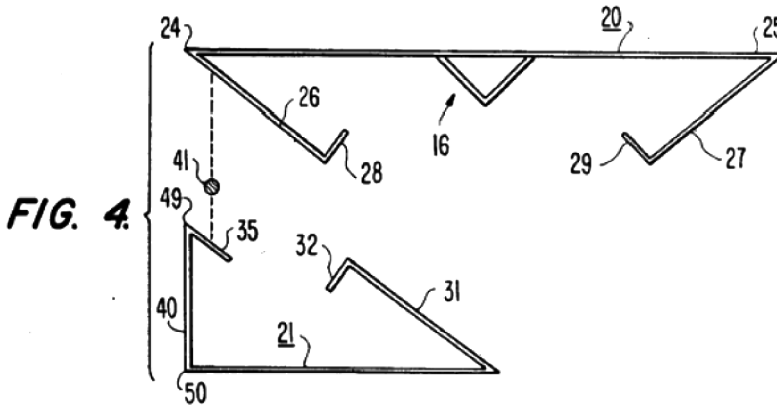
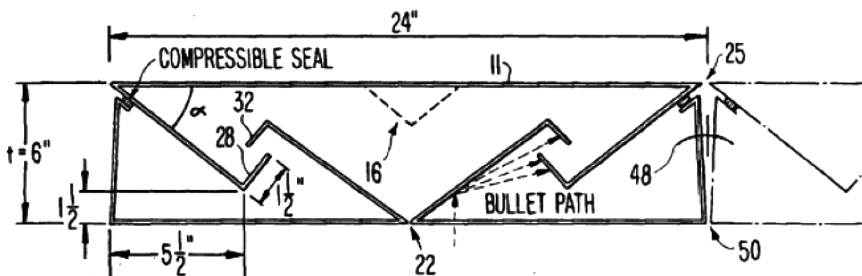
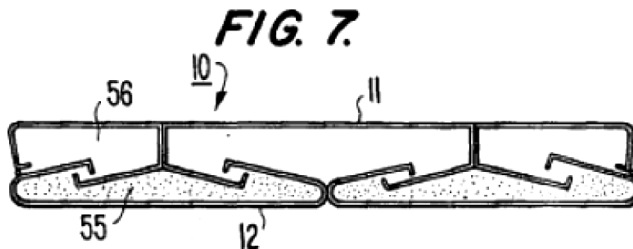


FIG. 6.



Other uses for the baffles are listed in the specification as well. In Figure 7, the overlapping flanges “provide for overlapping and interlocking the baffles to produce substantially an intermediate barrier wall between the opposite [wall] faces”:



'798 patent, col. 5, ll. 26-29. Those baffles thus create small compartments that can be filled with either sound and thermal insulation or rock and gravel to stop projectiles. *Id.*, col. 5, ll. 29-34. By separating the interwall area into compartments (see, e.g., compartment 55 in Figure 7), the user of the modules can choose different types of material for each compartment, so that the module can be “easily custom tailored for the specific needs of each installation.” *Id.*, col. 5, ll. 36-37. When material is placed into the wall during installation, the baffles obstruct the flow of material from one compartment to another so that this “custom tailoring” is possible.

The fact that the written description of the '798 patent sets forth multiple objectives to be served by the baffles recited in the claims confirms that the term “baffles” should not be read restrictively to require that the baffles in each case serve all of the recited functions. We have held that “[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives.” *Liebel-Flarsheim*, 358 F.3d at 908. Although deflecting projectiles is one of the advantages of the baffles of the '798 patent, the patent does not require that the inward extending structures always be capable of performing that function. Accordingly, we conclude that a person of skill in the art would not interpret the disclosure and claims of the '798 patent to mean that a structure extending inward from one of the wall faces is a “baffle” if it is at an acute or obtuse angle, but is not a “baffle” if it is disposed at a right angle.

* * *

VI

In our order granting rehearing en banc, we asked the parties to brief various questions, including the following: “Consistent with the Supreme Court’s decision in *Markman v. Westview Instruments*, 517 U.S. 370 (1996), and our en banc decision in *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998), is it appropriate for this court to accord any deference to any aspect of trial court claim construction rulings? If so, on what aspects, in what circumstances, and to what extent?” After consideration of the matter, we have

decided not to address that issue at this time. We therefore leave undisturbed our prior en banc decision in *Cybor*.

* * *

MAYER, Circuit Judge, with whom NEWMAN, Circuit Judge, joins, dissenting.

Now more than ever I am convinced of the futility, indeed the absurdity, of this court's persistence in adhering to the falsehood that claim construction is a matter of law devoid of any factual component. Because any attempt to fashion a coherent standard under this regime is pointless, as illustrated by our many failed attempts to do so, I dissent.

This court was created for the purpose of bringing consistency to the patent field. *See* H.R. Rep. No. 312, 97th Cong., 1st Sess. 20-23 (1981). Instead, we have taken this noble mandate, to reinvigorate the patent and introduce predictability to the field, and focused inappropriate power in this court. In our quest to elevate our importance, we have, however, disregarded our role as an appellate court; the resulting mayhem has seriously undermined the legitimacy of the process, if not the integrity of the institution.

In the name of uniformity, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), held that claim construction does not involve subsidiary or underlying questions of fact and that we are, therefore, unbridled by either the expertise or efforts of the district court.¹ What we have wrought, instead, is the substitution of a black box, as it so pejoratively has been said of the jury, with the black hole of this court. Out of this void we emit “legal” pronouncements by way of “interpretive necromancy”; these rulings resemble reality, if at all, only by chance. Regardless, and with a blind eye to the consequences, we continue to struggle under this irrational and reckless regime, trying every alternative—dictionaries first, dictionaries second, never dictionaries, etc., etc., etc.

Again today we vainly attempt to establish standards by which this court will interpret claims. But after proposing no fewer than seven questions, receiving more than thirty *amici curiae* briefs, and whipping the bar into a frenzy of expectation, we say nothing new, but merely restate what has become the practice over the last ten years—that we will decide cases according to whatever mode or method results in the outcome we desire, or at least allows us a seemingly plausible way out of the case. I am not surprised by this. Indeed, there can be no workable standards by which this court will interpret claims so long as we are blind to the factual component of the task.

* * *

While this court may persist in the delusion that claim construction is a purely legal determination, unaffected by underlying facts, it is plainly not the case. Claim construction is, or should be, made in context: a claim should

1. The Supreme Court did not suggest in affirming *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (1995) (en banc), that claim construction is a purely legal question. 517 U.S. 370 (1996). It held only that, as a policy matter, the judge, as opposed to the jury, should determine the meaning of a patent claim. *See Cybor*, 138 F.3d at 1464 (Mayer, C.J., dissenting) (explaining that “the [Supreme] Court chose not to accept our formulation of claim construction: as a pure question of law to be decided *de novo* in all cases on appeal”).

be interpreted both from the perspective of one of ordinary skill in the art and in view of the state of the art at the time of invention. These questions, which are critical to the correct interpretation of a claim, are inherently factual. They are hotly contested by the parties, not by resort to case law as one would expect for legal issues, but based on testimony and documentary evidence. During so called *Markman* “hearings,” which are often longer than jury trials, parties battle over experts offering conflicting evidence regarding who qualifies as one of ordinary skill in the art; the meaning of patent terms to that person; the state of the art at the time of the invention; contradictory dictionary definitions and which would be consulted by the skilled artisan; the scope of specialized terms; the problem a patent was solving; what is related or pertinent art; whether a construction was disallowed during prosecution; how one of skill in the art would understand statements during prosecution; and on and on. In order to reconcile the parties’ inconsistent submissions and arrive at a sound interpretation, the district court is required to sift through and weigh volumes of evidence. While this court treats the district court as an intake clerk, whose only role is to collect, shuffle and collate evidence, the reality, as revealed by conventional practice, is far different.

* * *

While the court flails about in an attempt to solve the claim construction “conundrum,” the solution to our plight is straightforward. We simply must follow the example of every other appellate court, which, regarding the vast majority of factual questions, reviews the trial court for clear error. Therefore, not only is it more efficient for the trial court to construct the record, the trial court is *better*, that is, more accurate, by way of both position and practice, at finding facts than appellate judges. Our rejection of this fundamental premise has resulted, not surprisingly, in several serious problems, including increased litigation costs, needless consumption of judicial resources, and uncertainty, as well as diminished respect for the court and less “decisional accuracy.” We should abandon this unsound course.

If we persist in deciding the subsidiary factual components of claim construction without deference, there is no reason why litigants should be required to parade their evidence before the district courts or for district courts to waste time and resources evaluating such evidence. It is excessive to require parties, who “have already been forced to concentrate their energies and resources on persuading the trial judge that their account of the facts is the correct one,” to “persuade three more judges at the appellate level.” *Anderson*, 470 U.S. at 575. If the proceedings before the district court are merely a “tryout on the road,” *id.*, as they are under our current regimen, it is wasteful to require such proceedings at all. Instead, all patent cases could be filed in this court; we would determine whether claim construction is necessary, and, if so, the meaning of the claims. Those few cases in which claim construction is not dispositive can be remanded to the district court for trial. In this way, we would at least eliminate the time and expense of the charade currently played out before the district court.

Eloquent words can mask much mischief. The court’s opinion today is akin to rearranging the deck chairs on the Titanic—the orchestra is playing as if nothing is amiss, but the ship is still heading for Davey Jones’ locker.

Comments

1. **The Phillips Interpretive Road Map and the Primacy of Context.** *Phillips* reaffirmed *Vitronics*, one of the first important claim interpretation cases following *Markman II*. In *Vitronics*, the court identified two different types of interpretive evidence: intrinsic and extrinsic. The former comprises the claims, specification, and prosecution history; the latter includes such things as expert testimony, dictionaries, and treatises, all of which are external to the patent document. The court expressed a preference for intrinsic evidence because it forms part of the public record and is consistent with the notice function of the patent claim. As the court stated in *Vitronics*:

The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention.

90 F.3d 1576, 1584 (Fed. Cir. 1996). While the intrinsic/extrinsic distinction is helpful, *Vitronics* failed to provide a workable framework that would allow a judge to determine which types of interpretive sources are more relevant than others.

It was thought that *Phillips* would provide that framework, but the court gave us little more than what was already established in patent doctrine and shied away from establishing interpretive rules. While *Phillips* reaffirmed the principle that claims are to be given their “ordinary and customary meaning” as interpreted by a person having ordinary skill in the art at the time of invention, the court also emphasized the importance of context, and gave the specification a more important role in claim interpretation. The claims, of course, are the starting point of any interpretive analysis. But the specification was “always highly relevant to the claim construction analysis”; indeed, it is the single best guide to the meaning of a disputed term, and is “usually dispositive.” As the Federal Circuit pithily noted in one of its earlier decisions: “Specifications teach. Claims claim.” *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985). But *Phillips* was less enthusiastic about the value of prosecution history. While noting that “the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution,” the court cautioned that because “the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” 415 F.3d at 1317. But arguments made during prosecution remain important. See *MBO Laboratories v. Becton Dickinson & Co.*, 474 F.3d 1423, 1430 (Fed. Cir. 2007) (stating “[p]rosecution arguments . . . which draw distinctions between the patented invention and the prior art are useful for determining whether the patentee intended to surrender territory, since they indicate in the inventor's own words what the invention is not”).

Extrinsic evidence is defined as “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” 415 F.3d at 1317. The *Phillips* court—echoing *Vitronics*—noted that extrinsic evidence is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* The court provided several reasons for this preference, but they all can be explained by the fact that extrinsic evidence, to varying degrees, is not as publicly available and is more of a moving target than the written intrinsic evidence, and therefore, does not serve the public notice function as well. But some forms of extrinsic evidence are more acceptable than others. For instance, dictionaries, particularly technical dictionaries, are viewed favorably because they “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” 415 F.3d at 1318. The least acceptable form of extrinsic evidence is expert testimony, particularly “conclusory, unsupported assertions by experts as to the definition of a claim term,” *id.*, and inventor testimony, which is “of little probative value for purposes of claim construction.” *E-Pass Technologies, Inc. v. 3Com Corp.*, 343 F.3d 1364, 1370 n.5 (Fed. Cir. 2003). See also *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000) (stating “litigation-derived inventor testimony in the context of claim construction . . . is entitled to little, if any, probative value”). In short, “extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1319.

In part because *Phillips* emphasized context over rules, there continues to be an ongoing debate among Federal Circuit judges and commentators about the proper role of intrinsic and extrinsic evidence, which is comparable to the longstanding debate within contract law circles that centers around the contrasting views of Arthur Corbin and Samuel Williston. Williston assumed a formalist approach to contract interpretation, what has been called the classical contract model. This model emphasized language of the contract and was reluctant to step outside the four corners of the contract. In contrast, Corbin, in addition to the language of the contract, stressed the importance of custom and trade usage, items extrinsic to the contract and what Corbin referred to as “undisputed contexts.” *Phillips* is more sympathetic to the Corbin approach. Indeed, several other notable thinkers such as Karl Llewellyn, in *THE COMMON LAW TRADITION: DECIDING APPEALS* 268-85 (1960) (discussing what he referred to as “situation sense”), Pierre Bourdieu, in *OUTLINE OF A THEORY OF PRACTICE* 72-95 (Richard Nice trans., 1977) (discussing the “habitus”), and John Searle, in *The Construction of Social Reality* 130 (1995) (referring to the “Background”), have expressed the importance of culture and extrinsic context in discerning meaning. Perhaps the most influential figure to do so was Ludwig Wittgenstein in his *Philosophical Investigations*, wherein he famously wrote, “the meaning of a word is its use in the language.” *PHILOSOPHICAL INVESTIGATIONS* § 43 (G.E.M. Anscombe trans., 2d ed. 1958). For a discussion of these two schools of interpretation, see Craig Allen Nard, 14 *HARV. J.L. & TECH.* 1 (2000).

2. ***The Phillips Dissent and District Court Perspective.*** The Federal Circuit's claim interpretation jurisprudence has arguably been the most significant and relevant patent law issue for district court judges. See Hon. Kathleen O'Malley, *The Past, Present and Future of the Federal Circuit*, 54 CASE W. RES. L. REV. 671, 673 (2004) (stating "[w]ithin the realm of patent law, the CAFC has had, in [district court judges'] view, its biggest impact in the claim construction area"). The issue of standard of review of district court claim interpretations is particularly germane to the district court judge's job. Judge Patti Saris of the U.S. District Court in Massachusetts, for example, views *de novo* review as a "key legal development" following *Markman*. She expressed her concerns in terms of institutional competence:

According to the literature, over fifty percent of all *Markman* hearings now involve the taking of evidence. Even in those cases where I do not hear evidence, I see terrific demonstratives. Because I am a visual learner, I understand evidence presented to me better when I receive a tutorial by live or video testimony, rather than by a cold affidavit. This is important because a *de novo* standard of review by definition is a fresh look by three people on an appellate level who did not have an opportunity to attend the hearing. . . . My perspective . . . is that there should be more deference given to the interpretation of the trial judge who had the opportunity to see, hear, and look at evidence.

Construction from the Perspective of the District Judge, 54 CASE W. RES. L. 671, 679 (2004). And Judge Marsha J. Pechman of the U.S. District Court for the Western District of Washington put it this way: Given the high reversal rate on claim construction, "you might as well throw darts." BNA PTCJ Daily, Sept 14, 2005. These views were reflected in the *Phillips* dissent, which began by bemoaning the "futility" and "absurdity" of "adhering to the falsehood that claim construction is a matter of law devoid of any factual component." According to the dissent, "[c]laim construction is, or should be, made in context: a claim should be interpreted both from the perspective of one of ordinary skill in the art and in view of the state of the art at the time of invention." 415 F.3d at 1332.

3. ***The Role of the Artisan in Claim Interpretation.*** As noted in Comment 1, it is a basic tenet of patent law — reaffirmed in *Phillips* — that claims are to be construed through the eyes of a person having ordinary skill in the art. But by circumscribing the role of expert testimony, one may ask whether *Phillips* and *Vitronics* pay too little attention to the central role of the artisan and technological context beyond the patent document. As Judge William Young stated in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 227 n.23 (D. Mass. 2004) (emphasis in original):

At first glance, the extrinsic evidence rule in *Vitronics* appears to create somewhat of a conundrum, in that it discourages resort to extrinsic evidence while at the same time urging courts to begin claim construction by considering the plain and customary meaning of a term *as understood by one skilled in the art*. How does a Court decipher the plain and customary meaning of a term as understood by one skilled in the art without resorting to extrinsic evidence about how one skilled in the art would construe the term?

The role of the artisan seems to be particularly important when words of degree (e.g., "substantial" or "about") are used in claims. See *Bj Services Co.*

v. Halliburton Energy Services, Inc., 338 F.3d 1368, 1372 (Fed. Cir. 2003) (noting that when words of degree are employed, the “question becomes whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification”). Yet the Federal Circuit has noted that “a sound claim construction need not always purge every shred of ambiguity.” *Acumed LLC v. Stryker Corporation*, 483 F.3d 800, 806 (Fed. Cir. 2007). See also *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) (“[A]fter the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.”); *Modine Mfg. Co. v. U.S. Int’l Trade Comm’n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996) (whether claim limitation requiring diameter of “about 0.040 inch” embodied held a matter of “technologic fact”).

4. **Canons of Claim Construction.** Throughout several decades of patent jurisprudence, the common law has developed various canons of claim construction. Two of the more interesting canons are: (1) “claims should be so construed, if possible, as to sustain their validity.” *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999). This canon is sometimes referred to as the “validity maxim.” See *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1423, 1432 (Fed. Cir. 2007); and (2) “where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning,” the notice function of the claim is best served by adopting the narrower meaning. See *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996). Other Federal Circuit panels have endorsed this canon. See, e.g., *Ethicon Endo-Surgery, Inc. v. United States Surgical Corp.*, 93 F.3d 1572, 1581-82 (Fed. Cir. 1996); *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998).

Recall that *Phillips* noted the court has limited the validity maxim, stating “we have limited the maxim to cases in which ‘the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.’” 415 F.3d at 1327 According to *Phillips*, “we have looked to whether it is reasonable to infer that the PTO would not have issued an invalid patent, and that the ambiguity in the claim language should therefore be resolved in a manner that would preserve the patent’s validity.” *Id.* Is limiting the validity maxim to ambiguous claims consistent with the notice function of patent law, embodied in § 112, ¶ 2? Shouldn’t a claim that is ambiguous be invalidated under § 112? Similarly, one could ask if the *Athletic Alternatives* principle is consistent with § 112, ¶ 2. As Judge Nies wrote in her concurrence in *Athletic Alternatives*:

I do not agree that the adoption of the narrower of two equally plausible interpretations somehow flows from the requirement of section 112, ¶ 2 that the patentee must particularly point out and distinctly claim the subject matter which he regards as his invention. The majority analysis is illogical to me. Narrowness cannot be equated with definiteness. The majority, in effect, eviscerates the requirement of section 112, ¶ 2 for the patentee to particularly point out and distinctly claim his invention while purporting to rely on it.

73 F.3d at 1583.

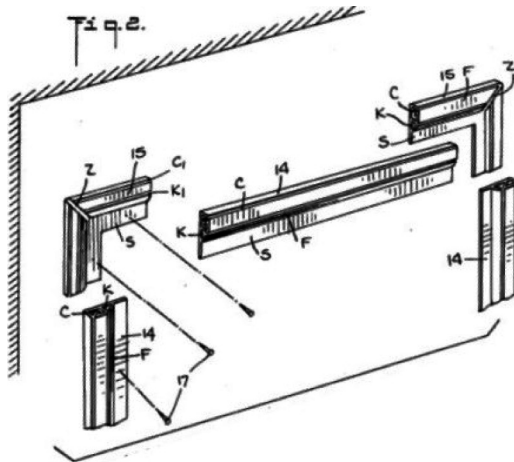
UNIQUE CONCEPTS, INC. v. BROWN**939 F.2d 1558 (Fed. Cir. 1991)**

LOURIE, Circuit Judge.

BACKGROUND**A. The Patent in Suit**

Unique is the exclusive licensee under U.S. Patent 4,108,260 ('260 patent), entitled "Fabric Wall Coverings," issued April 19, 1977, and owned by Floyd M. Baslow. Contrary to its title, the patent is not directed to wall coverings themselves, but to an "assembly of border pieces" used to attach a fabric wall covering to a wall. The assembly is made up of a number of "right angle corner border pieces" and "linear border pieces" which are arranged so as to form a frame around the area of a wall to be covered.

Below is Fig. 2 from the '260 patent, showing an exploded view of the assembly of border pieces forming the framework.



The '260 patent issued from application Serial No. 680,703, filed April 27, 1976 (Baslow application), which as originally filed contained 14 claims. Claim 1, the only independent claim, recited an assembly comprising "linear border pieces and right angle corner border pieces," each of the border pieces having a raised face, a storage channel, and a keyway. The original claims of the Baslow application were rejected by the Patent and Trademark Office (PTO) as being unpatentable in view of various references. The Examiner found that the references "show frames including corners in arrangements similar to that of applicant. . . ."

In response, the applicant amended his claims and argued against the references, stating that "[t]he main advantage of the present invention is that it greatly simplifies the mounting of a fabric covering. . . . Thus an amateur can practice the present invention. . . ."

The next item in the file history is a notice of allowability together with an examiner's amendment cancelling claims 1-3 and 5-14, and amending claim 4

to depend from claim 15. Application claims 15-17 and 4 issued as claims 1-4 of the '260 patent, respectively. Claim 1, the sole independent claim, reads:

1. An assembly of border pieces for creating a framework attachable to a wall or other flat surface for mounting a fabric sheet which is cut to dimensions at least sufficient to cover the surface, *said assembly comprising linear border pieces and right angle corner border pieces* which are arranged in end-to-end relation to define a framework that follows the perimeter of the area to be covered, *each piece* including a raised face, a storage channel running adjacent the outer edge of the piece and having a narrow inlet communicating with said face, the portion of the selvage of said sheet which includes fabric material in excess of that necessary to cover said surface being stuffed in said storage channel so that the exposed selvage of the sheet lies against said face to present a smooth appearance which extends to said inlet and is directly adjacent said perimeter, said linear pieces being formed of an integral one piece plastic material of sufficient elasticity to permit dilation of said inlet whereby said inlet may be temporarily expanded to admit said excess material and then contracted to retain said excess material in said storage channel.

(Emphasis added).

B. The Proceedings in the District Court

Unique brought the present suit in 1986, alleging that certain products made by Brown infringed claims 1-3 of the '260 patent. . . . Brown maintained that its accused products do not infringe [because] the accused products do not have corner pieces which were *preformed* at a right angle, but instead employ two linear pieces which are each mitered, *i.e.*, cut at a 45 degree angle, and then placed together to form a right angle. . . .

A trial was held, at which each party, by agreement, presented as its only witness a patent expert. After hearing the testimony, the judge entered judgment for Brown, finding that . . . the mitered linear pieces used by Brown do not meet the claim language "right angle corner border pieces," either literally or under the doctrine of equivalents. Unique appealed.

DISCUSSION

The '260 patent claims a framework for mounting a fabric sheet "comprising linear border pieces and right angle corner border pieces." The district court found the patent not infringed because, *inter alia*, the language "right angle corner pieces" is limited to preformed corner pieces, whereas the mitered linear pieces used by Brown do not meet this limitation either literally or under the doctrine of equivalents.

Unique argues that the district court erred in finding that the claims do not literally cover assemblies having mitered corners. To ascertain the meaning of claims, we consider three sources: the claims, the specification, and the prosecution history.

The language of claim 1 makes unambiguous reference to two distinct elements of the claimed structure: linear border pieces and right angle corner pieces. If, as Unique argues, linear border pieces of framing material, whose ends are mitered, are the same as linear border pieces *and* a right angle corner piece, the recitation of both types of pieces is redundant. Unique's argument for merging the two types of claim elements into one also violates the oft-quoted "all elements rule," the essence of which is that to prove infringement,

every element in the claim must be found in the accused device either literally or equivalently. The district court thus correctly held that the plain language of the claim includes two distinct types of elements, including right angle corner border pieces, thereby precluding literal infringement.

The specification also shows that the claim language “right angle corner border piece” means a single preformed piece. The specification repeatedly refers to the preformed pieces 15 and 16, using only the words “right angle” border pieces or “corner pieces.” In addition, the drawings show only preformed corner pieces and no mitered pieces.

The specification does refer once to “improvise[d] corner pieces” as an alternative to the preformed pieces:

Instead of using preformed right-angle corner pieces of the type previously disclosed, one may improvise corner pieces by miter-cutting the ends of a pair of short linear border pieces at right angles to each other and providing a space between the cut ends to define the necessary storage slot. For this purpose, a temporary spacer may be used to provide exactly the right amount of storage space. The advantage of such corner pieces resides in the fact that linear pieces may be mass-produced at low cost by continuous extrusion, whereas preformed corner pieces must be molded or otherwise fabricated by more expensive techniques. On the other hand, *a preformed corner piece is somewhat easier for a do-it-yourselfer to work with.*

Col. 8, lines 28-41 (emphasis added). However, this reference does not negate the claim language clearly reciting right angle corner pieces. This paragraph, rather than providing an illustration of a right angle corner border piece, as the dissent indicates, provides an alternative to it. The language right angle corner border piece is too clear to encompass linear pieces that are not right angle corner pieces. The fact that mitered linear border pieces meet to form a right angle corner does not make them right angle corner pieces, when the claim separately recites both linear border pieces and right angle corner border pieces. Such an interpretation would run counter to the clear meaning of the language. Linear border pieces are not right angle corner border pieces. Both types of pieces are required by the claim.

The statute requires that an inventor particularly point out and distinctly claim the subject matter of his invention. 35 U.S.C. § 112 (1988). It would run counter to this statutory provision for an applicant for patent to expressly state throughout his specification and in his claims that his invention includes right angle corner border pieces and then be allowed to avoid that claim limitation in a later infringement suit by pointing to one paragraph in his specification stating an alternative that lacks that limitation, and thus interpret the claim contrary to its plain meaning. Such a result would encourage an applicant to escape examination of a more broadly-claimed invention by filing narrow claims and then, after grant, asserting a broader scope of the claims based on a statement in the specification of an alternative never presented in the claims for examination.

The claims as granted contain the right angle corner border piece limitation. All the limitations of a claim must be considered meaningful, and Brown’s avoidance of that limitation avoids literal infringement.

It is also well-established that subject matter disclosed but not claimed in a patent application is dedicated to the public. *Edward Miller & Co. v. Bridgeport Brass Co.*, 104 U.S. 350, 352, 26 L. Ed. 783 (1881). That is what occurred here. If Unique intended to claim mitered linear border pieces as an alternative to

its right angle corner border pieces, it had to persuade the examiner to issue such a claim. As will be shown below, Unique failed to do so.

The prosecution history also supports the district court's decision. During the prosecution of the '260 patent, the examiner understood the right angle corner pieces of Claim 1 to be distinct from mitered linear pieces, because he initially rejected the claims, citing and referring to other references as showing preformed, right angle corner pieces or braces. The applicant overcame the rejection by arguing the advantage of simplification for the do-it-yourselfer. As noted in the specification, a preformed corner piece is one of the advantages of the invention making it attractive to the do-it-yourselfer.

There then occurred a telephone interview between the attorney and the examiner, following which the Examiner cancelled certain claims. Among the cancelled claims was original Claim 9, which depended from original Claim 1 (also cancelled) and recited short linear mitered pieces as forming a right angle corner piece.

The dissent relies upon Claim 9 to construe what is now Claim 1 as including linear pieces which are mitered to form a corner piece. It interprets "linear pieces whose ends are mitered" to be a species of generic Claim 1's "right angle corner border pieces," and therefore within its scope. Such a construction is unjustified because the language of Claim 1 is clear and is inconsistent with Claim 9 being dependent thereon.

The record contains no indication of what transpired in the interview and why Claim 9 was cancelled. A plausible reason is that Claim 9 was cancelled because it was not properly dependent upon original Claim 1. The court referred to Brown's expert, who stated that the claim was cancelled because it did not encompass an invention suitable for a do-it-yourselfer. The dissent finds this expert testimony to be "wholly incredible." We do not know why Claim 9 was cancelled and cannot speculate on the reasons for the cancellation; we can only interpret the clear language of the claims as granted.

When the language of a claim is clear, as here, and a different interpretation would render meaningless express claim limitations, we do not resort to speculative interpretation based on claims not granted. See *White v. Dunbar*, 119 U.S. 47, 52 (1886) ("The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms."). Our interpretation gives full effect to the recitation of two distinct elements in the claimed structure: linear border pieces and right angle corner border pieces. It also gives full effect to the specification and the expert testimony, and a reasonable interpretation of the prosecution history.

* * *

CONCLUSION

The district court was correct in concluding that the claim language "right angle corner border pieces," properly construed with reference to the specification and prosecution history, requires a preformed corner piece.

RICH, Circuit Judge, dissenting.

* * *

In the present posture of this appeal, the sole question is whether the majority has correctly construed the meaning of a single limitation in claim 1, which claim is set forth in full in its opinion. That limitation is: “right-angle corner border pieces.” I simply disagree with the majority’s conclusions and with its attempted supporting reasoning. We arrive at different “plain meanings.”

... We construe claims in the light of the *language of the claim* itself, the *specification* on which it is based, and the whole *prosecution history*. The majority has not properly done this and, in my judgment, has demonstrably come to a wrong conclusion. Significant statements in the specification and prosecution history are misapplied. I shall begin with the specification.

As the majority states, the specification first describes and illustrates the *one-piece* corner pieces 15 and 16, outside and inside corners respectively. True, these are the only corner pieces shown in drawings. Then the specification contains the significant statement quoted in the majority opinion from the patent at col. 8, lines 28-41. (*My emphasis*):

Instead of using *preformed* right-angle corner pieces of the type previously disclosed, one may improvise *corner pieces* by miter-cutting the ends of a pair of *short* linear border pieces placed *at right angles* to each other and providing a space between the cut ends to define the necessary storage slot. For this purpose, a temporary spacer may be used to provide exactly the right amount of storage space. The *advantage of such corner pieces* resides in the fact that linear pieces may be mass-produced at low cost by continuous extrusion, whereas *preformed* corner pieces must be molded or otherwise fabricated by more expensive techniques. On the other hand, a preformed corner piece is *somewhat* easier for a do-it-yourselfer to work with.

Perhaps this is a matter, on both sides, of seeing what you choose to see. Beyond question, however, the specification discloses *two species* of right-angle corner border pieces: (1) preformed one-piece and (2) mitered, *short*, linear pieces, arranged at right angles and properly spaced at their junction. The latter are to be joined to longer linear pieces. No drawing is needed to make (2) clear. In any case, there are always, in a single assembly, both *corner* pieces and *linear* pieces, even when the second species of corner is used.

Now I turn to the contents of the file-wrapper. From day one when the application was filed these two kinds of corners were not only described but claimed and we look to this, equally with the specification, to determine the correct construction of the claim 1 language. Original claim 1, as filed, used exactly the same terminology as patent claim 1, “right-angle corner border pieces.” There were 14 original claims on day one. Among them was claim 9, depending from claim 1, reading:

9. An assembly as set forth in claim 1, wherein *said right-angle corner pieces are formed by a pair of short linear pieces whose ends are mitered and spaced from each other to define a slot therebetween* to receive the pucker of the selvage when the selvage is locked into the keyway. [*My emphasis.*]

Note that claim 9 is referring back to “right angle” corners *as described in claim 1* and is thus defining a species of that genus. Now, what does that tell one skilled in the art about the meaning of “right-angle corner border pieces”? It tells one that the claim 1 phrase is, and was clearly intended by the applicant to be, broad enough to cover the species recited in claim 9, which

the majority says it does not cover. There is a genus-species relationship between the phrase in claim 1, which never changed throughout the prosecution, and the particular form of corner piece recited in claim 9.

I have to disagree with the majority's criticism or downplaying of my use of claim 9 as a construction aid in several particulars. The majority seems to start with an *a priori* assumption of what the "clear" language of claim 1 means. On the other hand, I am looking at the genealogical record of that claim to *find out* what it means.

The majority says, "we . . . cannot speculate on the reasons for the cancellation" of claim 9 because we have no idea of the content of the 'phone conversation between the examiner and the attorney which led to cancellation, along with many other claims. I agree. The majority then *speculates* that it may have been an improper dependent claim, though it is not apparent why and the majority gives no reason. I don't care why (or whether) claim 9 was cancelled—it was simply part of the original application and sheds a bright *light* on what claim 1 was intended to mean.

I see no significance to the fact that claim 9 was cancelled because it is part of the prosecution history, *all* of which is clearly before us. The majority correctly states that we must consider the prosecution history, of which claim 9 is a significant part.

The majority opines that the alternative corner piece described in claim 9 *has not been claimed* and is therefore dedicated to the public. This strange position begs the question. Of course it has not been claimed *specifically*. The question, however, is whether it is covered by or included in claim 1, which I say it is. Therefore, its subject matter is not "dedicated to the public."

35 U.S.C. § 112, which requires claims, is irrelevant to a consideration of what claims mean. Since Brown's so-called "expert" — expert only in the sense he was a patent lawyer — knew no more than the members of this panel, his speculations are of no value to us. The citation of cases is also of no help in finding out what claims mean.

To me, claim 9 is the only evidence of record, except for the specification itself, which is of any value in construing claim 1, and I think it is of great value.

The majority seems to say that my construction of claim 1 "would render meaningless express claim limitation." I await enlightenment on what those "express limitations" are. I have already said that I read both *corner* pieces and *linear* pieces in claim 1. The debate here is over the *kinds* of corner pieces claim 1 covers. It is clear that it is not limited to unitary or preformed or one-piece corner pieces as shown in the drawings at 15 and 16. That much is truly "clear."

Much has been made of the contention that using short mitered corner pieces is something that a "do-it-yourselfer" — an "amateur" — is unable to do. Defendants' expert speculated, with no support whatsoever, that, in his opinion, the examiner required claim 9 to be cancelled because "it was simply not something that a do-it-yourselfer could do." Both defendants and the district court relied heavily on this testimony. I find this opinion testimony to be wholly incredible. The sole basis given by the expert for his opinion was the fact that claim 9 was cancelled while claim 4 was not. However, there is

absolutely nothing in the record showing *why* the examiner allowed certain claims and cancelled certain other claims.

The fact is that this whole “do-it-yourselfer” argument has been blown way out of proportion. The specification does not state that do-it-yourselfers are *incapable* of using mitered corner pieces; it merely states, as quoted above, that preformed corner pieces are “somewhat easier for a do-it-yourselfer to work with.” Furthermore, the *only reference* to do-it-yourselfers during prosecution is a statement that certain known *prior art* arrangements are difficult for a do-it-yourselfer to use because the *fabric must be cut precisely to size* whereas according to the invention of the ’260 patent, the fabric need merely be cut *roughly* to size, with the excess fabric being stuffed in the storage channel. This is equally true as to either kind of corner. To infer from this one statement that the claims must be limited to features not recited in the claims (i.e., “*preformed*” corner pieces) is contrary to established patent law practice.

Let us consider next another lesson about meaning to be learned from the specification. In the quotation above from column 8, in the opening sentence the drafter of the specification exhibits a clear consciousness of the distinction between “preformed right-angle corner pieces” and those made by mitering and placing at right angles two short pieces of linear border pieces. Claim 1 does not contain the limiting word “preformed” yet the majority, without justification, is reading it into the claim in holding that the claim does not cover corner pieces which are made up as clearly described in the specification.

I also point out that the term “right-angle” is not a limitation to *preformed* unitary pieces since the specification makes clear that the made-up variety of corners are also right-angle corner pieces when assembled.

The majority’s argument based on alleged violation of the “all elements” rule is untenable. It overlooks the fact that the teaching in the specification is clear about making “corner pieces” by using two “*short linear border pieces*” (my emphasis) and then using such “improvised” *corner pieces in conjunction with linear pieces* to make the complete wall frame. Of course, it is the all-elements rule on which the defendants rely for non-infringement, arguing that they have no “corner pieces” when in fact they have a type of corner piece which is disclosed and claimed as an element of the combination of claim 1. I am not “merging the two types of claim elements into one”—whatever that may mean. I am simply saying that the element defined in claim 1 as “right-angle corner border pieces” is, as clearly shown by the patent and its prosecution history, a limitation generic to two types of corner pieces disclosed in the patent which is broad enough to read on defendants’ structure because it is clearly *not* limited to “preformed” or “unitary” corner pieces, as held below and by the majority. That is the sum and substance of my position and it calls for reversal.

The prosecution history contains nothing contradictory to my position and much to support it, as shown above. I have not found any evidence to contradict it or to support the district court opinion which demonstrates a dismal failure to comprehend many patent law fundamentals and accepts, as established fact, opinion statements of defendants’ expert witness unsupported by the record. The reader should also be aware that the district judge made no

separate “findings of fact.” He wrote a short, confused opinion which he concluded with the escape clause saying “The foregoing shall constitute the Findings of Fact and Conclusions of Law in accordance with Rule 54(b) [sic] of the Fed. R. Civ. P.”

Comments

1. *The Centrality of the Claim.* Even though *Unique Concepts* was decided several years before *Phillips*, the majority and dissent reveal what continues to be an ongoing debate within the court about the proper weight to be given the various forms of intrinsic evidence, and the relationship between intrinsic and extrinsic evidence. The claim is paramount for Judge Lourie, who assumes a more rule-oriented approach. Once clear claim meaning is discerned, resort to the specification and prosecution history is largely a perfunctory exercise. This view is consistent with the distinctiveness requirement (see Chapter Two), which serves the notice function of patent law, and demands that an applicant “particularly point out and distinctly claim” his invention. 35 U.S.C. § 112, ¶ 2. Judge Lourie is concerned with leaving the claim too early and embarking on an aggressive search of the intrinsic record. The emphasis here is on certainty and predictability, two virtues in a property-rights regime.

The dissent, like the majority, understands the importance of the claim, but is much more skeptical of finding clear meaning without visiting the specification and prosecution history. Recall Judge Rich’s comment: “The majority seems to start with an *a priori* assumption of what the ‘clear’ language of claim 1 means. On the other hand, I am looking at the genealogical record of that claim to *find out* what it means.” (Emphasis in original.). For Judge Rich, the claim cannot be read in isolation or in an overly literal fashion because to focus solely on the claim language when interpreting a claim is to adopt an acontextual approach to claim interpretation. As Richard Posner wrote, “meaning does not reside simply in the words of a text, for the words are always pointing to something outside.” RICHARD A. POSNER, *THE PROBLEMS OF JURISPRUDENCE* 296 (1990); Stanley Fish, *Almost Pragmatism: Richard Posner’s Jurisprudence*, 57 U. CHI. L. REV. 1447, 1456 (1990) (“No act of reading can stop at the plain meaning of a document, because that meaning itself will have emerged in the light of some stipulation of intentional circumstances, of purpose held by agents situated in real word situations.”). For more on this issue, see Comment 1 after *Phillips* on the Corbin/Williston debate in contract law.

2. *The Specification’s Import-Export Rule.* The standard rule that claims are to be interpreted in the light of the specification is subject to two complimentary caveats, both of which flow from the fundamental principle that “it is the function and purpose of claims, not the written description part of the specification itself,” to “delimit the right to exclude.” *Markman I*, 52 F.3d at 980. First, it is improper to import (*i.e.*, “read in”) a limitation from the specification’s general discussion, embodiments, and examples. See *Phillips*, 415 F.3d at 1323 (stating “although the specification often describes very specific embodiments of

the invention, we have repeatedly warned against confining the claims to those embodiments”); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (stating “[e]ven where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope”). Second, it is improper to eliminate or ignore (*i.e.*, “read out” or export) a claim limitation in order to extend a patent to subject matter disclosed, but not claimed.

The Federal Circuit has recognized that “there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.” *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). Indeed, Judge Dyk has written, “our decisions provide inadequate guidance as to when it is appropriate to look to the specification to narrow the claim by interpretation and when it is not appropriate to do so. Until we provide better guidance, I fear that the lower courts and litigants will remain confused.” *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337, 1347 (Fed. Cir. 2001). This fine line was on display in *Unique Concepts*. Did the majority read in a limitation (*i.e.*, “preformed”) into the claim from the specification? Did the dissent ignore a claim limitation? This lack of clarity leads to predictable arguments during litigation, with the patentee citing improper importation; and the accused infringer asserting the court disregarded a claim limitation.

These seemingly contradictory canons of claim construction were at issue in *Alloc, Inc. v. International Trade Commission*, 342 F.3d 1361 (Fed. Cir. 2003). The claims of the patents at issue, which related to floor panels, did not explicitly require “play” (or spacing) between the panels. The court, however, interpreted the claim and specification as requiring this limitation:

[T]his court recognizes that it must interpret the claims in light of the specification, yet avoid impermissibly importing limitations from the specification. That balance turns on how the specification characterizes the claimed invention. In this respect, this court looks to whether the specification refers to a limitation only as a part of less than all possible embodiments or whether the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment. For example, it is impermissible to read the one and only disclosed embodiment into a claim without other indicia that the patentee so intended to limit the invention. On the other hand, where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims. *SciMed Life Sys., Inc. v. Advance Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir. 2001). . . . Here [as in *SciMed*], the [patent] specification read as a whole leads to the inescapable conclusion that the claimed invention must include play in every embodiment. . . . [T]he patent specification indicates that the invention is indeed exclusively directed toward flooring products including play. Moreover, unlike the patent-at-issue in *SunRace [Roots Enters. Co. v. SRAM Corp.]*, 336 F.3d 1298 (Fed. Cir. 2003), the [patent] specification also distinguished the prior art on the basis of play.

Id. at 1370-71.

3. **The Role of the Accused Device in Interpreting Claims.** Another fundamental tenet of claim construction is that claims are not to be construed by reference to the accused device. See *SRI Intern. v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (en banc); *NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002). But recent decisions have suggested a greater role for the accused device. See *Wilson Sporting Goods v. Hillerich & Bradsby*, 442 F.3d 1322, 1326-27 (Fed. Cir. 2006) (“While a trial court should certainly not prejudice the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction.”); *Lava Trading, Inc. v. Sonic Trading Management, Inc.*, 445 F.3d 1348 (Fed. Cir. 2006) (“Without knowledge of the accused products, this court cannot assess the accuracy of the infringement judgment under review and lacks a proper context for an accurate claim construction.”); *Serio-US Industries, Inc. v. Plastic Recovery Technologies Corp.*, 459 F.3d 1311, 1319 (Fed. Cir. 2006) (stating “a trial court may consult the accused device for context that informs the claim construction process”).
4. **The Doctrine of Claim Differentiation.** This doctrine presumes “each claim in a patent is presumptively different in scope.” *Intermatic Inc. v. Lamson & Sessions Co.*, 273 F.3d 1355, 1364 (Fed. Cir. 2001). And this presumption is particularly applicable where “there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims.” *Id.* An example of the claim differentiation doctrine can be found in *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362 (Fed. Cir. 2002). The patent-in-suit related to a flying insect trap. Independent claim 16 required “[A] flying insect trap using reflected and radiated light as an insect attractant.” And dependent claim 17 stated: “The trap of claim 16 wherein the insect attractant light comprises a source of ultraviolet light.” The alleged infringer argued “claim 16 requires reflected ultraviolet (“UV”) light.” The Federal Circuit rejected this proposed construction, noting that claim 16 does not require ultraviolet light “[b]ecause the only meaningful difference between claims 16 and 17 is the limitation of ultraviolet light.” Accordingly, “under the doctrine of claim differentiation, claim 16 does not require ultraviolet light.” *Id.* at 1376-77.

Relatedly, a dependent claim can be a helpful interpretive tool when construing a term in an independent claim. Recall the *Phillips* court noted that “[d]ifferences among claims can also be a useful guide in understanding the meaning of particular claim terms,” and that “the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” In *Intamin Ltd. v. Magetar Technologies*, 483 F.3d 1328 (Fed. Cir. 2007), Claim 1 of the patent-in-suit claimed a rollercoaster “braking device” with “an intermediary disposed between adjacent pairs of . . . magnet elements.” Dependent claim 2 stated, “[t]he braking device of claim 1 wherein said intermediary is non-magnetic.” Based on its reading of the specification, which stated the “intermediary” related to non-magnetic substances only, the district court interpreted “intermediary” to mean a non-magnetic material between the adjacent magnetic

elements. Relying on *Phillips*, the Federal Circuit reversed, stating the dependent claim implied a broader meaning for the term “intermediary” in claim 1. According to the court the “dependent claim shows both that the claim drafter perceived a distinction between magnetic and non-magnetic intermediaries and that independent claim 1 impliedly embraced magnetic intermediaries.” *Id.* The court also cautioned that a narrow specification may not necessarily limit broader claim language; in this case, the “overall context of the patent . . . does not specifically disavow magnetic intermediaries,” and “[t]he single reference does not expressly limit the entire invention but only describes a single embodiment.” *Id.*

POLICY PERSPECTIVE

Claim Construction Methodology

One of the most important questions in patent law is what interpretive methodology should a court adopt in construing claims. On the one hand, a methodology that is wedded to the intrinsic evidence has several virtues. For instance, it relies on publicly available information, which may lend itself to more predictability and is consistent with the important notice function of the claim. Moreover, a strict textual approach forces patent attorneys and agents to be more careful in drafting patent applications. And the concerns of the *Vitronics* court about expert testimony are certainly legitimate. The patentee’s and defendant’s well-trained, technical experts, who are not part of the public record, will almost invariably provide the court and jury with divergent testimony relating to identical claim language. On the other hand, an interpretive approach that is more receptive to context outside of the express text may more accurately reflect how a person having ordinary skill in the art would understand the claim language. Such an approach is also more sensitive to technologic custom and linguistic meaning—so-called “facts on the ground.” Everyone agrees that claims are to be construed through the eyes of the skilled artisan. This tenet makes sense because patents are technical documents written largely to a technical audience. District court judges rarely have the requisite technical training or background to fully comprehend, for example, biotechnological or computer-related principles. As such, there may be a concern about judicial presumptions regarding the meaning of technological descriptions without the aid of technical experts or, at least, technical dictionaries. This approach would also most likely lead to greater deference to district court judges, and therefore, instill greater certainty earlier in the litigation process.

For more on the interpretive methodology of claim construction, see R. Polk Wagner & Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. PA. L. REV. 1105 (2004), Craig Allen Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH. 1 (2000); Christopher Cotropia, *Patent Claim Interpretation and Information Costs*, 9 LEWIS & CLARK L. REV. 57 (2005). See also Wagner’s ongoing empirical assessment of the Federal Circuit’s claim construction jurisprudence at www.claimconstruction.com.

B. INFRINGEMENT

1. Literal Infringement

Literal infringement is a straightforward doctrine that forms an important part of the patentee's enforcement rights. An accused device will be found to literally infringe when the device possesses each and every limitation recited in at least one patent claim. Sometimes patent professionals say the patentee's claim "reads on" the accused device. The principal case of *Larami v. Amron* explores literal infringement.

LARAMI CORPORATION v. AMRON

27 U.S.P.Q.2d 1280 (E.D. Pa. 1993)*

MEMORANDUM

REED, J.

This is a patent case concerning toy water guns manufactured by plaintiff Larami Corporation ("Larami"). Currently before me is Larami's motion for partial summary judgment of noninfringement of United States Patent No. 4,239,129 ("the '129 patent").

I. BACKGROUND

Larami manufactures a line of toy water guns called "SUPER SOAKERS." This line includes five models: SUPER SOAKER 20, SUPER SOAKER 30, SUPER SOAKER 50, SUPER SOAKER 100, and SUPER SOAKER 200. All use a hand-operated air pump to pressurize water and a "pinch trigger" valve mechanism for controlling the ejection of the pressurized water. All feature detachable water reservoirs prominently situated outside and above the barrel of the gun. The United States Patent and Trademark Office has issued patents covering four of these models. Larami does not claim to have a patent which covers SUPER SOAKER 20.

Defendants Alan Amron and Talk To Me Products, Inc. (hereinafter referred to collectively as "TTMP") claim that the SUPER SOAKER guns infringe on the '129 patent which TTMP obtained by assignment from Gary Esposito ("Esposito"), the inventor. The '129 patent covers a water gun which, like the SUPER SOAKERS, operates by pressurizing water housed in a tank with an air pump. In the '129 patent, the pressure enables the water to travel out of the tank through a trigger-operated valve into an outlet tube and to squirt through a nozzle. Unlike the SUPER SOAKERS, the '129 patent also contains various electrical features to illuminate the water stream and create noises. Also, the water tank in the '129 patent is not detachable, but is contained within a housing in the body of the water gun.

*The Federal Circuit affirmed, 91 F.3d 166 (Fed. Cir. 1996), in an unpublished "table" decision, which is a non-precedential decision without explanation.

The “Background of the Invention” contained in the ’129 patent reads as follows:

Children of all ages, especially boys, through the years have exhibited a fascination for water, lights and noise and the subject invention deals with these factors embodied in a toy simulating a pistol.

An appreciable number of U.S. patents have been issued which are directed to water pistols but none appear to disclose a unique assemble of components which can be utilized to simultaneously produce a jet or stream of water, means for illuminating the stream and a noise, or if so desired, one which can be operated without employing the noise and stream illuminating means. A reciprocal pump is employed to obtain sufficient pressure whereby the pistol can eject a stream an appreciable distance in the neighborhood of thirty feet and this stream can be illuminated to more or less simulate a lazer [sic] beam.

Larami brought this action seeking a declaration that the “SUPER SOAKER” does not infringe the ’129 patent (Count I). TTMP counterclaimed for infringement of the ’129 patent. Larami has moved for partial summary judgment of noninfringement of the ’129 patent (Count I) and for partial summary judgment on TTMP’s counterclaim for infringement of the ’129 patent.

II. DISCUSSION

* * *

B. Infringement and Claim Interpretation

A patent owner’s right to exclude others from making, using or selling the patented invention is defined and limited by the language in that patent’s claims. Thus, establishing infringement requires the interpretation of the “elements” or “limitations” of the claim and a comparison of the accused product with those elements as so interpreted. . . .

A patent holder can seek to establish patent infringement in either of two ways: by demonstrating that every element of a claim (1) is literally infringed or (2) is infringed under the doctrine of equivalents. To put it a different way, because every element of a claim is essential and material to that claim, a patent owner must, to meet the burden of establishing infringement, “show the presence of every element *or* its substantial equivalent in the accused device.” *Key Mfg. Group, Inc.*, 925 F.2d at 1447 (emphasis added). If even *one* element of a patent’s claim is missing from the accused product, then “[t]here can be no infringement as a matter of law. . . .” *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538-39 (Fed. Cir. 1991).

Larami contends, and TTMP does not dispute, that twenty-eight (28) of the thirty-five (35) claims in the ’129 patent are directed to the electrical components that create the light and noise. Larami’s SUPER SOAKER water guns have no light or noise components. Larami also contends, again with no rebuttal from TTMP, that claim 28 relates to a “poppet valve” mechanism for controlling the flow of water that is entirely different from Larami’s “pinch trigger” mechanism. Thus, according to Larami, the six remaining claims (claims 1, 5, 10, 11, 12 and 16) are the only ones in dispute. Larami admits that these six claims address the one thing that the SUPER SOAKERS and the

'129 patent have in common the use of air pressure created by a hand pump to dispense liquid. Larami argues, however, that the SUPER SOAKERS and the '129 patent go about this task in such fundamentally different ways that no claim of patent infringement is sustainable as a matter of law.

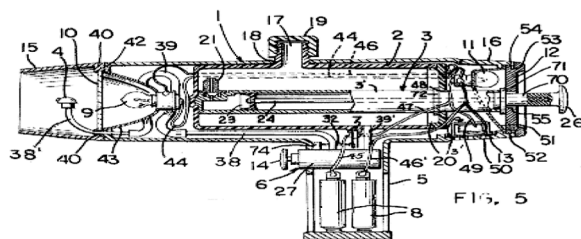
In its memorandum of law in opposition to Larami's motion for partial summary judgment, TTMP points to evidence to support its assertion that only SUPER SOAKER 20 literally infringes claim 1. TTMP has neither produced nor referred to evidence contradicting facts averred by Larami on all other claims of the '129 patent.

1. Literal Infringement of Claim 1

TTMP claims that SUPER SOAKER 20 literally infringes claim 1 of the '129 patent. Claim 1 describes the water gun as:

[a] toy comprising an elongated housing [case] having a chamber therein for a liquid [tank], a pump including a piston having an exposed rod [piston rod] and extending rearwardly of said toy facilitating manual operation for building up an appreciable amount of pressure in said chamber for ejecting a stream of liquid therefrom an appreciable distance substantially forwardly of said toy, and means for controlling the ejection.

U.S. Patent No. 4,239,129 (bracketed words supplied; [see Figure 5 of the '129 patent].



[The specification reads (emphasis added):

Referring to the drawings . . . the device or toy includes, among other things, wall structure forming an elongated barrel generally designated 1 and a chamber or tank 2 for liquid within the confines of the barrel, a pump generally designated 3 in the tank, for applying pressure to the liquid, for ejecting a jet stream of water through a nozzle 4 and a hollow handle 5 disposed intermediate the extremities of the barrel for containing a valve means generally designated 6, a switch 7 carried by the tank and a source of electricity preferably comprising a pair of batteries 8. The toy or device also includes a lamp 9 and a light responsive means 10 located at the front extremity of the barrel, a lamp 11, light responsive means or lens 12 and a buzzer 13 at its rear extremity and a trigger 14 for controlling the operation of the valve means 6 and the switch 7. . . . The tank 2 [is] located in the barrel]

Claim 1 requires, among other things, that the toy gun have “an elongated housing having a chamber therein for a liquid.” The SUPER SOAKER 20 water gun, in contrast, has an external water reservoir (chamber) that is detachable from the gun housing, and not contained within the housing. TTMP argues that SUPER SOAKER 20 contains a “chamber therein for a liquid” as well as a detachable water reservoir. It is difficult to discern from TTMP's

memorandum of law exactly where it contends the “chamber therein” is located in SUPER SOAKER 20. Furthermore, after having examined SUPER SOAKER 20, I find that it is plain that there is no “chamber” for liquid contained within the housing of the water gun. The only element of SUPER SOAKER 20 which could be described as a “chamber” for liquid is the external water reservoir located atop the housing. Indeed, liquid is located within the housing only when the trigger causes the liquid to pass from the external water reservoir through the tubing in the housing and out of the nozzle at the front end of the barrel. SUPER SOAKER 20 itself shows that such a transitory avenue for the release of liquid is clearly not a “chamber therein for liquid.” Therefore, because the absence of even one element of a patent’s claim from the accused product means there can be no finding of literal infringement, *London*, 946 F.2d at 1538-39, I find that SUPER SOAKER 20 does not infringe claim 1 of the ’129 patent as a matter of law.

Accordingly, I conclude that the SUPER SOAKER 20 water gun does not literally infringe claim 1 of the ’129 patent.

Comments

1. ***Each and Every Limitation Matters.*** Literal infringement demands that the accused product possess each and every limitation of at least one of the patent claims in suit. The *Larami* case highlights this rule as well as the importance of claim drafting, particularly drafting with an eye towards litigation and competitor conduct. Recall, claim 1 read: “[a] toy comprising an elongated housing [case] *having a chamber therein* for a liquid [tank].” The court found that the accused product—the SUPER SOAKER 20—did not have a “chamber therein,” and therefore, there was no literal infringement. Rather, the accused device comprised an external, detachable chamber “not contained within the housing.” The outcome may have been different if the “therein” limitation was omitted from claim 1, instead reading, for example, “[a] toy comprising an elongated housing [case] having a chamber for a liquid tank.” This broader claim language would have read on the SUPER SOAKER 20. Perhaps the “therein” language was used to distinguish the claimed invention from the prior art or in response to the prosecuting examiner’s office action, which could be discerned from studying the ’129 patent’s prosecution history.
2. ***Additional Elements and the Importance of Transition Terms.*** Literal infringement cannot be avoided if the accused device contains additional elements not found in the claim. For example, Inventor claims a widget, comprising A, B, and C; an accused device would still infringe if it possessed A, B, C, and D. There is one important caveat regarding this scenario. For literal infringement to hold, the claim must employ the open ended transition word, “comprising,” which has legal significance. The term comprising “raises a presumption that the list of elements is nonexclusive.” *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007); *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005) (“The transitional term ‘comprising’ . . . is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.”). So, in the above example, the addition of “D” would not preclude a finding of literal infringement.

In contrast, use of the transition phrase “consisting of” indicates that the claim is closed (that is, that invention is limited to no more and no fewer than the listed limitations). *See, e.g., In re Gray*, 53 F.2d 520 (CCPA 1931). Thus, a claim that reads a “widget consisting of A, B, and C” will not read on a device that contains A, B, C, and D. Moreover, the phrase “consisting essentially of” has been interpreted to exclude “ingredients that would materially affect the basic and novel characteristics of the claimed composition.” *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984). Yet another phrase, “composed of,” as been construed to be synonymous with either “consisting of” or “consisting essentially of,” depending upon the written disclosure. *See AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1244-45 (Fed. Cir. 2001).

3. ***Practical Significance of Literal Infringement.*** Literal infringement has considerable practical significance. While there are relatively few published opinions, literal infringement is a common occurrence in practice, largely because of the uncertainties relating to claim interpretation, namely, “the pre-litigation ambiguity of the literal scope of the claims.” JANICE M. MUELLER, *AN INTRODUCTION TO PATENT LAW* 287 (Aspen Publishing 2nd ed., 2006). Moreover, as explored in the next section, the doctrine of equivalents has, in the past several years, been reined in, making literal infringement a more reliable enforcement tool.

2. The Doctrine of Equivalents

The origins of the doctrine of equivalents (DOE) date to the early 19th century when courts assumed a generous posture toward the scope of the patentee’s protection. The patent claim was an innovation of the patent bar in the early 19th century, and was not instituted formally into the statutory framework until 1836.²⁶ As such, prior to 1836, juries determined infringement based on what can be characterized as a “substantiality” test, not unlike modern copyright law. The jury would compare the patentee’s invention as set forth in the specification with the accused device. For example, Justice Story charged the jury, in *Odiorne v. Winkley*,²⁷ “[t]he first question for consideration is, whether the machines used by the defendant are substantially, in their principles and mode of operation, like the plaintiff’s machines”; and adding, “[m]ere colorable alterations of a machine are not sufficient to protect the defendant.”²⁸

26. *See* John F. Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 309 (stating the claim “arose not from any administrative, judicial, or legislative requirement. Instead, it was an innovation of patent attorneys, and it was formulated to protect and to expand the rights of patentees”).

27. 18 F. Cas. 581, 582 (C.C.D. Mass. 1814).

28. The use of the word “substantially” in the context of patent infringement can be traced to the 1817 cases of *Gray v. James*, 10 F. Cas. 1015, 1016 (C.C.D. Pa. 1817) and *Lowell v. Lewis*, 15 F. Cas. 1018, 1021 (C.C. Mass. 1817). In the former, Circuit Judge Washington charged the jury that discerning differences in principle between two machines can be difficult, “[b]ut we think it may safely be laid down as a general rule, that where the machines are substantially the same, and operate in the same manner, to produce the same result, they must be in principle the same.” *Id.* In *Lowell*, Circuit Justice Story instructed the jury that “whether the defendant has violated the patent-right of the plaintiff . . . depends upon the fact, whether the pumps of Mr. Perkins and of Mr. Baker are substantially the same invention. I say substantially the same invention, because a mere change of the form or proportions of any machine cannot, per se, be deemed a new invention.”

By the mid-19th century, the fundamental tension between the DOE and providing clear notice in one's property right became apparent.²⁹ This tension remains in contemporary patent law.³⁰ On the one hand, there is an interest — primarily governed by § 112 — in providing a clear definition of the scope of the patent right because lack of clarity can impede legitimate investment in technology-based products and services. Certainty is key in any property-rights system. On the other hand, strict and literal adherence to the written claim in determining the scope of protection ignores the imprecise nature of language and can invite unfair subversion of a valuable right, which would substantially diminish the economic value of patents. As Judge Learned Hand noted, courts “resort to the ‘doctrine of equivalents’ to temper unsparing logic and prevent an infringer from stealing the benefit of the invention.” *Royal Typewriter Co. v. Remington Rand, Inc.*, 168 F.2d 691, 692 (2d Cir. 1948).

Somewhere beyond the literal claim language resides an “optimal” claim scope in any given case, and where exactly to strike this optimal balance is one of the most, if not the most, important and difficult questions in patent law. Using the DOE to strike an optimal balance has proved challenging because there are different views of what “optimal” means, and the DOE can be a blunt tool. As Justice Robin Jacob of the Court of Appeals in England and Wales stated, “[t]here is no general ‘doctrine of equivalents’; any student of patent law knows that various legal systems allow for such a concept, but that none of them can agree what it is or should be.” *Rockwater Ltd. v. Technip France SA*, [2004] EWCA Civ 381 ¶ 41. Recall the competing views of Justices Taney and Grier in *O'Reilly v. Morse* in Chapter 2.

COMPARATIVE PERSPECTIVE ***Non-Literal Infringement in Europe***

Non-literal infringement is part of the European patent law fabric. Article 69 of the European Patent Convention reflects a compromise between the U.K, which emphasized claim language, and Germany, which focused more on the nature of the underlying invention. Under Article 69, the “extent of the protection conferred by a European patent . . . shall be determined by the terms of the claims.” But “the description and drawings shall [also] be used to interpret the claims.” The U.K./German compromise is also reflected in the “Protocol on the Interpretation of Article 69,” which reads:

29. For instance, in *Winans v. Denmead*, a noteworthy 19th-century DOE case, four justices dissented to a finding an infringement finding under the DOE. In an opinion by Justice Campbell, the dissent emphasized that the patentee confined his claim to the conical form and may have been “unwilling to expose the validity of his patent, by the assertion of a right to any other.” The Patent Act required patentees to “specify and point out” what they claim as an invention. Requiring less than precision and particularity in claims would be “mischievous” and “productive of oppressive and costly litigation, of exorbitant and unjust pretensions and vexatious demands.” 56 U.S. (15 How.) 330, 347 (1853).

30. Indeed, some commentators have argued for the abolishment of the DOE. See, e.g., Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After Festo*, 19 BERKELEY TECH. L.J. 1157 (2004).

Article 1 General Principles

Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict literal meaning of the wording used in the claim, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.

Article 2 Equivalents

For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.

Two important cases issued by the House of Lords interpreted Article 69. In *Catnic v. Hill and Smith*,³¹ Lord Diplock stressed that a patent's specification should be given a purposive, rather than a literal interpretation, which meant that a patent should be construed through the eyes of a person skilled in the art. In a more recent House of Lords case, *Kirin-Amgen, Inc. v. Hoechst Marion Roussel Ltd.*,³² Lord Hoffmann provides an excellent discussion of *Catnic* and Article 69. *Kirin-Amgen* is a principal case, below. But first we turn to two prominent American Supreme Court cases that established the current parameters of the DOE: *Graver Tank* and *Warner-Jenkinson*.

GRAVER TANK v. LINDE AIR PRODS. CO.

339 U.S. 605 (1950)

Justice JACKSON delivered the opinion of the Court.

[The patent-in-suit, owned by Linde Air Products, related to fluxes that were compositions used in electric welding and assisted in the fusing of metals. The patent had two sets of claims, one of which described a major element as any "silicate," and the other set described the element as any "alkaline earth metal silicate." The first set—"silicate"—was held invalid as too broad. The validity of the "alkaline earth metal silicate" set was upheld and the question became whether this set of claims was infringed.]

* * *

31. [1982] RPC 183 (HL).

32. [2004] UKHL 46, [2004] All ER (D) 286 (Oct. 1, 2004).

At the outset it should be noted that the single issue before us is whether the trial court's holding that the four flux claims have been infringed will be sustained.

In determining whether an accused device or composition infringes a valid patent, resort must be had in the first instance to the words of the claim. If accused matter falls clearly within the claim, infringement is made out and that is the end of it.

But courts have also recognized that to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for—indeed encourage—the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law. One who seeks to pirate an invention, like one who seeks to pirate a copyrighted book or play, may be expected to introduce minor variations to conceal and shelter the piracy. Outright and forthright duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and would be subordinating substance to form. It would deprive him of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent system.

The doctrine of equivalents evolved in response to this experience. The essence of the doctrine is that one may not practice a fraud on a patent. Originating almost a century ago in the case of *Winans v. Denmead*, it has been consistently applied by this Court and the lower federal courts, and continues today ready and available for utilization when the proper circumstances for its application arise. “To temper unsparing logic and prevent an infringer from stealing the benefit of the invention” a patentee may invoke this doctrine to proceed against the producer of a device “if it performs substantially the same function in substantially the same way to obtain the same result.” *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42. The theory on which it is founded is that “if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape.” *Union Paper-Bag Machine Co. v. Murphy*, 97 U.S. 120, 125. The doctrine operates not only in favor of the patentee of a pioneer or primary invention, but also for the patentee of a secondary invention consisting of a combination of old ingredients which produce new and useful results, *Imhaeuser v. Buerk*, although the area of equivalence may vary under the circumstances. See *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 414-415, and cases cited; *Seymour v. Osborne*, 11 Wall. 516, 556. The wholesome realism of this doctrine is not always applied in favor of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement. *Westinghouse v. Boyden Power-Brake Co.*, 170 U.S. 537, 568. In its early development, the doctrine was usually applied in cases involving devices where

there was equivalence in mechanical components. Subsequently, however, the same principles were also applied to compositions, where there was equivalence between chemical ingredients. Today the doctrine is applied to mechanical or chemical equivalents in compositions or devices.

What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents. Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform. An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was.

A finding of equivalence is a determination of fact. Proof can be made in any form: through testimony of experts or others versed in the technology; by documents, including texts and treatises; and, of course, by the disclosures of the prior art. Like any other issue of fact, final determination requires a balancing of credibility, persuasiveness and weight of evidence. It is to be decided by the trial court and that court's decision, under general principles of appellate review, should not be disturbed unless clearly erroneous. Particularly is this so in a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience.

In the case before us, we have two electric welding compositions or fluxes: the patented composition, Unionmelt Grade 20, and the accused composition, Lincolnweld 660. The patent under which Unionmelt is made claims essentially a combination of alkaline earth metal silicate and calcium fluoride; Unionmelt actually contains, however, silicates of calcium and magnesium, two alkaline earth metal silicates. Lincolnweld's composition is similar to Unionmelt's, except that it substitutes silicates of calcium and manganese—the latter not an alkaline earth metal—for silicates of calcium and magnesium. In all other respects, the two compositions are alike. The mechanical methods in which these compositions are employed are similar. They are identical in operation and produce the same kind and quality of weld.

The question which thus emerges is whether the substitution of the manganese which is not an alkaline earth metal for the magnesium which is, under the circumstances of this case, and in view of the technology and the prior art, is a change of such substance as to make the doctrine of equivalents inapplicable; or conversely, whether under the circumstances the change was so insubstantial that the trial court's invocation of the doctrine of equivalents was justified.

Without attempting to be all-inclusive, we note the following evidence in the record: Chemists familiar with the two fluxes testified that manganese and

magnesium were similar in many of their reactions. There is testimony by a metallurgist that alkaline earth metals are often found in manganese ores in their natural state and that they serve the same purpose in the fluxes; and a chemist testified that "in the sense of the patent" manganese could be included as an alkaline earth metal. Much of this testimony was corroborated by reference to recognized texts on inorganic chemistry. Particularly important, in addition, were the disclosures of the prior art, also contained in the record. The Miller patent, No. 1,754,566, which preceded the patent in suit, taught the use of manganese silicate in welding fluxes. Manganese was similarly disclosed in the Armor patent, No. 1,467,825, which also described a welding composition. And the record contains no evidence of any kind to show that Lincolnweld was developed as the result of independent research or experiments.

It is not for this Court to even essay an independent evaluation of this evidence. This is the function of the trial court. And, as we have heretofore observed, "To no type of case is this . . . more appropriately applicable than to the one before us, where the evidence is largely the testimony of experts as to which a trial court may be enlightened by scientific demonstrations. This trial occupied some three weeks, during which, as the record shows, the trial judge visited laboratories with counsel and experts to observe actual demonstrations of welding as taught by the patent and of the welding accused of infringing it, and of various stages of the prior art. He viewed motion pictures of various welding operations and tests and heard many experts and other witnesses."

The trial judge found on the evidence before him that the Lincolnweld flux and the composition of the patent in suit are substantially identical in operation and in result. He found also that Lincolnweld is in all respects equivalent to Unionmelt for welding purposes. And he concluded that "for all practical purposes, manganese silicate can be efficiently and effectively substituted for calcium and magnesium silicates as the major constituent of the welding composition." These conclusions are adequately supported by the record; certainly they are not clearly erroneous.

It is difficult to conceive of a case more appropriate for application of the doctrine of equivalents. The disclosures of the prior art made clear that manganese silicate was a useful ingredient in welding compositions. Specialists familiar with the problems of welding compositions understood that manganese was equivalent to and could be substituted for magnesium in the composition of the patented flux and their observations were confirmed by the literature of chemistry. Without some explanation or indication that Lincolnweld was developed by independent research, the trial court could properly infer that the accused flux is the result of imitation rather than experimentation or invention. Though infringement was not literal, the changes which avoid literal infringement are colorable only. We conclude that the trial court's judgment of infringement respecting the four flux claims was proper, and we adhere to our prior decision on this aspect of the case.

Justice BLACK, with whom Justice DOUGLAS concurs, dissenting.

I heartily agree with the Court that “fraud” is bad, “piracy” is evil, and “stealing” is reprehensible. But in this case, where petitioners are not charged with any such malevolence, these lofty principles do not justify the Court’s sterilization of Acts of Congress and prior decisions, none of which are even mentioned in today’s opinion.

R.S. § 4888, as amended, 35 U.S.C. § 33, 35 U.S.C.A. § 33, provides that an applicant “shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery.” We have held in this very case that this statute precludes invoking the specifications to alter a claim free from ambiguous language, since “it is the claim which measures the grant to the patentee.” *Graver Mfg. Co. v. Linde Co.*, 336 U.S. 271, 277. What is not specifically claimed is dedicated to the public. *See, e.g., Miller v. Brass Co.*, 104 U.S. 350, 352. For the function of claims under R.S. § 4888, as we have frequently reiterated, is to exclude from the patent monopoly field all that is not specifically claimed, whatever may appear in the specifications. Today the Court tacitly rejects those cases. It departs from the underlying principle which, as the Court pointed out in *White v. Dunbar*, 119 U.S. 47, 51, forbids treating a patent claim “like a nose of wax, which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express. . . . The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.” Giving this patentee the benefit of a grant that it did not precisely claim is no less “unjust to the public” and no less an evasion of R.S. § 4888 merely because done in the name of the “doctrine of equivalents.”

In seeking to justify its emasculation of R.S. § 4888 by parading potential hardships which literal enforcement might conceivably impose on patentees who had for some reason failed to claim complete protection for their discoveries, the Court fails even to mention the program for alleviation of such hardships which Congress itself has provided. 35 U.S.C. § 64, 35 U.S.C.A. § 64, authorizes reissue of patents where a patent is “wholly or partly inoperative” due to certain errors arising from “inadvertence, accident, or mistake” of the patentee. And while the section does not expressly permit a patentee to expand his claim, this Court has reluctantly interpreted it to justify doing so. *Miller v. Brass Co.*, 104 U.S. 350, 353-354. That interpretation, however, was accompanied by a warning that “Reissues for the enlargement of claims should be the exception and not the rule.” 104 U.S. at page 355. And Congress was careful to hedge the privilege of reissue by exacting conditions. It also entrusted the Patent Office, not the courts, with initial authority to determine whether expansion of a claim was justified,³ and barred suits for retroactive

3. This provision was inserted in the law for the purpose of relieving the courts from the duty of ascertaining the exact invention of the patentee by inference and conjecture, derived from a laborious examination of previous inventions, and a comparison thereof with that claimed by him. This duty is now cast upon the Patent Office. There his claim is, or is supposed to be, examined, scrutinized, limited, and made to conform to what he is entitled to. If the office refuses to allow him all that he asks, he has an appeal. But the courts have no right to enlarge a patent beyond the scope of its claim as allowed by the Patent Office, or the appellate tribunal to

infringement based on such expansion. Like the Court's opinion, this congressional plan adequately protects patentees from "fraud," "piracy," and "stealing." Unlike the Court's opinion, it also protects business men from retroactive infringement suits and judicial expansion of a monopoly sphere beyond that which a patent expressly authorizes. The plan is just, fair, and reasonable. In effect it is nullified by this decision undercutting what the Court has heretofore recognized as wise safeguards. One need not be a prophet to suggest that today's rhapsody on the virtue of the "doctrine of equivalents" will, in direct contravention of the *Miller* case *supra*, make enlargement of patent claims the "rule" rather than the "exception."

Comments

1. ***Some Thoughts on Graver Tank.*** Prior to *Warner-Jenkinson* (the next principal case), *Graver Tank* was the most significant Supreme Court opinion on the doctrine of equivalents. Justice Jackson's opinion in *Graver Tank* is replete with equitable considerations. For example, he stated "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing" and limiting the patentee to his literal claim scope "would leave room for—indeed encourage—the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent." But did the majority opinion adequately address Justice Black's unease with non-literal infringement as expressed in his dissent.

For the dissent, the notice function is disserved by venturing beyond the claim. Indeed, as Justice Black wrote, "What is not specifically claimed is dedicated to the public." This point of view has been embraced by the Federal Circuit. See *Johnson & Johnston Associates, Inc. v. R.E. Service Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) ("[W]hen a patent drafter discloses but declines to claim a subject matter, . . . this action dedicates that unclaimed subject matter to the public"). (The public dedication rule is discussed in Section B.2.b, below.) Interestingly, *Johnson & Johnston* distinguished *Graver Tank*, noting that the patentee in *Graver Tank*—unlike the patentee in *Johnson & Johnston*—"initially claimed the 'equivalent' subject matter." *Id.* at 1053.

Perhaps Justice Black's most trenchant argument is the availability of reissue. The reissue proceeding was an innovation of the patent bar, and codified in 1832. See *Grant v. Raymond*, 31 U.S. 218 (1832) (recognizing the power of the patent office (more accurately, the Secretary of State) to cancel and reissue patents). The modern statutory reissue provision expressly allows for claim broadening if done within two years from issuance. According to § 251:

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

The reissue proceeding has been cited by several commentators—who view the DOE as an erosive force on patent law’s notice function—as a viable alternative to the doctrine of equivalents. *See, e.g.*, Paul M. Janicke, *Heat of Passion: What Really Happened in Graver Tank*, 24 AIPLA Q.J. 1 (1997) (suggesting reissue-like procedures for use in enlarging the scope of claims under certain circumstances as an alternative to the doctrine of equivalents); Michael J. Meurer & Craig Allen Nard, *Invention, Refinement, and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947 (2005) (embracing reissue as an alternative to DOE).

2. **Graver Establishes the DOE Debate for 50 years.** The arguments put forth by the majority and dissent remain as relevant today as when *Graver* was decided. Justice Jackson’s argument envisioned a world without the DOE, one where a patent would be converted “into a hollow and useless thing” subjected to the mercy of the “unscrupulous copyist.” 339 U.S. at 617. This equitable argument is consistent with 19th century justifications for non-literal infringement. For example, in the famous 19th century case of *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1853), Justice Curtis, writing for the majority, focused on the merit of the patentee/inventor and the bad motives of the defendant. Curtis highlighted the minor change made by the defendant, what he characterized as the “work of a constructor, not of an inventor,” and wrote to allow the defendant to escape infringement with such a minor change would render the property of inventors “valueless.” *Id.* at 341. For a thorough historical treatment of the DOE, *see* Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future: Part I (1790-1870)*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 371 (2005); Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future: Part II (1870-1952)*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 441 (2005).

But the role of the patent claim as guidepost had become increasingly important by the time *Graver* was decided. The claim was emphasized by Justice Black in his dissent, and has become the center of attention as the Federal Circuit and Supreme Court continue to wrestle with a way to, on the one hand, retain the DOE and, on the other hand, address the social costs associated with non-literal infringement. In *Warner-Jenkinson*, the Supreme Court revisited the DOE for the first time since *Graver Tank* and acknowledged the doctrine had “taken on a life of its own, unbounded by the patent claims.” In cases decided after *Warner-Jenkinson*, the Supreme Court and the Federal Circuit emphasized the primacy of the notice function of the claim and placed several limitations on the DOE. These cases are explored in Section 2 following *Warner-Jenkinson*.

WARNER-JENKINSON CO., INC. v. HILTON DAVIS CHEMICAL CO.

520 U.S. 17 (1997)

Justice THOMAS delivered the opinion of the Court.

Nearly 50 years ago, this Court in *Graver Tank & Mfg. Co. v. Linde Air Products Co.* set out the modern contours of what is known in patent law as the “doctrine of equivalents.” Under this doctrine, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is “equivalence” between the elements of

the accused product or process and the claimed elements of the patented invention. . . . Petitioner, which was found to have infringed upon respondent's patent under the doctrine of equivalents, invites us to speak the death of that doctrine. We decline that invitation. The significant disagreement within the Court of Appeals for the Federal Circuit concerning the application of *Graver Tank* suggests, however, that the doctrine is not free from confusion. We therefore will endeavor to clarify the proper scope of the doctrine.

I

The essential facts of this case are few. Petitioner Warner-Jenkinson Co. and respondent Hilton Davis Chemical Co. manufacture dyes. Impurities in those dyes must be removed. Hilton Davis holds United States Patent No. 4,560,746 ('746 patent), which discloses an improved purification process involving "ultrafiltration." The '746 process filters impure dye through a porous membrane at certain pressures and pH levels,¹ resulting in a high purity dye product.

The '746 patent issued in 1985. As relevant to this case, the patent claims as its invention an improvement in the ultrafiltration process as follows:

In a process for the purification of a dye . . . the improvement which comprises: subjecting an aqueous solution . . . to ultrafiltration through a membrane having a nominal pore diameter of 5-15 Angstroms under a hydrostatic pressure of approximately 200 to 400 p.s.i.g., *at a pH from approximately 6.0 to 9.0*, to thereby cause separation of said impurities from said dye. . . . App. 36-37 (emphasis added).

The inventors added the phrase "at a pH from approximately 6.0 to 9.0" during patent prosecution. At a minimum, this phrase was added to distinguish a previous patent (the "Booth" patent) that disclosed an ultrafiltration process operating at a pH above 9.0. The parties disagree as to why the low-end pH limit of 6.0 was included as part of the claim.²

In 1986, Warner-Jenkinson developed an ultrafiltration process that operated with membrane pore diameters assumed to be 5-15 Angstroms, at pressures of 200 to nearly 500 p.s.i.g., and at a pH of 5.0. Warner-Jenkinson did not learn of the '746 patent until after it had begun commercial use of its ultrafiltration process. Hilton Davis eventually learned of Warner-Jenkinson's use of ultrafiltration and, in 1991, sued Warner-Jenkinson for patent infringement.

1. The pH, or power (exponent) of Hydrogen, of a solution is a measure of its acidity or alkalinity. A pH of 7.0 is neutral; a pH below 7.0 is acidic; and a pH above 7.0 is alkaline. Although measurement of pH is on a logarithmic scale, with each whole number difference representing a ten-fold difference in acidity, the practical significance of any such difference will often depend on the context. Pure water, for example, has a neutral pH of 7.0, whereas carbonated water has an acidic pH of 3.0, and concentrated hydrochloric acid has a pH approaching 0.0. On the other end of the scale, milk of magnesia has a pH of 10.0, whereas household ammonia has a pH of 11.9. 21 Encyclopedia Americana 844 (Int'l ed. 1990).

2. Petitioner contends that the lower limit was added because below a pH of 6.0 the patented process created "foaming" problems in the plant and because the process was not shown to work below that pH level. Brief for Petitioner 4, n. 5, 37, n. 28. Respondent counters that the process was successfully tested to pH levels as low as 2.2 with no effect on the process because of foaming, but offers no particular explanation as to why the lower level of 6.0 pH was selected. Brief for Respondent 34, n.34.

As trial approached, Hilton Davis conceded that there was no literal infringement, and relied solely on the doctrine of equivalents. Over Warner-Jenkinson's objection that the doctrine of equivalents was an equitable doctrine to be applied by the court, the issue of equivalence was included among those sent to the jury. The jury found that the '746 patent was not invalid and that Warner-Jenkinson infringed upon the patent under the doctrine of equivalents. The jury also found, however, that Warner-Jenkinson had not intentionally infringed, and therefore awarded only 20% of the damages sought by Hilton Davis. The District Court denied Warner-Jenkinson's post-trial motions, and entered a permanent injunction prohibiting Warner-Jenkinson from practicing ultrafiltration below 500 p.s.i.g. and below 9.01 pH. A fractured *en banc* Court of Appeals for the Federal Circuit affirmed.

The majority below held that the doctrine of equivalents continues to exist and that its touchstone is whether substantial differences exist between the accused process and the patented process. The court also held that the question of equivalence is for the jury to decide and that the jury in this case had substantial evidence from which it could conclude that the Warner-Jenkinson process was not substantially different from the ultrafiltration process disclosed in the '746 patent.

There were three separate dissents, commanding a total of 5 of 12 judges. Four of the five dissenting judges viewed the doctrine of equivalents as allowing an improper expansion of claim scope, contrary to this Court's numerous holdings that it is the claim that defines the invention and gives notice to the public of the limits of the patent monopoly. *Id.* at 1537-1538 (Plager, J., dissenting). The fifth dissenter, the late Judge Nies, was able to reconcile the prohibition against enlarging the scope of claims and the doctrine of equivalents by applying the doctrine to each element of a claim, rather than to the accused product or process "overall." *Id.*, at 1574 (Nies, J., dissenting). As she explained it, "[t]he 'scope' is not enlarged if courts do not go beyond the substitution of equivalent elements." *Ibid.* All of the dissenters, however, would have found that a much narrowed doctrine of equivalents may be applied in whole or in part by the court. *Id.*, at 1540-1542 (Plager, J., dissenting); *id.*, at 1579 (Nies, J., dissenting).

We granted *certiorari*, and now reverse and remand.

II

* * *

A

Petitioner's primary argument in this Court is that the doctrine of equivalents, as set out in *Graver Tank* in 1950, did not survive the 1952 revision of the Patent Act, 35 U.S.C. § 100 *et seq.*, because it is inconsistent with several aspects of that Act. In particular, petitioner argues: (1) the doctrine of equivalents is inconsistent with the statutory requirement that a patentee specifically "claim" the invention covered by a patent, 35 U.S.C. § 112; (2) the doctrine circumvents the patent reissue process—designed to correct mistakes in drafting or the like—and avoids the express limitations on that process, 35 U.S.C. §§ 251-252; (3) the doctrine is inconsistent with the primacy of the Patent and Trademark Office (PTO) in setting the scope of a

patent through the patent prosecution process; and (4) the doctrine was implicitly rejected as a general matter by Congress' specific and limited inclusion of the doctrine in one section regarding "means" claiming, 35 U.S.C. § 112, ¶ 6. All but one of these arguments were made in *Graver Tank* in the context of the 1870 Patent Act, and failed to command a majority.³

The 1952 Patent Act is not materially different from the 1870 Act with regard to claiming, reissue, and the role of the PTO. Compare, *e.g.*, 35 U.S.C. § 112 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention") with The Consolidated Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201 (the applicant "shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery"). Such minor differences as exist between those provisions in the 1870 and the 1952 Acts have no bearing on the result reached in *Graver Tank*, and thus provide no basis for our overruling it. In the context of infringement, we have already held that pre-1952 precedent survived the passage of the 1952 Act. We see no reason to reach a different result here.

Petitioner's fourth argument for an implied congressional negation of the doctrine of equivalents turns on the reference to "equivalents" in the "means" claiming provision of the 1952 Act. . . . Because § 112, ¶ 6 was enacted as a targeted cure to a specific problem, and because the reference in that provision to "equivalents" appears to be no more than a prophylactic against potential side effects of that cure, such limited congressional action should not be overread for negative implications. Congress in 1952 could easily have responded to *Graver Tank* as it did to the *Halliburton* decision. But it did not. Absent something more compelling than the dubious negative inference offered by petitioner, the lengthy history of the doctrine of equivalents strongly supports adherence to our refusal in *Graver Tank* to find that the Patent Act conflicts with that doctrine. Congress can legislate the doctrine of equivalents out of existence any time it chooses. The various policy arguments now made by both sides are thus best addressed to Congress, not this Court.

B

We do, however, share the concern of the dissenters below that the doctrine of equivalents, as it has come to be applied since *Graver Tank*, has taken on a life of its own, unbounded by the patent claims. There can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the defini-

3. *Graver Tank* was decided over a vigorous dissent. In that dissent, Justice Black raised the first three of petitioner's four arguments against the doctrine of equivalents. *See* 339 U.S., at 613-614 (doctrine inconsistent with statutory requirement to "distinctly claim" the invention); *id.*, at 614-615 (patent reissue process available to correct mistakes); *id.*, at 615, n. 3 (duty lies with the Patent Office to examine claims and to conform them to the scope of the invention; inventors may appeal Patent Office determinations if they disagree with result).

Indeed, petitioner's first argument was not new even in 1950. Nearly 100 years before *Graver Tank*, this Court approved of the doctrine of equivalents in *Winans v. Denmead*, 15 How. 330, 14 L. Ed. 717 (1854). The dissent in *Winans* unsuccessfully argued that the majority result was inconsistent with the requirement in the 1836 Patent Act that the applicant "particularly 'specify and point' out what he claims as his invention," and that the patent protected nothing more. *Id.*, 15 How. at 347 (Campbell, J., dissenting).

tional and public-notice functions of the statutory claiming requirement. Judge Nies identified one means of avoiding this conflict:

[A] distinction can be drawn that is not too esoteric between substitution of an equivalent for a component *in* an invention and enlarging the metes and bounds of the invention *beyond* what is claimed.

* * *

Where a claim to an invention is expressed as a combination of elements, as here, “equivalents” in the sobriquet “Doctrine of Equivalents” refers to the equivalency of an *element* or *part* of the invention with one that is substituted in the accused product or process.

* * *

This view that the accused device or process must be more than “equivalent” *overall* reconciles the Supreme Court’s position on infringement by equivalents with its concurrent statements that “the courts have no right to enlarge a patent beyond the scope of its claims as allowed by the Patent Office.” The “scope” is not enlarged if courts do not go beyond the substitution of equivalent elements. 62 F.3d, at 1573-1574 (Nies, J., dissenting) (emphasis in original).

We concur with this apt reconciliation of our two lines of precedent. Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety. So long as the doctrine of equivalents does not encroach beyond the limits just described, or beyond related limits to be discussed *infra*, we are confident that the doctrine will not vitiate the central functions of the patent claims themselves.

III

Understandably reluctant to assume this Court would overrule *Graver Tank*, petitioner has offered alternative arguments in favor of a more restricted doctrine of equivalents than it feels was applied in this case. We address each in turn.

A

Petitioner first argues that *Graver Tank* never purported to supersede a well-established limit on non-literal infringement, known variously as “prosecution history estoppel” and “file wrapper estoppel.” According to petitioner, any surrender of subject matter during patent prosecution, regardless of the reason for such surrender, precludes recapturing any part of that subject matter, even if it is equivalent to the matter expressly claimed. Because, during patent prosecution, respondent limited the pH element of its claim to pH levels between 6.0 and 9.0, petitioner would have those limits form bright lines beyond which no equivalents may be claimed. Any inquiry into the reasons for a surrender, petitioner claims, would undermine the public’s right to clear notice of the scope of the patent as embodied in the patent file.

We can readily agree with petitioner that *Graver Tank* did not dispose of prosecution history estoppel as a legal limitation on the doctrine of equivalents. But petitioner reaches too far in arguing that the reason for an amendment during patent prosecution is irrelevant to any subsequent estoppel. In each of our cases cited by petitioner and by the dissent below, prosecution history estoppel was tied to amendments made to avoid the prior art, or otherwise to address a specific concern—such as obviousness—that arguably would have rendered the claimed subject matter unpatentable. Thus, in *Exhibit Supply Co. v. Ace Patents Corp.*, Chief Justice Stone distinguished inclusion of a limiting phrase in an original patent claim from the “very different” situation in which “the applicant, in order to meet objections in the Patent Office, *based on references to the prior art*, adopted the phrase as a substitute for the broader one” previously used. 315 U.S. 126, 136 (1942) (emphasis added). Similarly, in *Keystone Driller Co. v. Northwest Engineering Corp.*, 294 U.S. 42 (1935), estoppel was applied where the initial claims were “rejected on the prior art,” *id.*, at 48, n. 6, and where the allegedly infringing equivalent element was outside of the revised claims and within the prior art that formed the basis for the rejection of the earlier claims.

It is telling that in each case this Court probed the reasoning behind the Patent Office’s insistence upon a change in the claims. In each instance, a change was demanded because the claim as otherwise written was viewed as not describing a patentable invention at all—typically because what it described was encompassed within the prior art. But, as the United States informs us, there are a variety of other reasons why the PTO may request a change in claim language. Brief for United States as Amicus Curiae 22-23 (counsel for the PTO also appearing on the brief). And if the PTO has been requesting changes in claim language without the intent to limit equivalents or, indeed, with the expectation that language it required would in many cases allow for a range of equivalents, we should be extremely reluctant to upset the basic assumptions of the PTO without substantial reason for doing so. Our prior cases have consistently applied prosecution history estoppel only where claims have been amended for a limited set of reasons, and we see no substantial cause for requiring a more rigid rule invoking an estoppel regardless of the reasons for a change.⁶

In this case, the patent examiner objected to the patent claim due to a perceived overlap with the Booth patent, which revealed an ultrafiltration process operating at a pH above 9.0. In response to this objection, the phrase “at a pH from approximately 6.0 to 9.0” was added to the claim. While it is undisputed that the upper limit of 9.0 was added in order to distinguish the Booth patent, the reason for adding the lower limit of 6.0 is unclear. The lower limit certainly did not serve to distinguish the Booth patent, which said nothing about pH levels below 6.0. Thus, while a lower limit of 6.0, by its mere inclusion, became a material element of the claim, that did not necessarily

6. That petitioner’s rule might provide a brighter line for determining whether a patentee is estopped under certain circumstances is not a sufficient reason for adopting such a rule. This is especially true where, as here, the PTO may have relied upon a flexible rule of estoppel when deciding whether to ask for a change in the first place. To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision.

preclude the application of the doctrine of equivalents as to that element. See *Hubbell v. United States*, 179 U.S. 77, 82 (1900) (“[A]ll [specified elements] must be regarded as material,” though it remains an open “question whether an omitted part is supplied by an equivalent device or instrumentality.”) Where the reason for the change was not related to avoiding the prior art, the change may introduce a new element, but it does not necessarily preclude infringement by equivalents of that element.

We are left with the problem, however, of what to do in a case like the one at bar, where the record seems not to reveal the reason for including the lower pH limit of 6.0. In our view, holding that certain reasons for a claim amendment may avoid the application of prosecution history estoppel is not tantamount to holding that the absence of a reason for an amendment may similarly avoid such an estoppel. Mindful that claims do indeed serve both a definitional and a notice function, we think the better rule is to place the burden on the patent-holder to establish the reason for an amendment required during patent prosecution. The court then would decide whether that reason is sufficient to overcome prosecution history estoppel as a bar to application of the doctrine of equivalents to the element added by that amendment. Where no explanation is established, however, the court should presume that the PTO had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine of equivalents as to that element. The presumption we have described, one subject to rebuttal if an appropriate reason for a required amendment is established, gives proper deference to the role of claims in defining an invention and providing public notice, and to the primacy of the PTO in ensuring that the claims allowed cover only subject matter that is properly patentable in a proffered patent application. Applied in this fashion, prosecution history estoppel places reasonable limits on the doctrine of equivalents, and further insulates the doctrine from any feared conflict with the Patent Act.

Because respondent has not proffered in this Court a reason for the addition of a lower pH limit, it is impossible to tell whether the reason for that addition could properly avoid an estoppel. Whether a reason in fact exists, but simply was not adequately developed, we cannot say. On remand, the Federal Circuit can consider whether reasons for that portion of the amendment were offered or not and whether further opportunity to establish such reasons would be proper.

B

Petitioner next argues that even if *Graver Tank* remains good law, the case held only that the absence of substantial differences was a necessary element for infringement under the doctrine of equivalents, not that it was sufficient for such a result. Relying on *Graver Tank*’s references to the problem of an “unscrupulous copyist” and “piracy,” 339 U.S., at 607, petitioner would require judicial exploration of the equities of a case before allowing application of the doctrine of equivalents. To be sure, *Graver Tank* refers to the prevention of copying and piracy when describing the benefits of the doctrine of equivalents. That the doctrine produces such benefits, however, does not mean that its application is limited only to cases where those particular benefits are obtained.

Elsewhere in *Graver Tank* the doctrine is described in more neutral terms. And the history of the doctrine as relied upon by *Graver Tank* reflects a basis for the doctrine not so limited as petitioner would have it. In *Winans v. Denmead*, 15 How. 330, 343 (1854), we described the doctrine of equivalents as growing out of a legally implied term in each patent claim that “the claim extends to the thing patented, however its form or proportions may be varied.” Under that view, application of the doctrine of equivalents involves determining whether a particular accused product or process infringes upon the patent claim, where the claim takes the form — half express, half implied — of “X and its equivalents.”

If the essential predicate of the doctrine of equivalents is the notion of identity between a patented invention and its equivalent, there is no basis for treating an infringing equivalent any differently than a device that infringes the express terms of the patent. Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent.

Petitioner also points to *Graver Tank*’s seeming reliance on the absence of independent experimentation by the alleged infringer as supporting an equitable defense to the doctrine of equivalents. The Federal Circuit explained this factor by suggesting that an alleged infringer’s behavior, be it copying, designing around a patent, or independent experimentation, indirectly reflects the substantiality of the differences between the patented invention and the accused device or process. According to the Federal Circuit, a person aiming to copy or aiming to avoid a patent is imagined to be at least marginally skilled at copying or avoidance, and thus intentional copying raises an inference — rebuttable by proof of independent development — of having only insubstantial differences, and intentionally designing around a patent claim raises an inference of substantial differences. This explanation leaves much to be desired. At a minimum, one wonders how ever to distinguish between the intentional copyist making minor changes to lower the risk of legal action, and the incremental innovator designing around the claims, yet seeking to capture as much as is permissible of the patented advance.

But another explanation is available that does not require a divergence from generally objective principles of patent infringement. In both instances in *Graver Tank* where we referred to independent research or experiments, we were discussing the known interchangeability between the chemical compound claimed in the patent and the compound substituted by the alleged infringer. The need for independent experimentation thus could reflect knowledge — or lack thereof — of interchangeability possessed by one presumably skilled in the art. The known interchangeability of substitutes for an element of a patent is one of the express objective factors noted by *Graver Tank* as bearing upon whether the accused device is substantially the same as the patented invention. Independent experimentation by the alleged infringer would not always reflect upon the objective question whether a person skilled in the art would have known of the interchangeability between two elements, but in many cases it would likely be probative of such knowledge.

Although *Graver Tank* certainly leaves room for petitioner’s suggested inclusion of intent-based elements in the doctrine of equivalents, we do not read it as requiring them. The better view, and the one consistent with *Graver Tank*’s predecessors and the objective approach to infringement, is that intent plays no role in the application of the doctrine of equivalents.

C

Finally, petitioner proposes that in order to minimize conflict with the notice function of patent claims, the doctrine of equivalents should be limited to equivalents that are disclosed within the patent itself. A milder version of this argument, which found favor with the dissenters below, is that the doctrine should be limited to equivalents that were known at the time the patent was issued, and should not extend to after-arising equivalents.

As we have noted . . . with regard to the objective nature of the doctrine, a skilled practitioner’s knowledge of the interchangeability between claimed and accused elements is not relevant for its own sake, but rather for what it tells the fact-finder about the similarities or differences between those elements. Much as the perspective of the hypothetical “reasonable person” gives content to concepts such as “negligent” behavior, the perspective of a skilled practitioner provides content to, and limits on, the concept of “equivalence.” Insofar as the question under the doctrine of equivalents is whether an accused element is equivalent to a claimed element, the proper time for evaluating equivalency—and thus knowledge of interchangeability between elements—is at the time of infringement, not at the time the patent was issued. And rejecting the milder version of petitioner’s argument necessarily rejects the more severe proposition that equivalents must not only be known, but must also be actually disclosed in the patent in order for such equivalents to infringe upon the patent.

IV

The various opinions below, respondents, and amici devote considerable attention to whether application of the doctrine of equivalents is a task for the judge or for the jury. However, despite petitioner’s argument below that the doctrine should be applied by the judge, in this Court petitioner makes only passing reference to this issue. *See* Brief for Petitioner 22, n. 15 (“If this Court were to hold in *Markman v. Westview Instruments, Inc.*, that judges rather than juries are to construe patent claims, so as to provide a uniform definition of the scope of the legally protected monopoly, it would seem at cross-purposes to say that juries may nonetheless expand the claims by resort to a broad notion of ‘equivalents’”); Reply Brief for Petitioner 20 (whether judge or jury should apply the doctrine of equivalents depends on how the Court views the nature of the inquiry under the doctrine of equivalents).

Petitioner’s comments go more to the alleged inconsistency between the doctrine of equivalents and the claiming requirement than to the role of the jury in applying the doctrine as properly understood. Because resolution of whether, or how much of, the application of the doctrine of equivalents can be

resolved by the court is not necessary for us to answer the question presented, we decline to take it up. The Federal Circuit held that it was for the jury to decide whether the accused process was equivalent to the claimed process. There was ample support in our prior cases for that holding. Nothing in our recent *Markman* decision necessitates a different result than that reached by the Federal Circuit. Indeed, *Markman* cites with considerable favor, when discussing the role of judge and jury, the seminal *Winans* decision. *Markman v. Westview Instruments, Inc.* Whether, if the issue were squarely presented to us, we would reach a different conclusion than did the Federal Circuit is not a question we need decide today.⁸

V

All that remains is to address the debate regarding the linguistic framework under which “equivalence” is determined. Both the parties and the Federal Circuit spend considerable time arguing whether the so-called “triple identity” test—focusing on the function served by a particular claim element, the way that element serves that function, and the result thus obtained by that element—is a suitable method for determining equivalence, or whether an “insubstantial differences” approach is better. There seems to be substantial agreement that, while the triple identity test may be suitable for analyzing mechanical devices, it often provides a poor framework for analyzing other products or processes. On the other hand, the insubstantial differences test offers little additional guidance as to what might render any given difference “insubstantial.”

In our view, the particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? Different linguistic frameworks may be more suitable to different cases, depending on their particular facts. A focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements should reduce considerably the imprecision of whatever language is used. An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially

8. With regard to the concern over unreviewability due to black-box jury verdicts, we offer only guidance, not a specific mandate. Where the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment. See Fed. Rule Civ. Proc. 56. If there has been a reluctance to do so by some courts due to unfamiliarity with the subject matter, we are confident that the Federal Circuit can remedy the problem. Of course, the various legal limitations on the application of the doctrine of equivalents are to be determined by the court, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict. Fed. Rule Civ. Proc. 56; Fed. Rule Civ. Proc. 50. Thus, under the particular facts of a case, if prosecution history estoppel would apply or if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further material issue for the jury to resolve. Finally, in cases that reach the jury, a special verdict and/or interrogatories on each claim element could be very useful in facilitating review, uniformity, and possibly post verdict judgments as a matter of law. See Fed. Rule Civ. Proc. 49; Fed. Rule Civ. Proc. 50. We leave it to the Federal Circuit how best to implement procedural improvements to promote certainty, consistency, and reviewability to this area of the law.

different from the claimed element. With these limiting principles as a backdrop, we see no purpose in going further and micro-managing the Federal Circuit's particular word-choice for analyzing equivalence. We expect that the Federal Circuit will refine the formulation of the test for equivalence in the orderly course of case-by-case determinations, and we leave such refinement to that court's sound judgment in this area of its special expertise.

* * *

Comments

1. *The Growing Emphasis on Patent Law's Notice Function.* The patent law landscape had changed a great deal since the Supreme Court decided *Graver Tank*. In the mid-1990s, the Federal Circuit began to place greater emphasis on certainty and the notice function. One way to pursue these policy goals was to limit the role of juries in patent litigation and rein in the DOE, which some thought was increasingly unruly. Recall, the role of the jury in claim construction was eliminated in *Markman*; was the DOE next? When the Supreme Court agreed to hear *Warner-Jenkinson*, many in the patent community thought the viability of *Graver* was in danger and that the respective roles of judge and jury in the context of the DOE would be modified in a manner consistent with *Markman*. But, despite the "considerable attention" given to the judge-jury issue, the Court "decline[d] to take it up."

The Court did, however, recognize that the DOE had "taken on a life of its own, unbounded by the patent claims." In addressing this concern, the Court adopted the all-limitations rule advocated by the late Judge Nies. Under the all-limitations rule, "the patentee has the burden to present particularized evidence that links the accused products to the patent on a limitation by limitation basis." *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376 (Fed. Cir. 2007). *See also PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1364 (Fed. Cir. 2005) (stating the patentee must present "particularized evidence and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device, or with respect to the 'function, way, result' test"). The "all-limitations rule" is discussed below in Section 3.c.

Moreover, the Court constructed a rebuttable presumption, barring application of the DOE, when a patentee is unable to provide a reason for a narrowing amendment. Lastly, a strict liability framework was reaffirmed for patent infringement; as the Court stated, "intent plays no role in the application of the doctrine of equivalents." All of these moves were grounded in the desire for greater certainty and notice.

But the Court would only go so far, rebuffing Petitioner's argument that the DOE should be limited to equivalents disclosed in the patent specification or, at least, to equivalents known at the time the patent issued. By requiring equivalents to be measured at the time of infringement (not the time the patent issued), the Court implicitly acknowledged that application of the DOE will always be accompanied by some degree of uncertainty. Comment 2 explores the temporal dimension of the DOE.

2. ***DOE's Temporal Dimension and After-Arising Technology.*** Literal infringement is measured at the time of filing. Thus, literal claim scope cannot, by definition, extend to after-arising technologies. But, as noted by *Warner-Jenkinson*, equivalents are measured at the “time of infringement,” and are not limited to either “equivalents that are disclosed within the patent itself” or to “equivalents that were known at the time the patent was issued.” 520 U.S. at 41. *See also SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, 356 F.3d 1357, 1363-64 (Fed. Cir. 2004) (stating that after-arising technology is the “quintessential example of an enforceable equivalent,” and noting further “[u]sually, if the alleged equivalent represents later-developed technology (e.g., transistors in relation to vacuum tubes, or Velcro® in relation to fasteners) or technology that was not known in the relevant art, then it would not have been foreseeable. In contrast, old technology, while not always foreseeable, would more likely have been foreseeable”).

Therefore, the DOE is applied at the time of infringement, in part, to address the temporal constraints of literal infringement. Another reason is that the cumulative and unforeseeable nature of complex and ramified technologies, whereby the patentee opens a door for a subsequent improver-inventor, permitting the improver-inventor to benefit from the patentee's disclosure, thereby lowering the costs, accelerating the development, or simply making possible subsequent inventive activities. The DOE allows the patentee to capture some of this improvement activity; the difficult question is how big of a net should the patentee be permitted to cast. As we saw in Chapter 2 and the *Morse* case, allowing a patentee to capture after-arising technologies may provide an additional ex ante incentive, but may also negatively affect the incentive dynamic for follow-on inventors engaged in improvement activity—ex post incentives. *See Suzanne Scotchmer, Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, in JOURNAL OF ECONOMIC PERSPECTIVES, Vol. 5, No. 1, 29-41 (1991). For more on the DOE and after-arising technologies, *see* Christopher A. Cotropia, “After-Arising” Technologies and Tailoring Patent Scope, 61 NYU ANN. SURV. AM. L. 151 (2005).

An example of an after-arising technology was present in *Hughes Aircraft Co. v. United States*, 717 F.2d 1351 (Fed. Cir. 1983). In *Hughes*, the invention related to satellite technology, particularly controlling the attitude of a communications satellite. The inventor was a Hughes employee named Williams. The patent claimed the attitude was adjusted by communication between the satellite and a ground control station. As satellite technology evolved, self-contained, on-board computations using microprocessors would supplant the need for ground control communication to adjust the satellite's attitude. These types of microprocessors were unknown at the time the Hughes patent was filed. Nonetheless, the Federal Circuit held the on-board microprocessor technology infringed the Hughes patent. According to the court, “partial variation in technique, an embellishment made possible by post-Williams technology, does not allow the accused spacecraft to escape the web of infringement.” *Id.* at 1365. In other words, the inventor can capture after-arising technologies and is not required to predict all future developments that enable the practice of his invention in substantially the same way. *See also Pennwalt*

Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 941-42 (Fed. Cir. 1987) (*en banc*) (“It is clear that an equivalent can be found in technology known at the time of the invention, as well as in subsequently developed technology”); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries*, 145 F.3d 1303, 1310 (Fed. Cir. 1998) (“The doctrine of equivalents is necessary because one cannot predict the future. Due to technological advances, a variant of an invention may be developed after the patent is granted, and that variant may constitute so insubstantial a change from what is claimed in the patent that it should be held to be an infringement. Such a variant, based on after-developed technology, could not have been disclosed in the patent.”).

In addition, the United States added its weight to this issue in its amicus brief in *Warner-Jenkinson*:

Of course, when an accused equivalent (meeting the objective standard of insubstantiality) could not have been known because it was developed or discovered only after the patent issued, the case for application of the doctrine of equivalents becomes especially clear. For example, a claim to a chemical composition might include an inactive filler as a minor, unimportant ingredient. After the patent issues, a competitor of the patentee might manufacture a composition exactly as claimed but use a different, inactive filler, unknown in the art at the time the patent application was filed, that performs exactly as those literally covered by the claim. Such a substitution, once it became available, might be known to persons of skill in the relevant art to be interchangeable with the claimed filler, and yet it would not have been possible to include the accused element in the patent because it did not exist at the time of issue.

1996 WL 172221, *23 n.8.

Interestingly, despite the DOE’s role in expanding claim scope and the ability of patentee’s to capture after-arising technology, two commentators recently observed that “patentees rarely win doctrine of equivalents cases.” See John R. Allison & Mark A. Lemley, *The (Unnoticed) Demise of the Doctrine of Equivalents*, 59 STAN. L. REV. 955, 966 (2007) (finding “patentees won only 24% of the doctrine of equivalents cases decided in the last eight years [c]ompared to the overall patentee win rates on other issues—54% on validity alone in cases at various stages of litigation, and 58% overall in cases that make it to trial”).

- 3. *Timing Is Everything: The DOE’s Relationship with § 112?*** How can a patent claim be read to capture after-arising technology when the technology did not exist at the time the patent was filed? Another way of asking this question is, Isn’t there a conflict between satisfying the disclosure requirements and the DOE? The key to this apparent conflict is the *timing* of the inquiry. Recall from Chapter 2 that enablement is measured at the time of filing. In contrast, equivalents are measured at the time of infringement.

An illustrative case on time-shifting between enablement and DOE infringement is *In re Hogan*, 559 F.2d 595 (CCPA 1977). In *Hogan*, the issue involved the PTO’s use of “later state of the art” to support a § 112 rejection based on lack of commensurability. The appellant filed several continuations, all of which, appellant argued, enjoyed the filing date of the original application filed in 1953.

The PTO relied on numerous references that had an effective date prior to 1971, but after 1953. The PTO argued that the claims of the 1971 application cover both crystalline polymers and amorphous polymers. Since amorphous polymers did not exist in 1953, the PTO argued, the disclosure of the 1971 application “is not commensurate in scope with the breadth of the claims.” *Id.* at 605. The PTO pointed to the Edwards reference (filed in 1962)—which first disclosed amorphous polymers—as evidence that amorphous polymers did not exist in 1953.

The CCPA reversed the rejection. First, the court stated it was improper for the PTO to use later state of the art (*i.e.*, Edwards) to prove that amorphous polymers did not exist in 1953. As the court noted, “if appellants’ 1953 application provided sufficient enablement, considering all available evidence of the 1953 state of the art, then the fact of that enablement was established for all time and a later change in the state of the art cannot change it.” *Id.* at 605. In other words, the filing date (assuming a sufficient disclosure) locks in compliance with the enablement requirement, and it is impermissible to use later state of the art to prove non-compliance.

The court then discussed claim scope, asking “[t]o what scope of protection is this applicant’s particular contribution to the art entitled?” According to the court:

The PTO position, that claim 13 is of sufficient breadth to cover the later state of the art (amorphous polymers) shown in the “references,” reflects a concern that allowance of claim 13 might lead to enforcement efforts against the later developers. Any such conjecture, if it exists, is both irrelevant and unwarranted. The business of the PTO is patentability, not infringement. . . . The courts have consistently considered subsequently existing states of the art as raising questions of infringement, but never validity. It is, of course, a major and infinitely important function of the PTO to insure that those skilled in the art are enabled, as of the filing date, to practice the invention claimed. If, in the light of all proper evidence, the invention claimed be clearly enabled as of that date, the inquiry under § 112, first paragraph, is at an end.

Id. at 607.

4. **Patenting the Accused Device.** *Warner-Jenkinson* did not directly address the related issue of whether the patentability of a later-developed, accused device or method is relevant to equivalency. It is well-settled that a patent on an accused product or process does not give the owner of the patent a right to exploit the product or process. Existence of a patent provides no defense to literal infringement of a claim. For example, in *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996), Genentech’s patent claiming a recombinant process for producing a hormone read literally on the accused infringer’s process. The accused infringer argued that its process involved a unique, patented purification method. The court dismissed the argument: “That [the accused infringer] patented its unique purification method is irrelevant: ‘[T]he existence of one’s own patent does not constitute a defense to infringement of someone else’s patent. It is elementary that a patent grants only the right to *exclude others* and confers no right on its holder to make, use, or sell.’” 80 F.3d at 1559.

But some Federal Circuit decisions suggest that a patent on the accused device may be relevant to the substantiality of the difference between the

patent claim and the accused device, at least when the patent in suit was cited and considered by the PTO in issuing the subsequent patent. *See Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1570 (Fed. Cir. 1996) (stating the accused device is “presumed nonobvious” when it is patented, and “[t]he nonobviousness . . . is relevant to the issue of whether the change therein is substantial”); *Hoganas AB v. Dresser Industries, Inc.*, 9 F.3d 948, 954 (Fed. Cir. 1993) (stating “the PTO must have considered the accused product to be nonobvious with respect to the patented composition. Accordingly, the issuance of that patent is relevant to the equivalence issue”). In addition, a patent on an accused product prompts a comparison between the non-obviousness test and the insubstantial differences framework of the doctrine of equivalents. *See Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1128 (Fed. Cir. 1996) (Nies, J. additional views: “If the second patent requires practice of the first i.e., the second merely adds an element ‘D’ to a patented combination A+B+C, the combination A+B+C+D clearly infringes. Conversely, if the second patent is granted for A+B+D over one claiming A+B+C, the change from C to D must not have been obvious to be validly patented. Evidence of a patent covering the change, in my view, is clearly relevant unless the patent is invalid. A substitution in a patented invention cannot be both nonobvious and insubstantial. I would apply nonobviousness as the test for the ‘insubstantial change’ requirement of *Hilton Davis*.”). *See* Alan Durham, *Patent Symmetry*, 87 B.U. L. REV. — (forthcoming 2007) (exploring the relationship between equivalents and obviousness).

5. **The Linguistic Framework.** The Federal Circuit devoted a great deal of text to the proper linguistic framework for the DOE and the role of the jury in deciding equivalence infringement. Regarding the former, the debate at the Federal Circuit centered on the respective benefits and drawbacks between *Graver Tank*’s tripartite test and the “insubstantial differences” test. The Federal Circuit adopted “insubstantial differences” as the “ultimate test,” retaining the tripartite function-way-result test as a permissible formulation in particular cases. The Supreme Court expressed concern with each linguistic test, stating “[t]here seems to be substantial agreement that, while the triple identity test may be suitable for analyzing mechanical devices, it often provides a poor framework for analyzing other products or processes. On the other hand, the insubstantial differences test offers little additional guidance as to what might render any given difference “insubstantial.” The Court neither adopted a new linguistic framework, nor endorsed the two existing frameworks. Rather, the Court thought that focusing on individual claim elements during an equivalency determination and assuring against vitiation of claim elements would “reduce considerably the imprecision of whatever language is used.” In the end, the Court left to the Federal Circuit to “refine the formulation of the test for equivalence in the orderly course of case-by-case determinations.” Indeed, the Federal Circuit continues to use both linguistic test, and, at times, conflates the two. *See, e.g., Searfoss v. Pioneer Consol. Corp.*, 374 F.3d 1142, 1150 (Fed. Cir. 2002) (“An element in the accused product is equivalent to a claim limitation if the differences between the two are

“insubstantial” to one of ordinary skill in the art.’ In determining whether the differences between the accused product and the claim limitation are ‘insubstantial,’ it is axiomatic that we may determine whether the accused product performs the same function, in the same way with the same result.”).

3. Limitations on the Doctrine of Equivalents

There are four limitations to the DOE that are explored in this section. They include (1) prosecution history estoppel; (2) public dedication rule; (3) all-limitations and specific exclusion rule; and (4) prior art. Each of these limitations is explored in the following four subsections.

a. Prosecution History Estoppel

In its traditional setting, Prosecution History Estoppel (“PHE”) applies when a patentee attempts to acquire a claim scope during litigation that it surrendered during prosecution. For instance, PHE estops a patentee who narrowed his claim during prosecution to overcome a prior art rejection from recapturing—during litigation—the surrendered claim breadth. Thus, the PHE acts as a limitation on the DOE.

The Supreme Court *Festo* case (*Festo VIII*) reveals a broader and more rigorous application of PHE. *Festo VIII* held that a patentee who, during prosecution, narrowed his claim scope by amendment is presumed to have surrendered the “the territory between the original claim and the amended claim,” unless the patentee can show (1) the equivalent the he is seeking to capture was unforeseeable at the time of the amendment; (2) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (3) some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. The *Cross Medical* case, the principal case following *Festo VIII*, explores the “tangential relation” component of *Festo VIII*.

FESTO CORP. v. SHOKETSU KINZOKU KOGYO KABUSHIKI CO., LTD. (FESTO VIII)

535 U.S. 722 (2002)

Justice KENNEDY delivered the opinion of the Court.

This case requires us to address once again the relation between two patent law concepts, the doctrine of equivalents and the rule of prosecution history estoppel. The Court considered the same concepts in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, and reaffirmed that a patent protects its holder against efforts of copyists to evade liability for infringement by making only insubstantial changes to a patented invention. At the same time, we appreciated that by extending protection beyond the literal terms in a patent the doctrine of equivalents can create substantial uncertainty about where the patent monopoly ends. If the range of equivalents is unclear, competitors may be unable to determine what is a permitted alternative to a patented invention and what is an infringing equivalent.

To reduce the uncertainty, *Warner-Jenkinson* acknowledged that competitors may rely on the prosecution history, the public record of the patent proceedings. In some cases the Patent and Trademark Office (PTO) may have rejected an earlier version of the patent application on the ground that a claim does not meet a statutory requirement for patentability. When the patentee responds to the rejection by narrowing his claims, this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent. Competitors may rely on the estoppel to ensure that their own devices will not be found to infringe by equivalence.

In the decision now under review the Court of Appeals for the Federal Circuit held that by narrowing a claim to obtain a patent, the patentee surrenders all equivalents to the amended claim element. Petitioner asserts this holding departs from past precedent in two respects. First, it applies estoppel to every amendment made to satisfy the requirements of the Patent Act and not just to amendments made to avoid pre-emption by an earlier invention, *i.e.*, the prior art. Second, it holds that when estoppel arises, it bars suit against every equivalent to the amended claim element. The Court of Appeals acknowledged that this holding departed from its own cases, which applied a flexible bar when considering what claims of equivalence were estopped by the prosecution history. Petitioner argues that by replacing the flexible bar with a complete bar the Court of Appeals cast doubt on many existing patents that were amended during the application process when the law, as it then stood, did not apply so rigorous a standard.

We granted certiorari to consider these questions.

I

Petitioner Festo Corporation owns two patents for an improved magnetic rodless cylinder, a piston-driven device that relies on magnets to move objects in a conveying system. The device has many industrial uses and has been employed in machinery as diverse as sewing equipment and the Thunder Mountain ride at Disney World. Although the precise details of the cylinder's operation are not essential here, the prosecution history must be considered.

Petitioner's patent applications, as often occurs, were amended during the prosecution proceedings. The application for the first patent, the Stoll Patent (U.S. Patent No. 4,354,125), was amended after the patent examiner rejected the initial application because the exact method of operation was unclear and some claims were made in an impermissible way. (They were multiply dependent.) 35 U.S.C. § 112. The inventor, Dr. Stoll, submitted a new application designed to meet the examiner's objections and also added certain references to prior art. The second patent, the Carroll Patent (U.S. Patent No. 3,779,401), was also amended during a reexamination proceeding. The prior art references were added to this amended application as well. Both amended patents added a new limitation—that the inventions contain a pair of sealing rings, each having a lip on one side, which would prevent impurities from getting on the piston assembly. The amended Stoll Patent added the further limitation that the outer shell of the device, the sleeve, be made of a magnetizable material.

After Festo began selling its rodless cylinder, respondents (whom we refer to as SMC) entered the market with a device similar, but not identical, to the

ones disclosed by Festo's patents. SMC's cylinder, rather than using two one-way sealing rings, employs a single sealing ring with a two-way lip. Furthermore, SMC's sleeve is made of a nonmagnetizable alloy. SMC's device does not fall within the literal claims of either patent, but petitioner contends that it is so similar that it infringes under the doctrine of equivalents.

SMC contends that Festo is estopped from making this argument because of the prosecution history of its patents. The sealing rings and the magnetized alloy in the Festo product were both disclosed for the first time in the amended applications. In SMC's view, these amendments narrowed the earlier applications, surrendering alternatives that are the very points of difference in the competing devices—the sealing rings and the type of alloy used to make the sleeve. As Festo narrowed its claims in these ways in order to obtain the patents, says SMC, Festo is now estopped from saying that these features are immaterial and that SMC's device is an equivalent of its own.

The United States District Court for the District of Massachusetts disagreed. It held that Festo's amendments were not made to avoid prior art, and therefore the amendments were not the kind that give rise to estoppel. A panel of the Court of Appeals for the Federal Circuit affirmed. We granted certiorari, vacated, and remanded in light of our intervening decision in *Warner-Jenkinson v. Hilton Davis Chemical Co.* After a decision by the original panel on remand, the Court of Appeals ordered rehearing en banc to address questions that had divided its judges since our decision in *Warner-Jenkinson*.

The en banc court reversed, holding that prosecution history estoppel barred Festo from asserting that the accused device infringed its patents under the doctrine of equivalents. The court held, with only one judge dissenting, that estoppel arises from any amendment that narrows a claim to comply with the Patent Act, not only from amendments made to avoid prior art. More controversial in the Court of Appeals was its further holding: When estoppel applies, it stands as a complete bar against any claim of equivalence for the element that was amended. The court acknowledged that its own prior case law did not go so far. Previous decisions had held that prosecution history estoppel constituted a flexible bar, foreclosing some, but not all, claims of equivalence, depending on the purpose of the amendment and the alterations in the text. The court concluded, however, that its precedents applying the flexible-bar rule should be overruled because this case-by-case approach has proved unworkable. In the court's view a complete-bar rule, under which estoppel bars all claims of equivalence to the narrowed element, would promote certainty in the determination of infringement cases.

We granted certiorari.

II

The patent laws “promote the Progress of Science and useful Arts” by rewarding innovation with a temporary monopoly. U.S. Const., Art. I, § 8, cl. 8.

The monopoly is a property right; and like any property right, its boundaries should be clear. This clarity is essential to promote progress, because it enables efficient investment in innovation. A patent holder should know what he owns, and the public should know what he does not. For this reason, the patent laws require inventors to describe their work in “full, clear, concise, and exact terms,” 35 U.S.C. § 112, as part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor’s exclusive rights.

Unfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application. The inventor who chooses to patent an invention and disclose it to the public, rather than exploit it in secret, bears the risk that others will devote their efforts toward exploiting the limits of the patent’s language:

An invention exists most importantly as a tangible structure or a series of drawings. A verbal portrayal is usually an afterthought written to satisfy the requirements of patent law. This conversion of machine to words allows for unintended idea gaps which cannot be satisfactorily filled. Often the invention is novel and words do not exist to describe it. The dictionary does not always keep abreast of the inventor. It cannot. Things are not made for the sake of words, but words for things. *Autogiro Co. of America v. United States*, 181 Ct. Cl. 55 (1967).

The language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty. If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying. For this reason, the clearest rule of patent interpretation, literalism, may conserve judicial resources but is not necessarily the most efficient rule. The scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described. See *Winans v. Denmead*, 56 U.S. (15 How.) 330, 347 (1854). It is true that the doctrine of equivalents renders the scope of patents less certain. It may be difficult to determine what is, or is not, an equivalent to a particular element of an invention. If competitors cannot be certain about a patent’s extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures. In addition the uncertainty may lead to wasteful litigation between competitors, suits that a rule of literalism might avoid. These concerns with the doctrine of equivalents, however, are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule. When the Court in *Winans v. Denmead*, *supra*, first adopted what has become the doctrine of equivalents, it stated that “[t]he exclusive right to the thing patented is not secured, if the public are at liberty to make substantial copies of it, varying its form or proportions.” *Id.*, at 343. The dissent argued that the Court had sacrificed the objective of

“[f]ul[l]ness, clearness, exactness, preciseness, and particularity, in the description of the invention.” *Id.*, at 347 (opinion of Campbell, J.).

The debate continued in *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950), where the Court reaffirmed the doctrine. *Graver Tank* held that patent claims must protect the inventor not only from those who produce devices falling within the literal claims of the patent but also from copyists who “make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.” *Id.* at 607. Justice Black, in dissent, objected that under the doctrine of equivalents a competitor “cannot rely on what the language of a patent claims. He must be able, at the peril of heavy infringement damages, to forecast how far a court relatively unversed in a particular technological field will expand the claim’s language. . . .” *Id.*, at 617.

Most recently, in *Warner-Jenkinson*, the Court reaffirmed that equivalents remain a firmly entrenched part of the settled rights protected by the patent. A unanimous opinion concluded that if the doctrine is to be discarded, it is Congress and not the Court that should do so:

[T]he lengthy history of the doctrine of equivalents strongly supports adherence to our refusal in *Graver Tank* to find that the Patent Act conflicts with that doctrine. Congress can legislate the doctrine of equivalents out of existence any time it chooses. The various policy arguments now made by both sides are thus best addressed to Congress, not this Court. 520 U.S., at 28.

III

Prosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process. Estoppel is a “rule of patent construction” that ensures that claims are interpreted by reference to those “that have been cancelled or rejected.” *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-221 (1940). The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes. When, however, the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent. On the contrary, “[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases[,] . . . and [t]he difference which [the patentee] thus disclaimed must be regarded as material.” *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-137 (1942).

A rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim. See *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 228 (1880) (“In view of [the amendment] there can be no doubt of what [the patentee] understood he had patented, and that both he and the commissioner regarded

the patent to be for a manufacture made exclusively of vulcanites by the detailed process”); *Wang Laboratories, Inc. v. Mitsubishi Electronics America, Inc.*, 103 F.3d 1571, 1577-1578 (C.A. Fed. 1997) (“Prosecution history estoppel . . . preclud[es] a patentee from regaining, through litigation, coverage of subject matter relinquished during prosecution of the application for the patent”). Were it otherwise, the inventor might avoid the PTO’s gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent.

Prosecution history estoppel ensures that the doctrine of equivalents remains tied to its underlying purpose. Where the original application once embraced the purported equivalent but the patentee narrowed his claims to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question. The doctrine of equivalents is premised on language’s inability to capture the essence of innovation, but a prior application describing the precise element at issue undercuts that premise. In that instance the prosecution history has established that the inventor turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.

A

The first question in this case concerns the kinds of amendments that may give rise to estoppel. Petitioner argues that estoppel should arise when amendments are intended to narrow the subject matter of the patented invention, for instance, amendments to avoid prior art, but not when the amendments are made to comply with requirements concerning the form of the patent application. In *Warner-Jenkinson* we recognized that prosecution history estoppel does not arise in every instance when a patent application is amended. Our “prior cases have consistently applied prosecution history estoppel only where claims have been amended for a limited set of reasons,” such as “to avoid the prior art, or otherwise to address a specific concern—such as obviousness—that arguably would have rendered the claimed subject matter unpatentable.” 520 U.S., at 30-32. While we made clear that estoppel applies to amendments made for a “substantial reason related to patentability,” *id.*, at 33, we did not purport to define that term or to catalog every reason that might raise an estoppel. Indeed, we stated that even if the amendment’s purpose were unrelated to patentability, the court might consider whether it was the kind of reason that nonetheless might require resort to the estoppel doctrine. *Id.*, at 40-41.

Petitioner is correct that estoppel has been discussed most often in the context of amendments made to avoid the prior art. Amendment to accommodate prior art was the emphasis, too, of our decision in *Warner-Jenkinson*, *supra*, at 30. It does not follow, however, that amendments for other purposes will not give rise to estoppel. Prosecution history may rebut the inference that a thing not described was indescribable. That rationale does not cease simply because the narrowing amendment, submitted to secure a patent, was for some purpose other than avoiding prior art.

We agree with the Court of Appeals that a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel. As

that court explained, a number of statutory requirements must be satisfied before a patent can issue. The claimed subject matter must be useful, novel, and not obvious. 35 U.S.C. §§ 101-103. In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention. § 112. These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue. The patent also should not issue if the other requirements of § 112 are not satisfied, and an applicant's failure to meet these requirements could lead to the issued patent being held invalid in later litigation.

Petitioner contends that amendments made to comply with § 112 concerns the form of the application and not the subject matter of the invention. The PTO might require the applicant to clarify an ambiguous term, to improve the translation of a foreign word, or to rewrite a dependent claim as an independent one. In these cases, petitioner argues, the applicant has no intention of surrendering subject matter and should not be estopped from challenging equivalent devices. While this may be true in some cases, petitioner's argument conflates the patentee's reason for making the amendment with the impact the amendment has on the subject matter.

Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope. If a § 112 amendment is truly cosmetic, then it would not narrow the patent's scope or raise an estoppel. On the other hand, if a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply. A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112. We must regard the patentee as having conceded an inability to claim the broader subject matter or at least as having abandoned his right to appeal a rejection. In either case estoppel may apply.

B

Petitioner concedes that the limitations at issue—the sealing rings and the composition of the sleeve—were made for reasons related to § 112, if not also to avoid the prior art. Our conclusion that prosecution history estoppel arises when a claim is narrowed to comply with § 112 gives rise to the second question presented: Does the estoppel bar the inventor from asserting infringement against any equivalent to the narrowed element or might some equivalents still infringe? The Court of Appeals held that prosecution history estoppel is a complete bar, and so the narrowed element must be limited to its strict literal terms. Based upon its experience the Court of Appeals decided that the flexible-bar rule is unworkable because it leads to excessive uncertainty and burdens legitimate innovation. For the reasons that follow, we disagree with the decision to adopt the complete bar.

Though prosecution history estoppel can bar challenges to a wide range of equivalents, its reach requires an examination of the subject matter surren-

dered by the narrowing amendment. The complete bar avoids this inquiry by establishing a *per se* rule; but that approach is inconsistent with the purpose of applying the estoppel in the first place—to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment. By amending the application, the inventor is deemed to concede that the patent does not extend as far as the original claim. It does not follow, however, that the amended claim becomes so perfect in its description that no one could devise an equivalent. After amendment, as before, language remains an imperfect fit for invention. The narrowing amendment may demonstrate what the claim is not; but it may still fail to capture precisely what the claim is. There is no reason why a narrowing amendment should be deemed to relinquish equivalents unforeseeable at the time of the amendment and beyond a fair interpretation of what was surrendered. Nor is there any call to foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted. The amendment does not show that the inventor suddenly had more foresight in the drafting of claims than an inventor whose application was granted without amendments having been submitted. It shows only that he was familiar with the broader text and with the difference between the two. As a result, there is no more reason for holding the patentee to the literal terms of an amended claim than there is for abolishing the doctrine of equivalents altogether and holding every patentee to the literal terms of the patent.

This view of prosecution history estoppel is consistent with our precedents and respectful of the real practice before the PTO. While this Court has not weighed the merits of the complete bar against the flexible bar in its prior cases, we have consistently applied the doctrine in a flexible way, not a rigid one. We have considered what equivalents were surrendered during the prosecution of the patent, rather than imposing a complete bar that resorts to the very literalism the equivalents rule is designed to overcome.

The Court of Appeals ignored the guidance of *Warner-Jenkinson*, which instructed that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community. In that case we made it clear that the doctrine of equivalents and the rule of prosecution history estoppel are settled law. The responsibility for changing them rests with Congress. *Ibid.* Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property. The petitioner in *Warner-Jenkinson* requested another bright-line rule that would have provided more certainty in determining when estoppel applies but at the cost of disrupting the expectations of countless existing patent holders. We rejected that approach: “To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision.” *Id.*, at 32, n.6; see also *id.*, at 41 (Ginsburg, J., concurring) (“The new presumption, if applied woodenly, might in some instances unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such a presumption would apply”). As *Warner-Jenkinson* recognized, patent prosecution occurs in the light of our case law. Inventors who amended their claims under the previous regime had no reason to believe they were conceding all equivalents. If they had known, they

might have appealed the rejection instead. There is no justification for applying a new and more robust estoppel to those who relied on prior doctrine.

In *Warner-Jenkinson* we struck the appropriate balance by placing the burden on the patentee to show that an amendment was not for purposes of patentability:

Where no explanation is established, however, the court should presume that the patent application had a substantial reason related to patentability for including the limiting element added by amendment. In those circumstances, prosecution history estoppel would bar the application of the doctrine of equivalents as to that element. *Id.* at 33.

When the patentee is unable to explain the reason for amendment, estoppel not only applies but also “bar[s] the application of the doctrine of equivalents as to that element.” *Ibid.* These words do not mandate a complete bar; they are limited to the circumstance where “no explanation is established.” They do provide, however, that when the court is unable to determine the purpose underlying a narrowing amendment—and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language.

Just as *Warner-Jenkinson* held that the patentee bears the burden of proving that an amendment was not made for a reason that would give rise to estoppel, we hold here that the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question. This is the approach advocated by the United States, see Brief for United States as *Amicus Curiae* 22-28, and we regard it to be sound. The patentee, as the author of the claim language, may be expected to draft claims encompassing readily known equivalents. A patentee’s decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim. *Exhibit Supply*, 315 U.S., at 136-137 (“By the amendment [the patentee] recognized and emphasized the difference between the two phrases and proclaimed his abandonment of all that is embraced in that difference”). There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

This presumption is not, then, just the complete bar by another name. Rather, it reflects the fact that the interpretation of the patent must begin with its literal claims, and the prosecution history is relevant to construing those claims. When the patentee has chosen to narrow a claim, courts may presume the amended text was composed with awareness of this rule and that the territory surrendered is not an equivalent of the territory claimed. In those instances, however, the patentee still might rebut the presumption that estoppel bars a claim of equivalence. The patentee must show that at the time of the amendment

one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.

IV

On the record before us, we cannot say petitioner has rebutted the presumptions that estoppel applies and that the equivalents at issue have been surrendered. Petitioner concedes that the limitations at issue—the sealing rings and the composition of the sleeve—were made in response to a rejection for reasons under § 112, if not also because of the prior art references. As the amendments were made for a reason relating to patentability, the question is not whether estoppel applies but what territory the amendments surrendered. While estoppel does not effect a complete bar, the question remains whether petitioner can demonstrate that the narrowing amendments did not surrender the particular equivalents at issue. On these questions, respondents may well prevail, for the sealing rings and the composition of the sleeve both were noted expressly in the prosecution history. These matters, however, should be determined in the first instance by further proceedings in the Court of Appeals or the District Court.

The judgment of the Federal Circuit is vacated, and the case is remanded for further proceedings consistent with this opinion.

Comments

1. **Limiting and Tolerating Uncertainty.** The Supreme Court rejected the complete bar approach of the Federal Circuit, although it did acknowledge the importance of certainty in a rights-based system such as patent law. In adopting its framework of presumptions and burdens (see Comment 2 below), the Court recognized the inherent limitations of language in describing an invention. (For example, how would you describe something as simple as a pizza box or pencil?). And the Court candidly acknowledged that the patent system has tolerated “uncertainty as the price of ensuring the appropriate incentives for innovation.” This sentiment was echoed by Lord Hoffmann in *Kirin-Amgen*: “[U]ncertainty is inherent in any rule which involves the construction of any document. It afflicts the whole of the law of contract, to say nothing of legislation. In principle it is without remedy.” *Kirin-Amgen, Inc. v. Hoechst Marion Roussel Ltd* 2004] UKHL 46, [2004] All ER (D) 286 (Oct. 1, 2004), ¶ 48. *Kirin-Amgen* is discussed at the end of this section.
2. **The Age of Presumptions and Burdens.** The *Festo* Court, consistent with *Warner-Jenkinson*, favored the creation of a rebuttable presumption. Recall, in *Warner-Jenkinson*, the Court wrote, “[w]hen the patentee is unable to explain the reason for amendment, estoppel not only applies but also ‘bar[s] the application of the doctrine of equivalents as to that element.’” In *Festo*, the Supreme Court expanded this presumption, nothing that a narrowing of claim scope during prosecution “may be presumed to be a general disclaimer of the territory between the original and the amended claim”; that is, “the territory surrendered is not an equivalent of the territory claimed.” This

presumption led the Court to impose a burden on the patentee “of showing that the amendment does not surrender the particular equivalent in question.” According to the Court:

The patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.

In particular, to rebut the presumption, the patentee must show (1) the equivalent was unforeseeable at the time of amendment; (2) the rationale underlying the amendment was tangentially related to the equivalent; or (3) some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. (Tangential relation is explored in *Cross Medical*, the principal case following these comments.)

Recall also that the petitioner in *Warner-Jenkinson* argued, unsuccessfully, that the DOE should be “limited to equivalents that were known at the time the patent was issued, and should not extend to after-arising technologies.” 520 U.S. at 30. The Court rejected this argument because equivalents are measured at the time of infringement, implying that not only can the patentee capture technology that existed at the time the patent issued, but also after-arising technology. The *Festo* Court, however, prevents patentees from capturing extant technologies because what is known at the time of issuance is obviously foreseeable. Under *Festo*, only unforeseeable equivalents are eligible to be captured by the DOE, a position that is consistent with measuring equivalents at the time of infringement.

3. ***Recognizing a “Narrowing” Amendment Made for “Reasons Related to Patentability.”*** For the *Festo* presumption to apply, an amendment must have narrowed the claim and have been filed for substantial reasons related to patentability. Any amendment made in response to prior art based on §§ 102 and 103 would certainly be related to patentability. Indeed, most amendments filed in response to § 112 rejections would also satisfy this prong of *Festo*.

The question of what constitutes a narrowing of claim scope is not as straightforward as it seems. For instance, in *Honeywell Int’l, Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131 (Fed. Cir. 2004), the patentee rewrote a dependent claim into an independent claim and cancelled the original independent claim, which was rejected by the Examiner as obvious under § 103. In rejecting the independent claim (and the dependent claim because it was dependent on an obvious independent claim), the Examiner indicated that the dependent claim would be allowable if written in independent form. Importantly, the dependent claim contained an additional limitation not present in the original independent claim. The Federal Circuit held that this action constituted a narrowing of claim scope, and therefore, the *Festo* presumption applied. According to the court:

The fact that the scope of the rewritten claim has remained unchanged will not preclude the application of prosecution history estoppel if, by canceling the original independent claim and rewriting the dependent claims into inde-

pendent form, the scope of the subject matter claimed in the independent claim has been narrowed to secure the patent.

Id. at 1142.

4. **Defining and Refining Foreseeability.** The *Festo* saga has been pending before the courts for 20 years, and has gone through—according to the Federal Circuit’s count—13 rounds. In *Festo VIII*, the Supreme Court constructed the foreseeability test as a means of rebutting application of PHE. Defining foreseeability is, of course, quite challenging whether the subject is tort law or patent law. In *Festo XIII*, the Federal Circuit added resolution to this standard, and held that the DOE may be barred even if the function of the equivalent was unforeseeable. A PHOSITA, according to the court, does not have to foresee that an equivalent would perform the same function, in the same way, to achieve the same result. While use of a non-magnetizeable aluminum alloy was known at the time of the patentee’s amendment, the ability of the alloy to serve magnetic shielding function as set forth in the specification was unknown. As the court wrote, “[a]n equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown.”

In another *Festo* iteration, the Federal Circuit in *Festo IX*, decided immediately after the Supreme Court decision, emphasized the objective nature of the foreseeability inquiry:

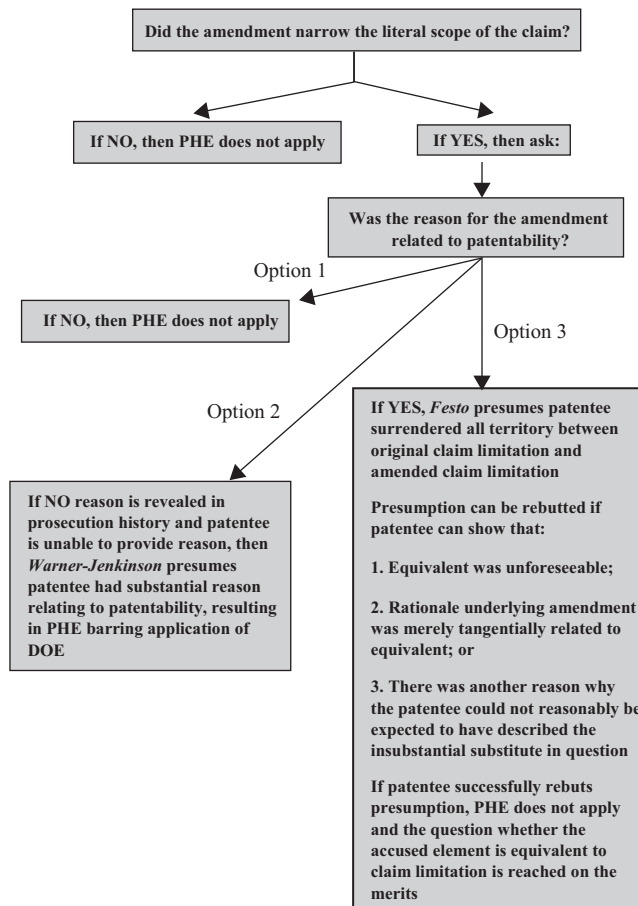
This criterion presents an objective inquiry, asking whether the alleged equivalent would have been unforeseeable to one of ordinary skill in the art at the time of the amendment. Usually, if the alleged equivalent represents later-developed technology (e.g., transistors in relation to vacuum tubes, or Velcro® in relation to fasteners) or technology that was not known in the relevant art, then it would not have been foreseeable. In contrast, old technology, while not always foreseeable, would more likely have been foreseeable. Indeed, if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment. By its very nature, objective unforeseeability depends on underlying factual issues relating to, for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment. Therefore, in determining whether an alleged equivalent would have been unforeseeable, a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries.

Festo IX, 356 F.3d at 1369. The 2007 *Festo* decision further refined the foreseeability component.

Foreseeability was also at issue in *SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, 356 F.3d 1357 (Fed. Cir. 2004). In *SmithKline*, the patent related to an antidepressant, particularly “controlled sustained release tablets” containing bupropion hydrochloride, which were developed to avoid multiple dosages. The key ingredient for obtaining sustained release was hydroxypropyl methylcellulose (HPMC). But the claims in question did not originally recite HPMC. Rather, HPMC was added through a narrowing amendment in response to a § 112 enablement

rejection. The accused product, made by Excel, did not literally infringe the patent because the accused product used polyvinyl alcohol or PVA (not HPMC) as its release agent. And Excel argued that the patentee is precluded from arguing that PVA is equivalent to HPMC because the patentee narrowed its claim to add HPMC. The patentee argued that it could not have claimed PVA because its patent disclosure only recited HPMC, and therefore, asserted (correctly) that there was no support in the specification as required by § 112 for PVA. The Federal Circuit rejected this argument because it did not fit into one of the three *Festo* exceptions. PVA was not an unforeseeable equivalent at the time of amendment, and the rationale underlying the amendment was germane to the equivalent in question — in other words, not tangentially related. As the court stated, “the Supreme Court in *Festo* neither excuses an applicant from failing to claim ‘readily known equivalents’ at the time of application nor allows a patentee to rebut the *Festo* presumption by invoking its own failure to include a known equivalent in its original disclosure.” *Id.* at 1364. *See also Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348 (Fed. Cir. 2004) (same); *Ranbaxy Pharm., Inc. v. Apotex, Inc.*, 350 F.3d 1235, 1241 (Fed. Cir. 2003) (holding that if an allegedly infringing product was readily known by those of skill in the art to be equivalent to the claim limitation, “it would have been foreseeable to literally include [it] in the claim”).

5. **Clarification and Elaboration.** The Federal Circuit has clarified and added resolution to the Supreme Court’s *Festo* decision.
 - a. **Time of Amendment or Application.** The timeframe for the foreseeability inquiry was identified by the Supreme Court—somewhat confusingly—as time of application and time of amendment. The Federal Circuit subsequently held the relevant time period for evaluating unforeseeability is time of amendment.
 - b. **Retroactivity.** The *Festo* presumption applies to extant patents and litigation. *See Festo IX*, 344 F.3d 1370 n.4 (“Consistent with Supreme Court precedent, the holdings of that Court and our own regarding the *Festo* presumption of surrender and its rebuttal apply to all granted patents and to all pending litigation that has not been concluded with a final judgment, including appeals”).
6. **Estoppel by Argument.** Prosecution history estoppel can be invoked by arguments made during prosecution regardless of whether claim language is amended. *See Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1373 (Fed. Cir. 2006) (“A surrender can occur by argument as well as by amendment.”).
7. ***Festo* Loses on Remand.** Ten years after the trial and Supreme Court intervention, District Court Judge Patti Saris, who wrote the original *Festo* opinion, held June 10, 2005 that SMC did not infringe *Festo*’s ’125 patent, thus reversing the originally jury verdict. The sole issue on remand was whether *Festo* could rebut the *Festo* presumption, something it was unable to do. The accused product did not have a single sealing ring and non-magnetizable sleeve, two elements, which, according to Judge Saris, were foreseeable to a person having ordinary skill in the art at the time the patent application were amended in November of 1981.

The *Festo* Flow Chart

POLICY PERSPECTIVE

Festo and the Devolution of Responsibility

The *Festo* decision can be viewed as re-focusing the temporal dimension of the patent game, what can be characterized as a devolution of responsibility. Although not expressly stating as much, the Court emphasized the decentralized nature of information, a central tenet of the Austrian school of economic thought. For instance, nearly 60 years ago, Friedrich Hayek wrote of the decentralized nature of knowledge, stating that “[t]he economic problem of society is . . . how to secure the best use of resources known to any of the members of society, for ends whose relative importance only these individuals know.” Friedrich A. Hayek, *The Use of Knowledge in Society*, in *INDIVIDUALISM AND ECONOMIC ORDER* 78 (1948). For Hayek,

[t]he peculiar character of the problem of a rational economic order is determined precisely by the fact that the knowledge of the circumstances of which we must make use never exists in concentrated or integrated form but

solely as the dispersed bits of incomplete and frequently contradictory knowledge which all the separate individuals possess. Or, to put it briefly, it is a problem of the utilization of knowledge which is not given to anyone in its totality.

Id. at 77-78. Hayek's insight is that the information about social wants and capabilities is naturally dispersed because it involves all of society. See Andrew P. Morriss & Susan E. Dudley, *Defining What to Regulate: Silica and the Problem of Regulatory Categorization*, 58 ADMIN. L. REV. 259, 281 (2006) (stating "Hayek's central point was that decentralized markets focus dispersed information—information that no one individual . . . can obtain—and convey it efficiently to market participants"); Maxwell L. Stearns, *Appellate Courts Inside and Out*, 101 MICH. L. REV. 1764, 1777 (2002) (noting "[o]ne major benefit of generating information as to value in this decentralized and uncoordinated manner is that countless subjective valuation measures—reflected in the individual transactions—produce an objective valuation that can be tested in the marketplace").

By emphasizing foreseeability, the *Festo* Court understood that the inventor—not the centralized PTO or the courts—is in the best position (and is the most highly motivated) to comprehend and understand the state of art and technologic trends relating to his claimed invention. The same point can be made regarding *Warner-Jenkinson's* presumption that the DOE is unavailable to a patentee who fails to provide a reason why he amended his claim. And it is the patentee who should bear the costs of a narrow claim scope. As the Federal Circuit noted in *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1361 (Fed. Cir. 2005), "as between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for [a] foreseeable alteration of its claimed structure." See also *SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, 356 F.3d 1357, 1364 (Fed. Cir. 2004) (stating "the Supreme Court in *Festo* neither excuses an applicant from failing to claim 'readily known equivalents' at the time of application nor allows a patentee to rebut the *Festo* presumption by invoking its own failure to include a known equivalent in its original disclosure").

**CROSS MEDICAL PRODUCTS, INC. v. MEDTRONIC SOFAMOR
DANEK, INC.**

480 F.3d 1335 (Fed. Cir. 2007)

PER CURIAM.

Cross Medical accuses Medtronic's polyaxial screws of infringing U.S. Patent No. 5,474,555 (the '555 patent). In this appeal, the district court issued [a] permanent injunction after Medtronic redesigned its polyaxial screws in an attempt to avoid the '555 patent. The court determined that claim 5 of the '555 patent was infringed under the doctrine of equivalents by Medtronic's

redesigned screws, but that claim 7 of the '555 patent was not infringed by either the original or redesigned screws.

Because Medtronic's redesigned polyaxial screws do not infringe the asserted claims literally or under the doctrine of equivalents, this court reverses the grant of summary judgment of infringement of claim 5. On the redesigned screws, the district court should grant Medtronic's motion for summary judgment of non-infringement.

I

Medtronic redesigned its polyaxial screws in an attempt to avoid infringement of claim 5. In response, Cross Medical asserted that the redesigned screws infringe claim 5 and that Medtronic's original and redesigned screws infringe claim 7.

On the claim 5 issue, the district court found that Medtronic's redesigned screws infringe under the doctrine of equivalents. In reaching this finding, the district court determined that a narrowing amendment to claim 5 during prosecution was only "tangentially related" to the accused equivalent and thus not subject to an estoppel under *Festo*.

II

Having already concluded that Medtronic's original screws infringe claim 5, the district court examined the redesigned screws for appropriation of the "thread depth" limitation as well as the rest of the claimed features. Specifically, claim 5 reads:

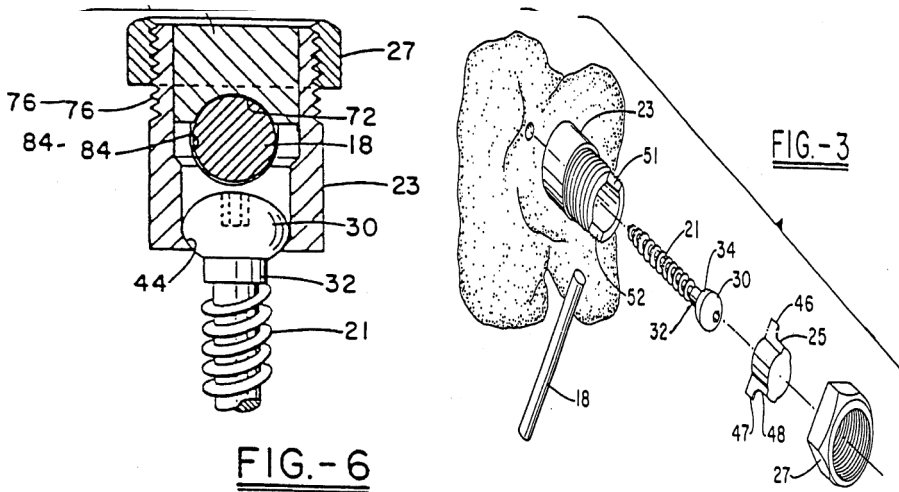
5. A fixation device for the posterior stabilization of one or more bone segments of the spine, comprising:

at least two anchors and an elongated stabilizer comprising a rod having a diameter and a longitudinal axis, said anchors each comprising anchoring means which secure said anchors to said bone segment and an anchor seat means which has a lower bone interface operatively joined to said bone segment and an anchor seat portion spaced apart from said bone interface including a channel to receive said rod; and

securing means which cooperate with each of said anchor seat portions spaced apart from said bone interface and exterior to the bone relative to said elongated rod, *said seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel*, and said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

'555 patent, col. 8 ll. 33-57 (emphasis added).

As described in the specification, the thread depth limitation corresponds to the anchor seat 23 shown in Figures 3 and 6 of the '555 patent and the threading thereon:



The embodiments of Figures 3 and 6 show that the threads on the anchor seat 23 extend to a depth below the top surface of the rod 18 as claimed. Notably, this thread depth requirement was not in the '555 patent's original application. Rather, the originally filed claim simply called for a "seat means including a vertical axis and first threads" without any particular limitation about the extent of the threading. The Examiner rejected this original claim, however, for lack of antecedent basis and lack of support in the specification (35 U.S.C. § 112, ¶¶ 1-2), for obviousness type double patenting over U.S. Patent No. 5,360,431, and for anticipation (35 U.S.C. § 102(b)) over U.S. Patent No. 4,805,602 (the '602 patent). In response, the Applicant amended the claim (originally numbered as claim 15) to recite:

15. (Amended) A fixation device for the posterior stabilization of one or more bone segments of the spine, comprising:

....

securing means which cooperate with each of said anchor seat portions spaced apart from said bone interface and exterior to the bone relative to said elongated rod, said seat means including a vertical axis and first threads *which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel*, and said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to bear against said channel through the application of substantially equal compressive forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

Thereafter, the Patent Office allowed the claim.

Medtronic apparently focused on this prosecution history in attempting to design around claim 5. Specifically, as noted by the district court, Medtronic altered its original screw design to terminate the corresponding threads at a position *above* the rod diameter. The district court agreed with Medtronic that the redesign took their screws outside the literal scope of claim 5. However, the district court still found the screws infringe claim 5 under the doctrine of equivalents' function-way-result test. In so holding, the district court rejected

Medtronic's argument that a *Festo* presumption barred application of the doctrine of equivalents:

[T]he rationale behind the amendment [to claim 5] was to adequately describe and enable a device, under § 112, in which the securing means could secure the rod without the use of a cap. The applicant was not attempting to overcome prior art using an undercut, and the amendment did not relate to an undercut. Therefore, the rationale was no more than tangentially related to Medtronic's new screw design, in which threads extend part of the way toward the rod and an undercut extends to a depth below the top of the rod. Medtronic's new screw design is "beyond a fair interpretation of what was surrendered." *Festo*, 535 U.S. at 738.

Trial Court Opinion, slip op. at 10. Medtronic challenges this reasoning and seeks summary judgment of non-infringement both under literal infringement and equivalents.

* * *

B. Infringement by Equivalents

Prosecution history estoppel prevents a patentee from recapturing under the doctrine of equivalents subject matter surrendered during prosecution to obtain a patent. Indeed, by surrendering subject matter, a narrowing amendment classically invokes the doctrine. In this case, the patentee narrowed claim 5 to address a § 112 rejection. An amendment made to comply with § 112 may give rise to estoppel. *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1142 (Fed. Cir. 2004) (*en banc*) ("[I]f a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply. A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112."). Although these circumstances create a presumption of estoppel under *Festo*, the patentee may still rebut that presumption. In this case, the district court determined that Cross Medical successfully overcame the *Festo* presumption by demonstrating that the amendment bore no more than a tangential relationship to the equivalent.

This court reaffirms the principle that the tangential relation criterion for overcoming the *Festo* presumption is very narrow and finds that neither the narrow tangential rebuttal principle nor the foreseeability principle applies to this case.

As discussed in the *Festo* opinion, the tangentially related

criterion requires a patentee to demonstrate that "the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question." In other words, this criterion asks whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.

Festo, 344 F.3d at 1369. The *Festo* court further stated: "Although we cannot anticipate the instances of mere tangentialness that may arise, we can say that an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim." *Id.* Finally, the

court observed that the inquiry into whether a patentee can rebut the *Festo* presumption under the “tangential” criterion focuses on the patentee’s objectively apparent reason for the narrowing amendment and that the reason “should be discernible from the prosecution history of record, if the public notice function of a patent and its prosecution history is to have significance.” *Id.*

Cross Medical’s reliance on *Insituform Technology, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), is misplaced. In *Insituform*, the invention claimed a method of impregnating an inner layer of resin with a limitation that specified the number and location of vacuum cups used in the method. The applicant added the number and location limitations to overcome prior art that disclosed a single vacuum source at the end of the tube opposite the resin source. In asserting a bar on the application of the doctrine of equivalents, the defendants argued that this narrowing amendment “necessarily gave up coverage of any process in which the vacuum was created at multiple vacuum sources,” as in the accused processes. This court found instead that the prosecution history showed that “the reason for the amendment was to overcome the prior art teaching creation of a single source vacuum at the far end of the liner.” *Id.* In other words, an amendment distinguishing prior art based on *where* the vacuum source was located was only tangentially related to an equivalent directed at the *number* of vacuum sources. See *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1299, 1306 (Fed. Cir. 2005) (explaining that, in *Insituform*, “the reason for the amendment and the alleged equivalent involved different aspects of the invention—the location of the vacuum source relative to the resin versus the number of vacuum cups”).

In *Insituform*, this court stated that in an analysis to determine if an amendment is tangential, “[t]he question we must address is ‘whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.’” 385 F.3d at 1370. Accordingly, this court has addressed the relationship between the narrowing amendment and the equivalent in broad terms: “[A]n amendment made to avoid prior art that contains the equivalent in question is not tangential.” *Rhodia Chimie*, 402 F.3d at 1383. This court also added, “[i]t does not follow, however, that equivalents not within the prior art must be tangential to the amendment.” *Id.* Indeed, in *Rhodia*, this court ultimately determined that the applicant “surrendered the range between its original claim and its amended claim and is therefore esopped from asserting . . . the doctrine of equivalents.” *Id.*

In this case, the prosecution history of the ’555 patent shows a narrowing amendment that also “contains the equivalent in question.” *Id.* The ’555 patent Applicant explained to the Examiner that:

the claims have . . . been amended to define the anchor seat means having a channel and threads which cooperate with the securing means (i.e., the nut) so as to capture the stabilizer between the channel and the securing means since the anchor [sic] seat *threads extend toward the channel to a depth below the top of the stabilizer* when it is in the channel.

In other words, the prosecution history explains that the thread depth limitation was added to capture the manner in which the stabilizer aspect of the

invention operated and thereby overcome the 35 U.S.C. § 112 rejections. Thus, the accused equivalent, which does *not* include threads extending “to a depth below the top of the stabilizer” and correspondingly does *not* capture this aspect of the invention relates to the amendment as shown even by the applicant’s own statements. For this reason, the district court erred in reliance on the tangential rebuttal principle to avoid the doctrine of equivalents.

RADER Circuit Judge, concurring.

I concur with the result in this case. I write separately to address further the issue of prosecution history estoppel of claim 5 of the ’555 patent.

* * *

This court made the tangential relation criterion for overcoming the *Festo* presumption very narrow. *Festo* itself recognized that rebuttals under the tangential principle will be rare. *Id.* (“[W]e cannot anticipate the instances of mere tangentialness that may arise. . .”). Cases in the interim have confirmed *Festo*’s insight; only two cases have successfully invoked the tangential rebuttal principle in this court. See *Insituform Tech. Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1368 (Fed. Cir. 2004); *Primos, Inc. v. Hunter’s Specialties, Inc.*, 451 F.3d 841, 849 (Fed. Cir. 2006). The facts of *Insituform* and *Primos* arguably related to situations where the prosecution history clearly demonstrated that the alleged equivalent and the narrowing amendment implicate entirely different aspects of the invention. Yet in reading those cases, frankly, this court might well have justifiably reached a different result in both. For example, in *Insituform*, this court seems to assume that the number of sources bears no relation to the location of those multiple sources. A contrary conclusion might have noted that anytime a technology adds another source it must also add another location for that new source. Multiple sources and locations for those sources would seem logically related.

In my view, the tangential rebuttal principle exacerbates the policy deficiencies of the doctrine of equivalents. Upon invoking tangentiality, the patentee has already admitted that the equivalent falls within the scope of surrendered subject matter. Further, if the case permitted, any patentee would invoke the primary “foreseeability” rebuttal factor. Thus, an invocation of “tangentiality” often admits that the equivalent was both within the scope of the surrender and foreseeable at the time of prosecution. In other words, the patent drafter could have claimed the surrendered and foreseeable technology, but declined to do so.

Furthermore, the tangentiality rebuttal principle, by its nature, undermines principles of public notice. This rebuttal principle operates because the patentee has expounded very different purposes for its narrowing amendment than those applicable to the tangential equivalent. The prosecution record thus does not address this “tangential” equivalent (which nonetheless was surrendered and was known and claimable during prosecution). In other words, the patentee gets a reward—coverage under the doctrine of equivalents—precisely because its explanations did not give the public any notice of the unclaimed and surrendered subject matter. The public might have believed it could practice technology that the patentee surrendered in prosecution. Moreover, the public might have reasonably

undertaken to practice that foreseeable technology because the patentee could have claimed it but declined to do so. Even beyond these principles, the public might have consulted the prosecution history and learned that the patentee gave no explanation for its surrender of this foreseeable technology. Thus, a diligent study of the patent and its prosecution history would give the public every reason to believe that the “tangential” subject matter would fall outside the scope of the invention and within the public domain. The basic principles of public notice would suggest these unclaimed and surrendered “tangential” technologies have no conceivable basis to expect patent protection.

This case is a classic example of the tangentiality principle running counter to principles of public notice. Medtronic had suffered an injunction. It deliberately sought to design around the patented technology—a response that patent law encourages. It undoubtedly consulted the patent and adjusted its technology with reference to the claim language and prosecution history of the patent. Then, after it adopted unclaimed technology that the patentee had deliberately surrendered to the public, it finds itself again subject to an injunction. Tangentiality thus, as in this case, can defeat principles of notice and proper procedures for designing around patented technology. Medtronic’s situation illustrates the difficulties of a broad application of tangentiality.

This “tangential” rebuttal principle becomes even more difficult in practice. What neutral standard makes some surrendered and unclaimed technologies infringing equivalents while others enjoy no protection? This tangential concept has no analogue in patent law. How tangential does it have to be?

In any event, this case reaffirms that the tangential rebuttal principle remains very narrow. See *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005) (distinguishing *Insituform* as limited to situations in which the prosecution history clearly demonstrates that “the amendment and alleged equivalent involve different aspects of the invention”). *Biagro* thus explains that the factual circumstances that could give rise to the tangential rebuttal principle will very rarely occur (even less often successfully). *Biagro* emphasizes that the evidence of tangentiality must appear in the prosecution history in order to prevent litigation-driven or hindsight reconstruction of the reasons for an amendment. The applicant is not likely to have made a prosecution record that makes some subject matter (the equivalent) tangential to the purpose for the rest of the amendment. In any event, I would reemphasize that the application of the tangentiality factor in this case preserves the *Biagro* narrowness principle and stress that tangentiality always threatens the public notice that enables designing around.

Comments

1. **The Tangential-Relation Principle.** The *Festo* presumption can be rebutted if the rationale underlying the amendment was tangentially related to the equivalent. The *Cross Medical* case is one example of the Federal Circuit refining the tangential relation factor. Although, as Judge Rader noted, applying the tangential rebuttal can be quite difficult in practice.

2. **Other “Tangentially Related” Cases.** In another significant opinion (discussed in *Cross Medical*), the Federal Circuit held that the patentee successfully rebutted the *Festo* presumption. In *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), the patent related to a process for repairing cracks and structural defects of underground pipes (e.g., sewer pipes) without having to dig up the pipe. The repair was accomplished by installing a liner into the pipe. The liner had an impermeable film on the outside and a resin-absorbent, felt layer on the inside. A vacuum is applied to the inside of the liner by cutting a window into the outer, impermeable film, applying a single “vacuum cup” to the outside of the window, and connecting the other end of the cup to a vacuum source. Using the created vacuum, a section of the inside of the liner is impregnated with resin, which is drawn through the liner. The vacuum cup is then moved to another section of the liner while the previously used window is sealed. This process for impregnating the liner with resin allows for impregnation at the jobsite, eliminating the need to transport a heavier, already impregnated liner to the site. The originally filed claim covered a process using single or multiple cups at any location downstream of the resin front. The claim was rejected for reasons related to the location of the cups at the far end of the line. The patentee narrowed the claim to address the placement issue, but also narrowed the claim to include only a single cup. The defendant used multiple cups to create a vacuum. In response to the defendant’s *Festo* argument, the patentee argued that the reason for the amendment was to overcome the prior art teaching of the *location* of a single vacuum source (i.e., cup) at the far end of the tube liner, and did not relate to the number of cups. Therefore, argued the patentee, the amendment was tangentially related to the equivalent, a multiple cup method. The Federal Circuit agreed. See also *Primos Inc. v. Hunter’s Specialties, Inc.*, 451 F.3d 841 (Fed. Cir. 2006) (holding patentee’s amendment was tangentially related to an alleged equivalent of the accused device).

b. Public Dedication Rule

The “Public Dedication Rule” or “Disclosure-Dedication Rule” has its basis in the 19th century Supreme Court case of *Miller v. Bridgeport Brass Co.*, cited by the *Graver* dissent. The *Miller* Court held that subject matter disclosed in the patent specification, but not claimed, is dedicated to the public.

JOHNSON & JOHNSTON ASSOCS., INC. v. R.E. SERVICE CO., INC.

285 F.3d 1046 (Fed. Cir. 2002) (en banc)

PER CURIAM

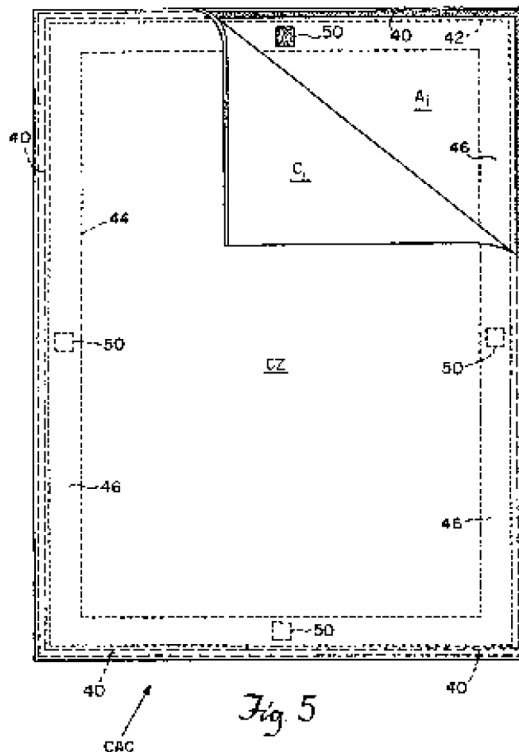
Johnson and Johnston Associates (Johnston) asserted United States Patent No. 5,153,050 (the ‘050 patent) against R.E. Service Co. and Mark Frater (collectively RES). A jury found that RES willfully infringed claims 1 and 2 of the patent under the doctrine of equivalents and awarded Johnston \$1,138,764 in damages. After a hearing before a three-judge panel on December 7, 1999, this court ordered *en banc* rehearing of the doctrine

of equivalents issue. Because this court concludes that RES, as a matter of law, could not have infringed the '050 patent under the doctrine of equivalents, this court reverses the district court's judgment of infringement under the doctrine of equivalents, willfulness, damages, attorneys fees, and expenses.

I.

The '050 patent, which issued October 6, 1992, relates to the manufacture of printed circuit boards. Printed circuit boards are composed of extremely thin sheets of conductive copper foil joined to sheets of a dielectric (non-conductive) resin-impregnated material called "prepreg." The process for making multi-layered printed circuit boards stacks sheets of copper foil and prepreg in a press, heats them to melt the resin in the prepreg, and thereby bonds the layers.

In creating these circuit boards, workers manually handle the thin sheets of copper foil during the layering process. Without the invention claimed in the '050 patent, stacking by hand can damage or contaminate the fragile foil, causing discontinuities in the etched copper circuits. The '050 patent claims an assembly that prevents most damage during manual handling. The invention adheres the fragile copper foil to a stiffer substrate sheet of aluminum. With the aluminum substrate for protection, workers can handle the assembly without damaging the fragile copper foil. After the pressing and heating steps, workers can remove and even recycle the aluminum substrate. Figure 5 of the '050 patent shows the foil-substrate combination, with the foil layer peeled back at one corner for illustration:



Surface C_i is the protected inner surface of the copper foil; A_i is the inner surface of the aluminum substrate. A band of flexible adhesive 40 joins the substrate and the foil at the edges, creating a protected central zone CZ. The specification explains:

Because the frail, thin copper foil C was adhesively secured to its aluminum substrate A, the [laminate] is stiffer and more readily handled resulting in far fewer spoils due to damaged copper foil. The use of the adhered substrate A, regardless of what material it is made of, makes the consumer's (manufacturer's) objective of using thinner and thinner foils and ultimately automating the procedure more realistic since the foil, by use of the invention, is no longer without the much needed physical support.

'050 patent, col. 8, ll. 21-30.

The specification further describes the composition of the substrate sheet:

While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys, may be used. In some instances . . . polypropelene [sic] can be used.

'050 patent, col. 5, ll. 5-8.

As noted, the jury found infringement of claims 1 and 2:

Claim 1. A component for use in manufacturing articles such as printed circuit boards comprising:

a laminate constructed of a sheet of copper foil which, in a finished printed circuit board, constitutes a functional element and a sheet of *aluminum* which constitutes a discardable element;

one surface of each of the copper sheet and the *aluminum* sheet being essentially uncontaminated and engageable with each other at an interface;

a band of flexible adhesive joining the uncontaminated surfaces of the sheets together at their borders and defining a substantially uncontaminated central zone inwardly of the edges of the sheets and unjoined at the interface;

'050 patent, Claim 1, col. 8, ll. 47-60 (emphasis supplied). Claim 2 defines a similar laminate having sheets of copper foil adhered to both sides of the aluminum sheet.

* * *

In 1997, RES began making new laminates for manufacture of printed circuit boards. The RES products, designated "SC2" and "SC3," joined copper foil to a sheet of steel as the substrate instead of a sheet of aluminum. Johnston filed a suit for infringement. In this case, the district court granted RES's motion for summary judgment of no literal infringement. With respect to the doctrine of equivalents, RES argued, citing *Maxwell v. J. Baker, Inc.*, that the '050 specification, which disclosed a steel substrate but did not claim it, constituted a dedication of the steel substrate to the public. Johnston argued that the steel substrate was not dedicated to the public, citing *YBM Magnex, Inc. v. Int'l Trade Comm'n.* On cross-motions for summary judgment, the district court ruled that the '050 patent did not dedicate the steel substrate to the public,

and set the question of infringement by equivalents for trial, along with the issues of damages and willful infringement.

* * *

II.

On appeal, RES does not challenge the jury's factual finding of equivalency between the copper-steel and copper-aluminum laminates. Instead, citing *Maxwell*, RES argues that Johnston did not claim steel substrates, but limited its patent scope to aluminum substrates, thus dedicating to the public this unclaimed subject matter. On this ground, RES challenges the district court's denial of its motion for summary judgment that RES's copper-steel laminates are not equivalent, as a matter of law, to the claimed copper-aluminum laminates. Johnston responds that the steel substrates are not dedicated to the public, citing *YBM Magnex*. In other words, the two parties dispute whether *Maxwell* or *YBM Magnex* applies in this case with regard to infringement under the doctrine of equivalents.

In *Maxwell*, the patent claimed a system for attaching together a mated pair of shoes. Maxwell claimed fastening tabs between the inner and outer soles of the attached shoes. Maxwell disclosed in the specification, but did not claim, fastening tabs that could be "stitched into a lining seam of the shoes." Based on the "well-established rule that 'subject matter disclosed but not claimed in a patent application is dedicated to the public,'" this court held that Baker could not, as a matter of law, infringe under the doctrine of equivalents by using the disclosed but unclaimed shoe attachment system. *Maxwell*, 86 F.3d at 1106 (quoting *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562-63 (Fed. Cir. 1991)). This court stated further:

By [Maxwell's failure] to claim these alternatives, the Patent and Trademark Office was deprived of the opportunity to consider whether these alternatives were patentable. A person of ordinary skill in the shoe industry, reading the specification and prosecution history, and interpreting the claims, would conclude that Maxwell, by failing to claim the alternate shoe attachment systems in which the tabs were attached to the inside shoe lining, dedicated the use of such systems to the public.

Maxwell, 86 F.3d at 1108.

In *YBM Magnex*, the patent claimed a permanent magnet alloy comprising certain elements, including "6,000 to 35,000 ppm oxygen." The accused infringer used similar magnet alloys with an oxygen content between 5,450 and 6,000 ppm (parts per million), which was allegedly disclosed but not claimed in the '439 patent. In *YBM Magnex*, this court stated that *Maxwell* did not create a new rule of law that doctrine of equivalents could never encompass subject matter disclosed in the specification but not claimed. Distinguishing *Maxwell*, this court noted:

Maxwell avoided examination of the unclaimed alternative, which was distinct from the claimed alternative. In view of the distinctness of the two embodiments, both of which were fully described in the specification, the Federal Circuit denied Maxwell the opportunity to enforce the unclaimed embodiment as an equivalent of the one that was claimed.

145 F.3d at 1320. In other words, this court in *YBM Magnex* purported to limit *Maxwell* to situations where a patent discloses an unclaimed alternative distinct from the claimed invention. Thus, this court must decide whether a patentee can apply the doctrine of equivalents to cover unclaimed subject matter disclosed in the specification.

III.

Both the Supreme Court and this court have adhered to the fundamental principle that claims define the scope of patent protection. *See, e.g., Aro Mfg. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) (“[T]he claims made in the patent are the sole measure of the grant. . . .”); *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1299, 1300 (Fed. Cir. 1992) (“The claims alone define the patent right”). The claims give notice both to the examiner at the U.S. Patent and Trademark Office during prosecution, and to the public at large, including potential competitors, after the patent has issued. Consistent with its scope definition and notice functions, the claim requirement presupposes that a patent applicant defines his invention in the claims, not in the specification. After all, the claims, not the specification, provide the measure of the patentee’s right to exclude. Moreover, the law of infringement compares the accused product with the claims as construed by the court. Infringement, either literally or under the doctrine of equivalents, does not arise by comparing the accused product “with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee.” *SRI Int’l*, 775 F.2d at 1121.

Even as early as the 1880s, the Supreme Court emphasized the predominant role of claims. For example, in *Miller v. Bridgeport Brass Co.*, a case addressing a reissue patent filed fifteen years after the original patent, the Supreme Court broadly stated: “[T]he claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the patent, are, in law, a dedication to the public of that which is not claimed.” 104 U.S. 350, 352 (1881). Just a few years later, the Court repeated that sentiment in another reissue patent case: “[T]he claim actually made operates in law as a disclaimer of what is not claimed; and of all this the law charges the patentee with the fullest notice.” *Mahn*, 112 U.S. at 361. The Court explained further:

Of course, what is not claimed is public property. The presumption is, and such is generally the fact, that what is not claimed was not invented by the patentee, but was known and used before he made his invention. But, whether so or not, his own act has made it public property if it was not so before. The patent itself, as soon as it is issued, is the evidence of this. The public has the undoubted right to use, and it is to be presumed does use, what is not specifically claimed in the patent.

Id. at 361.

The doctrine of equivalents extends the right to exclude beyond the literal scope of the claims. The Supreme Court first applied the modern doctrine of equivalents in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.* (*Graver Tank II*). In that case, the Court explained: “equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case.” 339 U.S. 605, 609 (1950). In *Graver I*, a predecessor case addressing the

validity of the claims at issue, the Court held invalid composition claims 24 and 26 comprising “silicates” and “metallic silicates.” *Graver Tank & Mfg. v. Linde Air Prods. Co.*, 336 U.S. 271, 276-77 (1949) (*Graver I*). Specifically, the Court found those claims too broad because they encompassed some inoperative silicates along with the nine operative metallic silicates in the specification. The Court did not hold invalid narrower claims comprising “alkaline earth metals.”

Thus, in the infringement action of *Graver II*, the Supreme Court addressed only the narrower claims comprising “alkaline earth metals.” The alleged infringing compositions in *Graver II* are similar to the compositions of the narrower claims, except that they substitute silicate of manganese—a metallic silicate such as in the earlier invalidated claims—for silicates of “alkaline earth metals” (e.g., magnesium or calcium) claimed in the narrower claims. Because the Court determined that “under the circumstances the change was so insubstantial,” and because the accused compositions “perform[ed] substantially the same function in substantially the same way to obtain the same result,” the Court upheld the finding of infringement under the doctrine of equivalents. *Graver II*. The Court’s holding and the history of *Graver II* show that the patentee had not dedicated unclaimed subject matter to the public. In fact, the patentee had claimed the “equivalent” subject matter, even if the Court eventually held the relevant claims too broad.

In 1997, less than a year after this court decided *Maxwell*, the Supreme Court addressed the doctrine of equivalents again in *Warner-Jenkinson v. Hilton Davis*. In that case, Warner-Jenkinson invited the Court “to speak the death” of the doctrine of equivalents. 520 U.S. at 21. The Court declined that invitation. In *Warner-Jenkinson*, the patentee added the phrase “at a pH from approximately 6.0 to 9.0” to claim 1 during prosecution. The alleged infringer operated its ultrafiltration process at a pH of 5.0. The Supreme Court stated that “while a lower limit of [pH] 6.0, by its mere inclusion, became a material element of the claim, that did not necessarily preclude the application of the doctrine of equivalents as to that element.” *Id.* at 32. On remand, the Supreme Court instructed this court to determine the patentee’s reason, if any, for adding the lower pH limit of 6.0 during prosecution.

The patent at issue in *Warner-Jenkinson* did not disclose or suggest an ultrafiltration process where the pH of the reaction mixture was 5.0. In fact, the specification practically repeated the claim language: “it is preferred to adjust the pH to approximately 6.0 to 8.0 before passage through the ultrafiltration membrane.” U.S. Patent No. 4,560,746, col. 7, ll. 59-61 (emphasis added). Thus, *Warner-Jenkinson* did not present an instance of the patentee dedicating subject matter to the public in its specification. In 1998, less than a year later, this court decided *YBM Magnex*.

V.

As stated in *Maxwell*, when a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public. Application of the doctrine of equivalents to recapture subject matter deliberately left unclaimed would “conflict with the primacy of the claims in defining the scope of the patentee’s exclusive right.” *Sage Prods. Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997) (citing *Warner-Jenkinson*, 520 U.S. at 29).

Moreover, a patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents. “Such a result would merely encourage a patent applicant to present a broad disclosure in the specification of the application and file narrow claims, avoiding examination of broader claims that the applicant could have filed consistent with the specification.” *Maxwell*, 86 F.3d at 1107 (citing *Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1564 (Fed. Cir. 1994)). By enforcing the *Maxwell* rule, the courts avoid the problem of extending the coverage of an exclusive right to encompass more than that properly examined by the PTO. *Keystone Bridge Co. v. Phoenix Iron Co.* 95 U.S. 274, 278 (1877) (“[T]he courts have no right to enlarge a patent beyond the scope of its claim as allowed by the Patent Office, or the appellate tribunal to which contested applications are referred.”).

IV.

In this case, Johnston’s ’050 patent specifically limited the claims to “a sheet of aluminum” and “the aluminum sheet.” The specification of the ’050 patent, however, reads: “While aluminum is currently the preferred material for the substrate, other metals, such as stainless steel or nickel alloys may be used.” Col. 5, ll. 5-10. Having disclosed without claiming the steel substrates, Johnston cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel. Thus, Johnston cannot assert the doctrine of equivalents to cover the disclosed but unclaimed steel substrate. To the extent that *YBM Magnex* conflicts with this holding, this *en banc* court now overrules that case.

A patentee who inadvertently fails to claim disclosed subject matter, however, is not left without remedy. Within two years from the grant of the original patent, a patentee may file a reissue application and attempt to enlarge the scope of the original claims to include the disclosed but previously unclaimed subject matter. 35 U.S.C. § 251 (2000). In addition, a patentee can file a separate application claiming the disclosed subject matter under 35 U.S.C. § 120 (2000) (allowing filing as a continuation application if filed before all applications in the chain issue). Notably, Johnston took advantage of the latter of the two options by filing two continuation applications that literally claim the relevant subject matter.

PAULINE NEWMAN, Circuit Judge, dissenting.

Patentees often must draw lines in order to claim their invention with specificity. See 35 U.S.C. § 112 (the claims must “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention.”) The establishment of a *per se* rule so heavily weighted against disclosure is not only inappropriately simplistic, but is contrary to the policy of the patent law.

* * *

The public interest in fostering innovation and technological advance is not served by a judicial decision that imposes legal obstacles to the disclosure of scientific and technologic information. Information dissemination is a critical purpose of the patent system. By penalizing the inclusion of information in

the specification the patent becomes less useful as a source of knowledge, and more a guarded legal contract.

No patentee deliberately chooses the doctrine of equivalents to protect commercial investment. Yet every patentee must guard against infringement at the edges of the invention. After today, whenever a patentee draws a line in a disclosed continuum, the copier who simply crosses the line can avoid even the charge of equivalency; a safe and cheap way to garner the successes of another. Each new pitfall for inventors simply diminishes the value of the patent incentive, and ultimately inhibits technological innovation. Concern for the effectiveness of the patent system has always been a factor in innovation activity. A study by Wesley M. Cohen *et al.*, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)*, Nat'l Bureau of Econ. Research Working Paper 7552, at 14 (2000), reported that in a 1994 survey of R & D managers 65% of the respondents cited the ease of avoiding patent claims as the main deterrent to patent-based investment in technology, and 47% also cited concern for disclosing technical information without adequate protection.

Discovery of and commercialization of new things is notoriously risk-laden, yet it is the inventor and the innovator, those whose ingenuity and ambition create new things while taking the risk of loss, who provide the basis of industrial advance and economic growth.

* * *

A judicial change in the balance between innovator and imitator should not be made in disregard of the consequences. The neatness of a *per se* rule is not necessarily sound legal or economic policy. Nor is it sound judicial policy, for in addition to issues of commerce and technology-based industry, this case raises questions of fundamental fairness as to disputes that will now be excluded from judicial review. Fairness is the foundation of due process; it is superior to, not subordinate to, *per se* rules.

Comments

1. ***Sufficiency of the Disclosure.*** How specific must the disclosure be to dedicate subject matter to the public? Does the disclosure have to be enabling or simply mention the equivalent? The Federal Circuit addressed these questions in *PSC Computer Products, Inc. v. Foxconn Intern., Inc.*, 355 F.3d 1353 (Fed. Cir. 2004). According to the court, a mere “generic reference in a written specification” does not “necessarily dedicate[] all members of that particular genus to the public.” *Id.* at 1360. Rather, for subject matter to be dedicated to the public, a PHOSITA must be able to “understand the unclaimed disclosed teaching upon reading the written description.” The court also added that the “disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed,” but this standard “does not impose a § 112 [enablement] requirement on the disclosed but unclaimed subject matter.” *Toro Co. v. White Consolidated Industries, Inc.*, 383 F.3d 1326 (Fed. Cir. 2004).

In *Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005), the Federal Circuit seems to have required more express language to invoke the public-dedication rule, stating that “in *PSC Computer Products* the driving force behind the court’s holding was the public notice function of patents. And in our view, the public notice function of patents suggests that before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation.”

2. **Distinguishing *Graver*.** In *Johnston* and *Maxwell*, the court tried to distinguish *Graver Tank*. Recall in *Graver*, manganese silicate was set forth in the specification and the patent claimed manganese silicates (the broad claim) and also claimed alkaline earth silicates, of which manganese was not a part (the narrow claim). Unlike the narrow claim, which was valid and infringed, the broad claim was invalidated as too broad. So why weren’t manganese silicates dedicated to the public according to *Johnston* and *Maxwell*? Because manganese silicates were originally claimed. The fact that this claim was later invalidated is irrelevant.
3. **The *Revenge of Justice Black’s Graver Dissent*.** The public-dedication rule is reminiscent of Justice Black’s dissent in *Graver*. Recall Justice Black’s statement, “[w]hat is not specifically claimed is dedicated to the public.” 339 U.S. at 614. Compare the language in *Johnston*, “when a patent drafter discloses but declines to claim subject matter, as in this case, this action dedicates that unclaimed subject matter to the public.” 285 F.3d at 1054. In addition, Justice Black highlighted the availability of reissue for patentees “who had for some reason failed to claim complete protection for their discoveries.” 339 U.S. at 614. Similarly, in *Johnston*, the court wrote, “[a] patentee who inadvertently fails to claim disclosed subject matter . . . is not left without remedy” because “[w]ithin two years from the grant of the original patent, a patentee may file a reissue application and attempt to enlarge the scope of the original claims to include the disclosed but previously unclaimed subject matter.” 285 F.3d at 1055.
4. **Beyond *Warner-Jenkinson*.** In *Warner-Jenkinson*, the Court rejected Petitioner’s argument that the DOE should be “limited to equivalents that are disclosed within the patent itself.” The public-dedication rule, however, holds unclaimed subject matter disclosed in the specification is surrendered to the public, as long as the language in the specification satisfies *PSC* and *Pfizer* (see Comment 1, above). Is the public-dedication rule inconsistent with *Warner-Jenkinson*? The rule is consistent with *Festo* because disclosed, yet unclaimed subject matter is foreseeable.
5. **Public Dedication in English Common Law.** Prior to the European Patent Convention of 1977, English common law principles placed a great deal of emphasis on the patent claim, and embraced what can be characterized as a “public dedication rule.” For instance, Lord Russell in *Electric and Musical Industries Ltd. v. Lissen Ltd.* (1938) 56 RPC 23, 29, wrote of patent claims:

Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed. The claims must undoubtedly be read as part of the entire document and not as a separate document; but the forbidden field must be found in the language of the claims and not elsewhere.

c. All-Limitations Rule and Specific Exclusion

The *all-limitations rule* demands that each limitation of a patent claim is material to defining the scope of the patented invention and must not be vitiated or rendered meaningless. For there to be infringement under the DOE an equivalent of each claim limitation must be found in the accused device. In other words, the DOE is applied to each limitation, not to the invention as a whole. The *specific exclusion rule*, which is a corollary to the all-limitations rule, holds that the DOE is unavailable to capture subject matter that the claim specifically excludes. The reasoning behind this rule is that by defining a claim in a way that specially excludes certain subject matter, the patentee implicitly disclaimed the subject matter and is therefore prevented from invoking the DOE. The principal case of *SciMed Life Systems* provides a discussion of these two related principles.

SCIMED LIFE SYSTEMS, INC. v. ADVANCED CARDIOVASCULAR SYSTEMS, INC.

242 F.3d 1337 (Fed. Cir. 2001)

BRYSON, Circuit Judge.

SciMed Life Systems, Inc. (SciMed) owns three U.S. patents drawn to features of balloon dilatation catheters: U.S. Patent Nos. 5,156,594 (the '594 patent), 5,217,482 (the '482 patent), and 5,395,334 (the '334 patent). SciMed filed suit against Advanced Cardiovascular Systems, Inc. (ACS) in the United States District Court for the Northern District of California, charging ACS with infringement of each of the three patents. On ACS's motion for summary judgment, the district court ruled that ACS had not infringed the disputed patents. The district court's ruling was based on the court's conclusion that the asserted claims were limited to a structure not found in ACS's accused devices and on the court's conclusion that ACS's devices did not infringe SciMed's patents under the doctrine of equivalents. We agree with the district court's claim construction and its ruling on the equivalents issue. We therefore affirm the summary judgment of non-infringement.

I

Balloon dilatation catheters are used in coronary angioplasty procedures to remove restrictions in coronary arteries. The SciMed patents describe catheters having three sections: a first shaft section, a second shaft section, and a transition section between the two. The first shaft section is long, relatively stiff, and generally tubular. The second shaft section is relatively flexible and contains a balloon at the end, which is inflated to relieve the arterial restriction. The transition section connects the first and second shaft sections and provides a gradual transition in stiffness between the two shaft sections.

The catheters claimed in the SciMed patents contain two passageways, or lumens. The first lumen, the guide-wire lumen, is used to guide the catheter through a patient's arteries to the site of the arterial restriction. A guide wire is first inserted into one of the patient's arteries. The guide-wire lumen is then threaded over the guide wire to guide the catheter through the patient's arteries until the catheter reaches the coronary restriction. In the invention

recited in the SciMed patents, the guide wire does not enter the catheter at the proximal end of the catheter, *i.e.*, the end closer to the surgeon, but at a point nearer to the distal end of the catheter, *i.e.*, the leading end of the catheter as it is inserted into the patient. The guide-wire lumen is present only in the distal portion of the catheter and does not extend the entire length of the catheter. The second lumen is the inflation lumen. It extends through all sections of the catheter and terminates in a connection with the balloon. The balloon is inflated by forcing fluid into the inflation lumen. The balloon then compresses the material restricting the artery, thereby relieving the restriction.

The parties agree that only two arrangements of the two lumens are known and practiced in the art. In the dual (or adjacent) lumen configuration, the two lumens are positioned side-by-side within the catheter. In the coaxial lumen configuration, the guide wire lumen runs inside the inflation lumen; in that configuration the inflation lumen, viewed in cross-section, is annular in shape. The parties also agree that the accused ACS devices employ only the dual lumen configuration and that the preferred embodiment described in the SciMed patents employs the coaxial lumen configuration.

Based on language in the common written description portion of the three SciMed patents, the district court construed the asserted claims of the patents to be limited to catheters with coaxial lumens, and not to read on catheters with a dual lumen configuration. The court noted that “the language contained in SciMed’s specifications *expressly* limits all embodiments of the claimed invention to a coaxial structure.” The court focused in particular on language from the common specification describing the coaxial lumen structure as the “basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein.” That language, the court concluded, “leaves no doubt that a person skilled in the art would conclude that the inventor envisioned only one design for the catheters taught in SciMed’s patents—an intermediate sleeve section containing two . . . lumens arranged coaxially.”

In light of the district court’s construction of the asserted claims, SciMed conceded that ACS’s accused catheters did not literally infringe any of the asserted claims. In addition, the court held on summary judgment that the two lumen arrangements were sufficiently different that no reasonable jury could find the accused catheters to infringe the SciMed patents under the doctrine of equivalents. SciMed appeals the claim construction and the summary judgment based on that construction.

II

The principal question in this case is a narrow one: whether the common specification of the three patents limits the scope of the asserted claims to catheters with coaxial lumens. There is nothing pertinent to this issue in the prosecution history of the three patents; the case turns entirely on an interpretation of the asserted claims in light of the specification, which is essentially identical for each of the three patents. Like the district court, we interpret the specification to disclaim the dual lumen configuration and to limit the scope of the asserted claims to catheters with coaxial lumen structures having annular inflation lumens. We therefore construe the asserted claims to read only on catheters with coaxial lumens, and not on catheters with dual or side-by-side lumens.

Claim 19 of the '594 patent is representative of the asserted claims of the three patents in suit. It claims the following:

In an elongate dilatation catheter of the type that can be slidably moved along a guide wire that can extend past a distal end of the catheter, wherein the guide wire is received in a guide wire lumen of the catheter, the guide wire extending from a distal guide wire lumen opening to a proximal guide wire lumen opening disposed in a portion of the catheter that is spaced distally from a proximal end of the catheter, the dilatation catheter including an inflatable balloon and an inflation lumen extending through the catheter separate from the guide wire lumen, an improvement comprising:

a first proximal shaft section of the catheter defined by a relatively rigid metallic tube;

a second shaft section disposed distally of the first shaft section, the second shaft section being relatively more flexible than the first shaft section; and

a transition section disposed between the first shaft section and the second shaft section, the transition section including a transition member comprising a metallic element of gradually diminished dimension, the transition member extending adjacent to the proximal guide wire lumen opening, and the transition member having gradually decreasing rigidity in the distal direction to provide a relatively smooth transition between the first shaft section and the second shaft section.

SciMed argues at length that in construing the claims based on the written description, the district court has committed one of the cardinal sins of patent law—reading a limitation from the written description into the claims. But that is not an accurate characterization of what the district court did. Instead, the district court properly followed the invocation that “[c]laims must be read in view of the specification, of which they are a part.” *Markman v. Westview Instruments*, 52 F.3d 967, 979-980 (Fed. Cir. 1995).

As this court has recently explained, “[o]ne purpose for examining the specification is to determine if the patentee has limited the scope of the claims.” *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000). Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question. Thus, in the *Watts* case, the claim in dispute recited pipe joints that could be “sealingly connected.” The court noted that the specification described only one method to achieve the sealing connection, that is, to misalign the taper angles of the respective threads of the joined pipes. The court pointed out that the specification “actually limits the invention to structures that utilize misaligned taper angles, stating that ‘the present invention utilizes [the varying taper angle] feature.’” 232 F.3d at 883. In light of that statement, the court construed the claim language as “limited to connections effected by misaligned taper angles. . . .”

Finally, we find instructive the analysis in *Toro Co. v. White Consolidated Industries, Inc.*, 199 F.3d 1295 (Fed. Cir. 1999). The patent at issue described and claimed a hand-held convertible vacuum-blower for vacuuming and blowing leaves and yard debris. In the claimed device, the cover was fitted with a ring that restricted the size of the air inlet when the device was being used in

blower mode. One of the questions before the court was whether the cover, which the claim characterized as “including” a restriction ring, had to be permanently attached to the restriction ring. To answer that question the court looked to the specification. The court observed that the specification and drawings showed the ring as part of and permanently attached to the cover, and did not illustrate or describe any other structure. Indeed, the court pointed out, the specification described the advantages of the unitary structure as important to the invention. Based on the specification, the court construed the term “including” in the asserted claims as requiring that the restriction ring be attached to the cover.

The analysis in these cases is directly applicable to the claim construction issue presented here. At various points, the common specification of the three patents indicates that the claimed invention uses coaxial, rather than side-by-side lumens, *i.e.*, that the guide wire lumen is contained within the inflation lumen and that the inflation lumen is annular. Read together, these portions of the common specification lead to the inescapable conclusion that the references in the asserted claims to an inflation lumen “separate from” the guide wire lumen must be understood as referring to coaxial lumens, and thus that the asserted claims read only on catheters having coaxial lumens.

First, the abstract of each of the patents refers to the intermediate sleeve section of the invention as including “an inner core tube which defines a guide wire lumen.” The abstract adds that the inflation lumen is “continued as an annular inflation lumen” through the sleeve section of the catheter. Thus, from the outset the specification identifies the inflation lumen, as that term is used in the SciMed patents, as annular, *i.e.*, coaxial rather than dual in structure.

Second, in discussing the disadvantages of certain prior art structures, the written description of each of the patents explains that the prior art catheters with shortened guide wire lumens “suffer from several disadvantages.” The first cited disadvantage is that “[s]uch catheters have been one piece polyethylene catheters having dual lumen configurations adjacent their distal regions. Typically, such catheters have larger than necessary shaft sizes and are stiffer in their distal regions than would be desired. . . .” Thus, the SciMed patents distinguish the prior art on the basis of the use of dual lumens and point out the advantages of the coaxial lumens used in the catheters that are the subjects of the SciMed patents. That discussion in the written description supports the district court’s conclusion that the claims should not be read so broadly as to encompass the distinguished prior art structure.

Third, the “Summary of the Invention” portion of the patents describes “the present invention” as having a sleeve section with an inner core tube [80 in FIG. 3 below] having a guide wire lumen [52 in FIG. 3] extending through it and an outer sleeve [82 in FIG. 3] defining “a longitudinally extending annular inflation lumen.” The characterization of the “present invention” includes several more references to the “annular inflation lumen” as well, and the “Conclusion” section of the written description again refers to the “guide wire lumen and annular inflation lumen” in the distal portions of the catheter. As in *Wang Labs*, the characterization of the coaxial configuration as part of the “present invention” is strong evidence that the claims should not be read to encompass the opposite structure.

The most compelling portion of the specification, and the portion on which the district court principally focused, is the passage in the section entitled “Catheter Intermediate Sleeve Section” in which the inflation lumen is described as annular in structure, being formed from an outer sleeve or tube (the inflation lumen) and an inner core tube (the guide wire lumen). The patents then recite:

The intermediate sleeve structure defined above is the basic sleeve structure for *all embodiments of the present invention contemplated and disclosed herein* — namely, an inner core tube [80] bonded to a distal portion of the main catheter shaft, with an outer sleeve [82] forming an annular continuation of the inflation lumen through the main shaft between the core tube and outer sleeve. As discussed below and illustrated herein, various configurations of the connections and components relative to the formation of the distal guide wire lumen, including the coupling of the main shaft to the intermediate sleeve section, are contemplated.

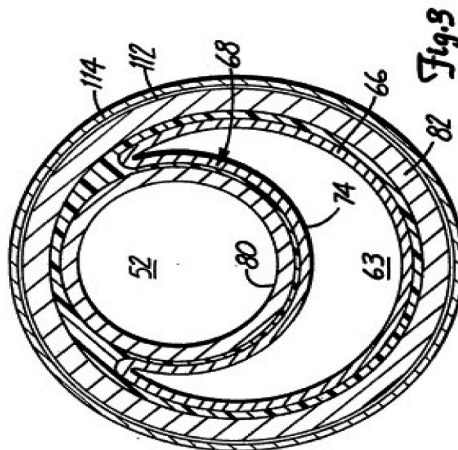
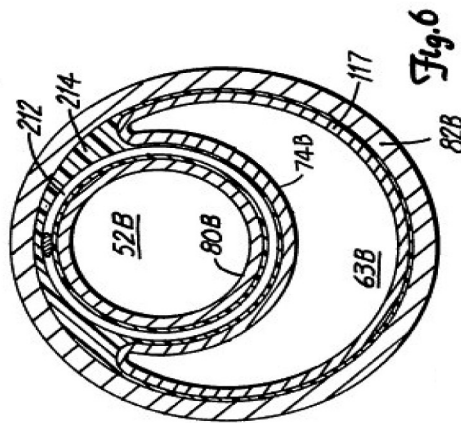
(emphasis added).

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This language defines SciMed's invention in a way that excludes the dual, or side-by-side, lumen arrangement. SciMed argues that the references to the annular inflation lumen are meant only to refer to the preferred embodiment of the invention, and not to indicate that the claims should be construed as limited to a structure employing coaxial lumens. That argument, however, flies in the face of the many statements in the written description that define "the invention" as employing a coaxial lumen structure and distinguish the prior art in part on the ground that it used a dual lumen structure, which had the disadvantage of making the shaft sizes of the catheters larger than necessary and making the catheters "stiffer in their distal regions than would be desired." SciMed's argument is particularly unconvincing in the face of its own statement in the written description that the structure containing coaxial lumens ("namely, an inner core tube bonded to a distal portion of the main catheter shaft, with an outer sleeve forming an annular continuation of the inflation lumen through the main shaft between the core tube and the outer sleeve") is "the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein." That characterization of the invention cannot reasonably be interpreted as limited to the preferred embodiment, as SciMed argues, but is expressly made applicable to "all embodiments of the present invention."

The words "all embodiments of the present invention" are broad and unequivocal. It is difficult to imagine how the patents could have been clearer in making the point that the coaxial lumen configuration was a necessary element of every variant of the claimed invention. Moreover, there is no suggestion that the patentee made that statement unaware of the alternative dual lumen configuration, because earlier in the patent the patentee had distinguished the dual lumen configuration used in prior art devices as having disadvantages that the coaxial lumens used in the patented invention had overcome. This is therefore a clear case of disclaimer of subject matter that, absent the disclaimer, could have been considered to fall within the scope of the claim language.

. . . . In this case, the written description makes clear that when the asserted claims refer to the respective locations of the guide wire and inflation lumens, and in particular when the claims refer to the inflation lumen as "extending through the catheter separate from" the guide wire lumen, the claim language refers to coaxial lumens. Because the three SciMed patents make clear that the lumens referred to in the claims are all coaxial in structure, the district court was correct to construe the patents as disclaiming the dual lumen configuration. Under such a construction, SciMed concedes that no literal infringement can be found. The district court therefore properly entered summary judgment in favor of ACS on the issue of literal infringement.

III

[T]he district court rejected SciMed's argument that ACS's accused devices infringed the three asserted patents under the doctrine of equivalents. We agree with the court that the doctrine of equivalents is inapplicable in this case and that the district court properly granted summary judgment to ACS on that issue.

As noted above, the common specification of SciMed's patents referred to prior art catheters, identified them as using the dual lumen configuration, and

criticized them as suffering from the disadvantages of having “larger than necessary shaft sizes” and being “stiffer in their distal regions than would be desired.” That criticism of the dual lumen configuration was consistent with the evidence from SciMed witnesses and documents, which noted the advantages of the coaxial lumen configuration in increasing the flexibility of catheters and their ability to track through the coronary arterial system. The disclaimer of dual lumens was made even more explicit in the portion of the written description in which the patentee identified coaxial lumens as the configuration used in “all embodiments of the present invention.”

Having specifically identified, criticized, and disclaimed the dual lumen configuration, the patentee cannot now invoke the doctrine of equivalents to “embrace a structure that was specifically excluded from the claims.” *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 400 (Fed. Cir. 1994). A particular structure can be deemed outside the reach of the doctrine of equivalents because that structure is clearly excluded from the claims whether the exclusion is express or implied. In *Moore, U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091 (Fed. Cir. 2000), for example, the court considered a claim to a mailer-type business form in which the longitudinal strips of adhesive extend “the majority of the lengths” of the longitudinal margins of the form. The patentee argued that the accused form, in which the longitudinal strips of adhesive extended a minority of the length of the longitudinal margin of the form, infringed under the doctrine of equivalents. The court rejected the argument, holding that “it would defy logic to conclude that a minority—the very antithesis of a majority—could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise.” 229 F.3d at 1106. Similarly, in *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547 (Fed. Cir. 1997), the patent claimed a process that included crystallizing a particular substance at high temperature “under an inert gas atmosphere.” The patentee argued that certain of the accused processes, which used “heated air” rather than “an inert gas atmosphere” infringed under the doctrine of equivalents. The court rejected that argument, explaining that “the claim language specifically excludes reactive gases—such as ‘heated air’—from the scope of the claims” and in light of that specific exclusion, the accused processes could not infringe under the doctrine of equivalents. 114 F.3d at 1561. In each of these cases, by defining the claim in a way that clearly excluded certain subject matter, the patent implicitly disclaimed the subject matter that was excluded and thereby barred the patentee from asserting infringement under the doctrine of equivalents.

The court did effectively the same thing in *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420 (Fed. Cir. 1997). In that case, the claim was to a syringe disposal container having an elongated slot at the top of the container body and a “first constriction extending over said slot.” Although those limitations did not literally read on the accused device, the patentee argued that the device infringed under the doctrine of equivalents. The court rejected that argument, noting that the claim

defines a relatively simple structural device. No subtlety of language or complexity of the technology, nor any subsequent change in the state of the art, such as later-developed technology, obfuscated the significance of this limitation at the time of its incorporation into the claim. . . . If Sage desired broad patent

protection for any container that performed a function similar to its claimed container, it could have sought claims with fewer structural encumbrances. . . . [A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed structure.

126 F.3d at 1425. Thus, the court determined that because the scope of the claim was limited in a way that plainly and necessarily excluded a structural feature that was the opposite of the one recited in the claim, that different structure could not be brought within the scope of patent protection through the doctrine of equivalents.

The principle articulated in these cases is akin to the familiar rule that the doctrine of equivalents cannot be employed in a manner that wholly vitiates a claim limitation. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29-30 (1997). Thus, if a patent states that the claimed device must be “non-metallic,” the patentee cannot assert the patent against a metallic device on the ground that a metallic device is equivalent to a non-metallic device. The unavailability of the doctrine of equivalents could be explained either as the product of an impermissible vitiation of the “non-metallic” claim limitation, or as the product of a clear and binding statement to the public that metallic structures are excluded from the protection of the patent. As the court made clear in *Sage*, the foreclosure of reliance on the doctrine of equivalents in such a case depends on whether the patent clearly excludes the asserted equivalent structure, either implicitly or explicitly.

Each of the SciMed patents specifically recognized and disclaimed the dual lumen structure, making clear that the patentee regarded the dual lumen configuration as significantly inferior to the coaxial lumen configuration used in the invention. Where such an explicit disclaimer is present, the principles of those cases apply *a fortiori*, and the patentee cannot be allowed to recapture the excluded subject matter under the doctrine of equivalents without undermining the notice function of the patent. As the court observed in *Sage*, the patentee had an opportunity to draft the patent in a way that would make clear that dual lumens as well as coaxial lumens were within the scope of the invention, but the patentee did just the opposite, leaving competitors and the public to draw the reasonable conclusion that the patentee was not seeking patent protection for catheters that used a dual lumen configuration. Under these circumstances, the district court was justified in concluding that a reasonable jury could not find that the accused devices infringe the SciMed patents under the doctrine of equivalents.

Comments

1. **The Specific-Exclusion Rule.** Specific-exclusion is very similar to the vitiation principle. A recent example can be found in *Cook Biotech Inc. v. ACell, Inc.*, 460 F.3d 1365 (Fed. Cir. 2006). In *Cook*, the patentee claimed “[a] composition comprising *urinary bladder submucosa* delaminated from both the abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of a urinary bladder of a warm blooded

vertebrate.” The accused infringer, ACell, argued that the “all limitations rule” bars the capture of equivalents specifically excluded by the claims at issue. Specifically, because the patent claims a composition comprising urinary bladder submucosa, and such submucosa must have been delaminated from “the luminal portion of the tunica mucosa,” an accused product that contains some or all of “the luminal portion of the tunica mucosa” cannot infringe under the doctrine of equivalents. The Federal Circuit agreed with ACell, noting that the patentee’s “theory of equivalence with respect to asserted claims would violate a corollary to the all limitations rule . . . that ‘the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims.’” The accused product consists of two tissue layers specifically excluded from the claimed composition by delaminating the luminal portion of the tunica mucosa. The court stated:

A claim that specifically excludes an element cannot through a theory of equivalence be used to capture a composition that contains that expressly excluded element without violating the “all limitations rule.” Permitting appellees to assert such a theory of equivalence would effectively remove the requirement that the urinary bladder submucosa be delaminated from “the luminal portion of the tunica mucosa.” *See Warner-Jenkinson*.

Id. at 1379.

2. **The All-Limitations Rule.** The court in *SciMed* referred “to the familiar rule that the doctrine of equivalents cannot be employed in a manner that wholly vitiates a claim limitation.” This rule is known as the all-limitations rule. In *Warner-Jenkinson* the Court, relying on the late Judge Nies’s dissent, adopted an all-limitations rule when applying the DOE. According to the Court, this rule “reconcile[s] the prohibition against enlarging the scope of claims and the doctrine of equivalents by applying the doctrine to each element of a claim, rather than to the accused product or process ‘overall.’” *Warner-Jenkinson*, 517 U.S. at 25. Recall the Court’s language:

Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.

Warner-Jenkinson, 520 U.S. at 29. Thus, each claim limitation must not be vitiated or read completely out of the claim. *See Bell Atlantic Network Services, Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1279-80 (Fed. Cir. 2001) (stating “if a court determines that a finding of infringement under the doctrine of equivalents ‘would entirely vitiate a particular claim element,’ then the court should rule that there is no infringement under the doctrine of equivalents.”) (citing *Warner-Jenkinson*). Thus, for there to be infringement under the DOE, “the patentee has the burden to present particularized evidence that links the accused products to the patent on a limitation by limitation basis.” *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376 (Fed. Cir. 2007).

In *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1017 (Fed. Cir. 2006), the Federal Circuit, informed by *Warner-Jenkinson*, elaborated on the all-limitations rule:

[W]e have held that in certain instances, the “all elements” rule* forecloses resort to the doctrine of equivalents because, on the facts or theories presented in a case, a limitation would be read completely out of the claim — *i.e.*, the limitation would be effectively removed or “vitiated.” For instance, we have concluded that in some cases, the evidence was such that no reasonable jury could determine a proffered equivalent to be insubstantially different from the claimed limitation. *See, e.g., Freedman Seating*, 420 F.3d at 1361 (holding that a limitation was vitiated in part because the structural difference in the accused device “is not a ‘subtle difference in degree,’ but rather ‘a clear, substantial difference or difference in kind’”; *Ethicon*, 149 F.3d 1309, 1319 (Fed. Cir. 1998) (holding that the “all elements” rule barred application of the doctrine of equivalents because, on the facts presented, no reasonable jury could find the differences to be insubstantial). We have also concluded that in some cases, the patentee’s theory of equivalence was legally insufficient because, rather than demonstrate an insubstantial difference between a limitation and an element in the accused device, the theory effectively eliminated a limitation in its entirety. *See, e.g., Tronzo*, 156 F.3d at 1160 (holding that the patentee’s theory of equivalence — that “any shape would be equivalent to the conical limitation” — would write such a limitation out of the claims (emphasis in original)); *Forest Labs., Inc. v. Abbott Labs.*, 239 F.3d 1305, 1313 (Fed. Cir. 2001) (holding that the patentee’s theory of equivalence — that a limitation on the percentages of water in a composition was “irrelevant” when compared to the accused composition — vitiated such a limitation). Thus, the “all elements” rule generally is not met — and therefore a claim limitation can be said to be vitiated — if the theory or evidence of equivalence is legally incapable of establishing that the differences between the limitation in the claim and the accused device are insubstantial; *i.e.*, if the theory or evidence is so legally insufficient as to warrant a holding of non-infringement as a matter of law.

- 3. Identifying Vitiating.** Identifying what exactly constitutes a limitation, and when a claim limitation is vitiated are questions that are sometimes difficult to answer. For example, in *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251 (Fed. Cir. 1989), the court recognized that the all-limitations rule has led to “confusion . . . because of misunderstanding or misleading uses of the term ‘element’ in discussing claims.” According to the court, an “[e]lement” may be used to mean a single limitation, but it has

*The Federal Circuit has expressed a preference, although inconsistently applied, for the word “limitation” (instead of “element”) when referring to claim language, and “element” when referring to the accused device. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Inc.*, 234 F.3d 558, 563 n.1 (Fed. Cir. 2000) (*en banc*) (“In our prior cases, we have used both the term ‘element’ and the term ‘limitation’ to refer to words in a claim. It is preferable to use the term ‘limitation’ when referring to claim language and the term ‘element’ when referring to the accused device”). In fact, one member of the court stated that he prefers to call the “all-elements rule” the “all-limitations rule.” *See* Raj S. Dav, *A Mathematical Approach to Claim Elements and the Doctrine of Equivalents*, 16 HARV. J.L. & TECH. 507, 532 n.133, quoting Judge Paul Michel as follows:

I like to call it [referring to the “all-elements rule”] the “all-limitations rule,” because I don’t know what an element is. And every time I’ve had to debate with someone, it’s clear that they have a slightly different idea of what an element is than what I think it is. Once you get past atomic elements, I don’t think it’s a useful word.

Nonetheless, as *Depuy* reveals, the court continues to use the phrase “all-elements rule.” — ED.]

also been used to mean a series of limitations which, taken together, make up a component of the claimed invention.” *Id.* at 1259. The court continued, stating that under the all-limitations rule, “[a]n equivalent must be found for every limitation of the claim somewhere in an accused device, but not necessarily in a corresponding component, although that is generally the case.” *Id.* This language suggests the all-limitations rule is more flexible than a one-to-one correspondence that demands each claim limitation to have a corresponding equivalent in the accused device.

But subsequent decisions sought to clarify *Corning Glass*. In *Dolly, Inc. v. Spalding & Evenflo Companies, Inc.*, 16 F.3d 394 (Fed. Cir. 1994), for instance, the Federal Circuit, referring to the *Corning Glass* language noted above, stated the “language in *Corning Glass* did not substitute a broader limitation-by-limitation comparison for the doctrine of equivalents than the element-by-element comparison in *Pennwalt*. Rather, . . . *Corning Glass* reaffirmed that the rule requires an equivalent for every limitation of the claim, even though the equivalent may not be present in the corresponding component of the accused device.” *Id.* at 399. See also *Forest Labs v. Abbott Labs*, 239 F.3d 1305, 1313 (Fed. Cir. 2001) (noting *Corning Glass* “did not dispense with the need for one-to-one correspondence of limitations and elements”). Thus, the court remarked that equivalency will result “when two components of the accused device perform a single function of the patented invention” or “when separate claim limitations are combined into a single component of the accused device.” *Dolly*, 16 F.3d at 398. A recent example of the latter can be found in *Eagle Comtronics, Inc. v. Arrow Communication Laboratories, Inc.*, 305 F.3d 1303 (Fed. Cir. 2002). In *Eagle*, the invention related to an improved cable filter structure used to decode or unscramble protected television signals. Claim 1, the only independent claim, recited several limitations, three of which included a (1) front cap, (2) a rear insert body including a rear end portion, and (3) a seal located between the front cap and the rear insert body. The accused products did not have separate elements corresponding to the front cap and rear insert body limitations, but did have a seal located along the periphery of the accused products. The patentee conceded there was no literal infringement, but argued infringement under the DOE. The accused infringer asserted because the accused devices do not possess a corresponding element to the aforementioned claim limitations, therefore, applying of the DOE would impermissibly vitiate these limitations. The Federal Circuit disagreed, stating:

While a claim limitation cannot be totally missing from an accused device, whether or not a limitation is deemed to be vitiated must take into account that when two elements of the accused device perform a single function of the patented invention, or when separate claim limitations are combined into a single element of the accused device, a claim limitation is not necessarily vitiated, and the doctrine of equivalents may still apply if the differences are insubstantial.

Id. at 1317.

In *Sage Prods. v. Devon Indus.*, 126 F.3d 1420 (Fed. Cir. 1997), however, vitiation was a concern and led to a finding of no infringement under the DOE. In *Sage*, the invention was a container for disposing of hazardous

medical waste. The relevant claim language stated the invention comprised a container body with “an elongated slot at the top of the container body. . . .” *Id.* at 1422. The defendant made a similar container, but the slot for disposing the waste was within the container body. *Id.* at 1423. Both containers featured two constrictions that kept the waste securely within the container. The plaintiff argued “having two constrictions below the top of the container is the same, for purposes of infringement, as having one constriction above and one constriction below.” *Id.* at 1424. The court found no literal infringement and ruled the all-limitations rule would be violated if the patentee were allowed to show the slot within the container was equivalent to a slot at the top of the container.

d. Prior Art

Claim coverage under the DOE cannot extend to include subject matter that forms part of the prior art. The reason for this limitation is straightforward: Claims that read on the prior art do not satisfy the patentability requirements, and therefore, the PTO would never have issued the patent of such claim breadth. Indeed, it is not uncommon for a party accused of infringement to assert that it is merely practicing the prior art, thus implying that a finding of infringement leads to a finding of invalidity. The principal case of *Wilson Sporting Goods Co.* explores the role of prior art as a limitation on the DOE.

WILSON SPORTING GOODS CO. v. DAVID GEOFFREY & ASSOCIATES

904 F.2d 677 (Fed. Cir. 1990)

RICH, Circuit Judge.

These appeals, consolidated by agreement, are from judgments of the United States District Court for the District of South Carolina in two actions brought by Wilson Sporting Goods Co. (Wilson) for infringement of United States Patent 4,560,168 ('168), entitled “Golf Ball.” In the first action, the magistrate entered judgment of liability against Dunlop Slazenger Corporation (Dunlop) upon jury verdicts of patent validity and willful infringement.

BACKGROUND

A. The Proceedings

Wilson is a full-line sporting goods company and is one of about six major competitors in the golf ball business. Among its well-known balls are the ProStaff and Ultra. Dunlop is also a major player in the golf ball business. It competes head-to-head with Wilson by selling the Maxfli Tour Limited and Slazenger balls. It sells the Maxfli Tour Limited ball to numerous distributors, but sells the Slazenger ball only to DGA, which distributes the ball to U.S. customers.

Wilson accused Dunlop of infringing claims 1, 7, 15-16, and 19-22 of its '168 patent, and made a general accusation of infringement against DGA.

After a five day jury trial on the issue of liability, the jury returned special interrogatories finding the asserted claims “valid” (i.e., not proved invalid)

and willfully infringed. Judgment was entered upon the verdict, Dunlop's motion for JNOV was denied, and Dunlop appealed.

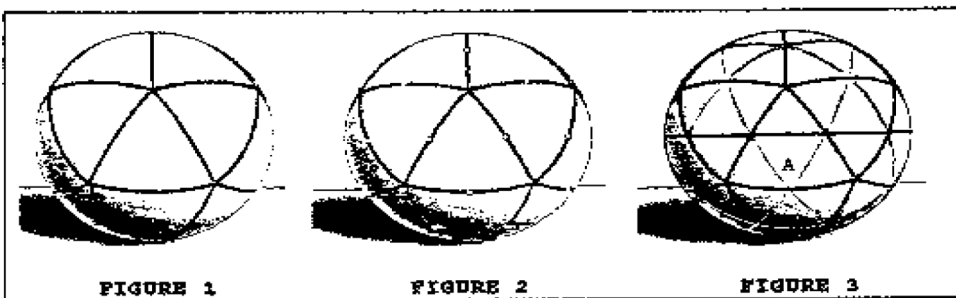
B. The Technology

For more than a century, golfers have been searching for a "longer" ball. As one of the parties put it, "distance sells." Inventors have experimented with numerous aspects of ball design over the years, but as United States Golf Association (U.S.G.A.) rules began to strictly control ball size, weight, and other parameters, inventors focused their efforts on the "dimples" in the ball's surface. According to one witness, new dimple designs provide the only real opportunity for increasing distance within the confines of U.S.G.A. rules.

Dimples create surface turbulence around a flying ball, lessening drag and increasing lift. In lay terms, they make the ball fly higher and farther. While this much is clear, "dimple science" is otherwise quite complicated and inexact: dimples can be numerous or few, and can vary as to shape, width, depth, location, and more.

Wilson's '168 patent claims a certain configuration of dimples on a golf ball cover. The shape and width of the dimples in the '168 patent is for the most part immaterial. What is critical is their location on the ball. The goal is to create a more symmetrical distribution of dimples.

Generally speaking, the dimples in the patent are arranged by dividing the cover of a spherical golf ball into 80 imaginary spherical triangles and then placing the dimples (typically several hundred) into strategic locations in the triangles. The triangles are constructed as follows. First, the ball is divided into an imaginary "icosahedron," as shown in Figure 1. An icosahedral golf ball is completely covered by 20 imaginary equilateral triangles, 5 of which cover each pole of the ball and ten of which surround its equator. Second, the midpoints of each of the sides of each of the 20 icosahedral triangles are located, as shown in Figure 2. Third, the midpoints are joined, thus subdividing each icosahedral triangle into four smaller triangles.



The resulting 80 imaginary triangles are shown in Figure 3. Critically important are the light lines which join the midpoints. As can be seen from Figure 3, they form the arcs of circles which pass completely around the widest part of the ball. There are six such circles, referred to in the patent as "great circles."

All of the claims of the '168 patent require this basic golf ball having eighty sub-triangles and six great circles. Particular claims require variations on the placement of dimples in the triangles, with one common theme — the dimples

must be arranged on the surface of the ball so that no dimple intersects any great circle. Equivalently stated, the dimples must be arranged on the surface of the ball so that no dimple intersects the side of any central triangle. *See* Figure 4, below. When the dimples are arranged in this manner, the ball has six axes of symmetry, compared to prior balls which had only one axis of symmetry.

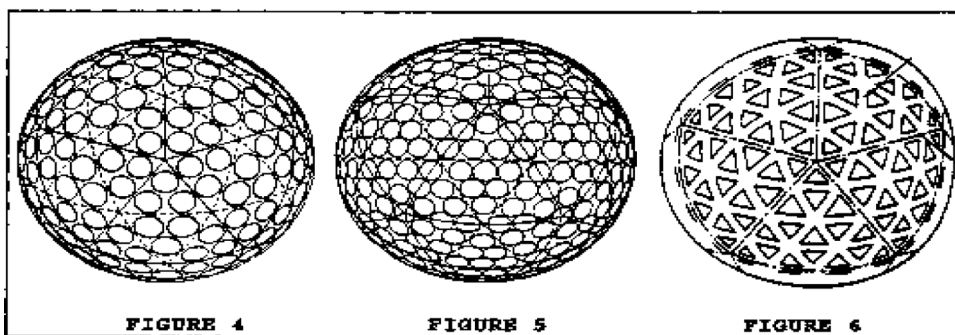
C. Patent and Trademark Office (PTO) Proceedings

Wilson employee Steven Aoyama filed his patent application on April 27, 1984. Twenty seven claims were presented. All were allowed on the first action without comment by the examiner. The patent issued on December 24, 1985, to Wilson as assignee of Aoyama.

Claim 1, the only independent claim, reads:

1. A golf ball having a spherical surface with a plurality of dimples formed therein and six great circle paths which do not intersect any di[m]ples, the dimples being arranged by dividing the spherical surface into twenty spherical triangles corresponding to the faces of a regular icosahedron, each of the twenty triangles being sub-divided into four smaller triangles consisting of a central triangle and three apical triangles by connecting the midpoints [of the sides] of each of said twenty triangles along great circle paths, said dimples being arranged so that the dimples do not intersect the sides of any of the central triangles. [Bracketed insertions ours.]

The remaining 26 claims are dependent upon claim 1. They contain further limitations as to the number and location of dimples in the sub-triangles. Claim 7, for example, requires that all “central triangles [have] the same number of dimples.” Other dependent claims locate dimples on the perimeter of the apical triangles, so that dimples are shared by adjacent apical triangles. *See* Figure 5.



D. The Prior Art

* * *

The prior art . . . includes several patents to Uniroyal and a Uniroyal golf ball sold in the 1970's. The Uniroyal ball is an icosahedral ball having six great circles with 30 or more dimples intersecting the great circles by about 12-15 thousandths of an inch. We discuss it extensively below.

E. The Accused Balls

There are four accused products, all of which the jury found to infringe. . . . The accused balls (collectively “Dunlop’s balls”) have dimples which are arranged in an icosahedral pattern having six great circles, but the six great circles are not dimple-free as the claims literally require. The number of dimples which intersect great circles and the extent of their intersection were disputed by the parties, but the evidence most favorable to appellee Wilson can be summarized as follows (units of last two columns are 0.001”):

Ball	Dimples	Dimples Intersected	Dimple Radius	Extent of Intersection
Maxfli Tour MD	432	60	60-80	7.5
Maxfli Tour HT	432	60	60-80	8.7
Interlock (S)	480	60	60-80	4.0
Interlock (B)	480	60	60-80	4.0

OPINION

* * *

B. Denial of JNOV on Infringement

1. Dunlop’s Argument

The only theory of liability presented to the jury by Wilson was infringement under the doctrine of equivalents. Dunlop’s argument for reversal is straightforward. It contends that there is no principled difference between the balls which the jury found to infringe and the prior art Uniroyal ball; thus to allow the patent to reach Dunlop’s balls under the doctrine of equivalents would improperly ensnare the prior art Uniroyal ball as well.

2. Independent Claim 1

Infringement *may* be found under the doctrine of equivalents if an accused product “performs substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result as the claimed invention.” *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc). Even if this test is met, however, there can be no infringement if the asserted scope of equivalency of what is literally claimed would encompass the prior art. *Id.* This issue—whether an asserted range of equivalents would cover what is already in the public domain—is one of law, which we review *de novo*, but we presume that the jury resolved underlying evidentiary conflicts in Wilson’s favor.

This court on occasion has characterized claims as being “expanded” or “broadened” under the doctrine of equivalents. Precisely speaking, these characterizations are inaccurate.

To say that the doctrine of equivalents extends or enlarges *the claims* is a contradiction in terms. The claims—i.e., the scope of patent protection *as defined by* the claims—remain the same and application of the doctrine *expands the right to exclude* to “equivalents” of what is claimed.

The doctrine of equivalents, by definition, involves going beyond any permissible interpretation of the claim language; i.e., it involves determining whether the accused product is “equivalent” to what is described by the claim language.

This distinction raises an interesting question: If the doctrine of equivalents does not involve expanding the claims, why should the *prior art* be a limitation on the range of permissible equivalents? It is *not* because we construe claims narrowly if necessary to sustain their validity. As we have said, the doctrine of equivalents does not involve expansion of the *claims*. Nor is it because to hold otherwise would allow the patentee to preempt a product that was in the public domain prior to the invention. The accused products here, as in most infringement cases, were never “in the public domain.” They were developed long after the invention and differ in several respects from the prior art.

The answer is that a patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims. The doctrine of equivalents exists to prevent a fraud on a patent, *Graver Tank*, *not* to give a patentee something which he could not lawfully have obtained from the PTO had he tried. Thus, since prior art always limits what an inventor could have claimed, it limits the range of permissible equivalents of a claim.

Whether prior art restricts the range of equivalents of what is literally claimed can be a difficult question to answer. To simplify analysis and bring the issue onto familiar turf, it may be helpful to conceptualize the limitation on the scope of equivalents by visualizing a *hypothetical* patent claim, sufficient in scope to *literally* cover the accused product. The pertinent question then becomes whether that hypothetical claim could have been allowed by the PTO over the prior art. If not, then it would be improper to permit the patentee to obtain that coverage in an infringement suit under the doctrine of equivalents. If the hypothetical claim could have been allowed, then *prior art* is not a bar to infringement under the doctrine of equivalents.

Viewing the issue in this manner allows use of traditional patentability rules and permits a more precise analysis than determining whether an *accused product* (which has no claim limitations on which to focus) would have been obvious in view of the prior art. In fact, the utility of this hypothetical broader claim may explain why “expanded claim” phraseology, which we now abandon, had crept into our jurisprudence. Finally, it reminds us that Wilson is seeking patent coverage beyond the limits considered by the PTO examiner.

In this context it is important to remember that the burden is on Wilson to prove that the range of equivalents which it seeks would not ensnare the prior art Uniroyal ball. The patent owner has always borne the burden of proving infringement, and there is no logical reason why that burden should shift to the accused infringer simply because infringement in this context might require an inquiry into the patentability of a *hypothetical* claim. Any other approach would ignore the realities of what happens in the PTO and violate established patent law. Leaving this burden on Wilson does not, of course, in any way undermine the presumed validity of Wilson’s actual patent claims. In the present situation, Wilson’s claims will remain valid whether or not Wilson persuades us that it is entitled to the range of equivalents sought here.

The specific question before us, then, is whether Wilson has proved that a hypothetical claim, similar to claim 1 but broad enough to literally cover Dunlop's balls, could have been patentable. As we have explained above, Dunlop's balls are icosahedral balls with six great circles, five of which are intersected by dimples. The balls contain 432 to 480 dimples, 60 of which intersect great circles in amounts from 4 to 9 thousandths of an inch. In order for a hypothetical claim to cover Dunlop's balls, its limitations must permit 60 dimples to intersect the great circles by at least 9 thousandths of an inch. Thus, the issue is whether a hypothetical claim directed to an icosahedral ball having six great circles intersected by 60 dimples in amounts up to 9 thousandths of an inch could have been patentable in view of the prior art Uniroyal ball.

On the Uniroyal ball, the extent to which the dimples intersect the great circles is from 12 to 15 thousandths of an inch. Stated as a percentage of dimple radius, the intersection permitted in the hypothetical claim is 13% or less, and the dimples on the Uniroyal ball intersect by 17% to 21%. The number of dimples which intersect the great circles is also similar for the hypothetical claim and the prior art Uniroyal ball. The pertinent hypothetical claim limitation reads on any ball having 60 or less intersecting dimples. This limitation reads on the prior art Uniroyal ball, which has 30 intersecting dimples. If viewed in relative terms, the hypothetical claim limitation reads on any ball which has less than 14% of its dimples intersecting great circles. Roughly 12% of the dimples on the Uniroyal ball intersect great circles.

We hold that these differences are so slight and relatively minor that the hypothetical claim—which permits twice as many intersecting dimples, but with slightly smaller intersections—viewed as a whole would have been obvious in view of the Uniroyal ball. As Dunlop puts it, there is simply “no principled difference” between the hypothetical claim and the prior art Uniroyal ball. Accordingly, Wilson's claim 1 cannot be given a range of equivalents broad enough to encompass the accused Dunlop balls.

3. Dependent Claims

Before separately analyzing the asserted dependent claims, we should first explain why we are bothering to do so. This court has stated: “It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed.” *Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1553 & n. 9 (Fed. Cir. 1989). While this proposition is no doubt generally correct, it does not apply in the circumstances of this case.

Here, we have reversed the judgment of infringement of independent claim 1 solely because the asserted range of equivalents of the claim limitations would encompass the prior art Uniroyal ball. The dependent claims, of course, are *narrower* than claim 1; therefore, it does not automatically follow that the ranges of equivalents of these narrower claims would encompass the prior art, because of their added limitations. In contrast, in *Wahpeton Canvas* the court affirmed the judgment of noninfringement of the independent claims because the accused products did not include particular claim limitations or their substantial equivalents. Where that is the reason for noninfringement of the independent claim, it follows that, for the same reason, the dependent claims will not be infringed. But that is not true here and we therefore turn to the asserted dependent claims, to determine whether they can be infringed under the doctrine of equivalents.

Implicit in the jury's conclusion that the Dunlop balls infringe the asserted dependent claims is a finding that the Dunlop balls have, in addition to the features we have described above, the further limitations of the dependent claims. Each dependent claim contains a small variation on the theme of an icosahedral ball having six great circles. We have considered each asserted dependent claim and conclude that none could be given a range of equivalents broad enough to encompass Dunlop's balls because that would extend Wilson's patent protection beyond hypothetical claims it could lawfully have obtained from the PTO. . . .

CONCLUSION

We conclude that the magistrate erred in denying Dunlop's motion for JNOV on infringement, because, as a matter of law, a range of equivalents broad enough to cover Dunlop's balls would also have encompassed the prior art. Accordingly, we reverse the judgment of infringement by Dunlop.

Comments

1. **The Hypothetical Claim: Back to the Future.** The *Wilson* court asks us to cast our minds back to the prosecution phase to determine if the hypothetical claim, "sufficient in scope to literally cover the accused product," would have been allowed to issue by the PTO over the prior art. *Wilson* was based on "the fundamental principle that no one deserves an exclusive right to technology already in the public domain." *Marquip, Inc. v. Fosber America, Inc.*, 198 F.3d 1363, 1366 (Fed. Cir. 1999). The hypothetical claim construct is not obligatory, but a methodology to help "define the limits imposed by the prior art on the range of equivalents." *Key Mfg. Group, Inc. v. Microdot, Inc.*, 925 F.2d 1444, 1449 (Fed. Cir. 1991).
2. **Applying *Wilson*.** The *Wilson* framework has generated a great deal of commentary, and has been applied in numerous cases. See, e.g., *Streamfeeder LLC v. Sure-Feed Systems, Inc.*, 175 F.3d 974 (Fed. Cir. 1999) (holding hypothetical claim would not have issued over prior art, and therefore no infringement); *Key Manufacturing, supra* (same); *Abbott Laboratories v. Dey LP*, 287 F.3d 1097 (Fed. Cir. 2002) (applying *Wilson* and holding prior art does not preclude application of DOE). One particular difficulty in applying *Wilson* is defining the breadth of a hypothetical claim that includes the equivalent in question.

COMPARATIVE PERSPECTIVE

Claim Interpretation and Non-Literal Infringement in the United Kingdom

In the following opinion, Lord Hoffmann explores claim interpretation and the role of non-literal infringement under U.K. law. He also discusses the American approach to claim interpretation and the DOE. As you read the opinion, ask yourself what are the differences between the U.S. and U.K. approaches to claim interpretation and the DOE, and how these approaches further the policies of patent law.

KIRIN-AMGEN, INC. v. HOECHST MARION ROUSSEL LTD.**[2004] UKHL 46, [2004] All ER (D) 286 (Oct 1, 2004)**

LORD HOFFMANN

[The patent-in-suit related to the production of erythropoietin (“EPO”) by recombinant DNA technology. The Court discussed the technology and the claim language in question.]

Extent of Protection: The Statutory Provisions

18. Until the Patents Act 1977, which gave effect to the European Patent Convention (“EPC”) there was nothing in any UK statute about the extent of protection conferred by a patent. It was governed by the common law, the terms of the royal grant and general principles of construction. It was these principles which Lord Diplock expounded in the leading case of *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, which concerned a patent granted before 1977. But the EPC and the Act deal expressly with the matter in some detail. Article 84 specifies the role of the claims in an application to the European Patent Office for a European patent:

The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.

19. For present purposes, the most important provision is article 69 of the EPC, which applies to infringement proceedings in the domestic courts of all Contracting States:

The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

20. In stating unequivocally that the extent of protection shall be “determined” (in German, “bestimmt”) by the “terms of the claims” (den Inhalt der Patentansprüche) the Convention followed what had long been the law in the United Kingdom. During the course of the 18th and 19th centuries, practice and common law had come to distinguish between the part of the specification in which the patentee discharged his duty to disclose the best way of performing the invention and the section which delimited the scope of the monopoly which he claimed: see *Fletcher-Moulton LJ in British United Shoe Machinery Co Ltd v A. Fussell & Sons Ltd* (1908) 25 RPC 631, 650. The best-known statement of the status of the claims in UK law is by Lord Russell of Killowen in *Electric and Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 39:

The function of the claims is to define clearly and with precision the monopoly claimed, so that others may know the exact boundary of the area within which they will be trespassers. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed. The claims must undoubtedly be read as part of the entire document and not as a separate document; but the forbidden field must be found in the language of the claims and not elsewhere.

21. The need to set clear limits upon the monopoly is not only, as Lord Russell emphasised, in the interests of others who need to know the area “within which they will be trespassers” but also in the interests of the patentee, who

needs to be able to make it clear that he lays no claim to prior art or insufficiently enabled products or processes which would invalidate the patent.

22. In Germany, however, the practice before 1977 in infringement proceedings (validity is determined by a different court) was commonly to treat the claims as a point of departure (“Ausgangspunkt”) in determining the extent of protection, for which the criterion was the inventive achievement (“erfinderische Leistung”) disclosed by the specification as a whole. Likewise in the Netherlands, Professor Jan Brinkhof, former Vice-President of the Hague Court of Appeals, has written that the role of the claims before 1977 was “extremely modest”: see *Is there a European Doctrine of Equivalence?* (2002) 33 IIC 911, 915. What mattered was the “essence of the invention” or what we would call the inventive concept.

The Protocol

23. Although the EPC thus adopted the United Kingdom principle of using the claims to determine the extent of protection, the Contracting States were unwilling to accept what were understood to be the principles of construction which United Kingdom courts applied in deciding what the claims meant. These principles, which I shall explain in greater detail in a moment, were perceived as having sometimes resulted in claims being given an unduly narrow and literal construction. The Contracting Parties wanted to make it clear that legal technicalities of this kind should be rejected. On the other hand, it was accepted that countries which had previously looked to the “essence of the invention” rather than the actual terms of the claims should not carry on exactly as before under the guise of giving the claims a generous interpretation.

24. This compromise was given effect by the “Protocol on the Interpretation of Article 69”:

Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.

25. It is often said, on the basis of the words “a position between these extremes,” that the Protocol represents a compromise between two different approaches to the interpretation of claims. But that is not quite accurate. It is a protocol on the interpretation of article 69, not a protocol on the interpretation of claims. The first sentence does deal with interpretation of the claims and, to understand it, one needs to know something about the rules which English courts used to apply, or impose on themselves, when construing not merely patents but documents in general. The second sentence does not deal with the interpretation of claims. Instead, it makes it clear that one cannot go beyond the claims to what, on the basis of the specification as a whole, it appears that “the patentee has contemplated.” But the last sentence indicates that, in determin-

ing the extent of protection according to the content of the claims but avoiding literalism, the courts of the Contracting States should combine “a fair protection for the patentee with a reasonable degree of certainty for third parties.”

26. Both article 69 and the Protocol are given effect in United Kingdom law, in relation to infringement, by sections 60 and 125 of the Act. Section 60 provides that a person infringes a patent if he does various things in the United Kingdom “in relation to the invention” without the consent of the proprietor of the patent. Section 125 defines the extent of “the invention”:

(1) For the purpose of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.

The English Rules of Construction

27. As I indicated a moment ago, it is impossible to understand what the first sentence of the Protocol was intending to prohibit without knowing what used to be the principles applied (at any rate in theory) by an English court construing a legal document. These required the words and grammar of a sentence to be given their “natural and ordinary meaning,” that is to say, the meanings assigned to the words by a dictionary and to the syntax by a grammar. This meaning was to be adopted regardless of the context or background against which the words were used, unless they were “ambiguous”, that is to say, capable of having more than one meaning. As Lord Porter said in *Electric & Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 57:

If the Claims have a plain meaning in themselves, then advantage cannot be taken of the language used in the body of the Specification to make them mean something different.

28. On the other hand, if the language of the claim “in itself” was ambiguous, capable of having more than one meaning, the court could have regard to the context provided by the specification and drawings. If that was insufficient to resolve the ambiguity, the court could have regard to the background, or what was called the “extrinsic evidence” of facts which an intended reader would reasonably have expected to have been within the knowledge of the author when he wrote the document.

29. These rules, if remorselessly applied, meant that unless the court could find some ambiguity in the language, it might be obliged to construe the document in a sense which a reasonable reader, aware of its context and background, would not have thought the author intended. Such a rule, adopted in the interests of certainty at an early stage in the development of English law, was capable of causing considerable injustice and occasionally did so. The fact that it did not do so more often was because judges were generally astute to find the

necessary “ambiguity” which enabled them to interpret the document in its proper context. Indeed, the attempt to treat the words of the claim as having meanings “in themselves” and without regard to the context in which or the purpose for which they were used was always a highly artificial exercise.

30. It seems to me clear that the Protocol, with its reference to “resolving an ambiguity,” was intended to reject these artificial English rules for the construction of patent claims. As it happens, though, by the time the Protocol was signed, the English courts had already begun to abandon them, not only for patent claims, but for commercial documents generally. The speeches of Lord Wilberforce in *Prenn v Simmonds* [1971] 1 WLR 1381 and *Reardon Smith Line Ltd. v Yngvar Hansen-Tangen* [1976] 1 WLR 989 are milestones along this road. It came to be recognised that the author of a document such as a contract or patent specification is using language to make a communication for a practical purpose and that a rule of construction which gives his language a meaning different from the way it would have been understood by the people to whom it was actually addressed is liable to defeat his intentions. It is against that background that one must read the well known passage in the speech of Lord Diplock in *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, 243 when he said that the new approach should also be applied to the construction of patent claims:

A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge.

31. This was all of a piece with Lord Diplock’s approach a few years later in *The Antaios* [1985] AC 191, 201 to the construction of a charterparty:

I take this opportunity of re-stating that if detailed semantic and syntactical analysis of words in a commercial contract is going to lead to a conclusion that flouts business commonsense, it must be made to yield to business commonsense.

32. Construction, whether of a patent or any other document, is of course not directly concerned with what the author meant to say. There is no window into the mind of the patentee or the author of any other document. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean. Notice, however, that it is not, as is sometimes said, “the meaning of the words the author used,” but rather what the notional addressee would have understood the author to mean by using those words. The meaning of words is a matter of convention, governed by rules, which can be found in dictionaries and grammars. What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of and background to the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience. I have discussed these questions at some length in *Mannai Investment Co Ltd v Eagle Star Life Assurance Co Ltd* [1997] AC 749 and *Investors Compensation Scheme Ltd v West Bromwich Building Society* [1998] 1 WLR 896.

33. In the case of a patent specification, the notional addressee is the person skilled in the art. He (or, I say once and for all, she) comes to a reading of the specification with common general knowledge of the art. And he reads the specification on the assumption that its purpose is to both to describe and to demarcate an invention—a practical idea which the patentee has had for a new product or process—and not to be a textbook in mathematics or chemistry or a shopping list of chemicals or hardware. It is this insight which lies at the heart of “purposive construction.” If Lord Diplock did not invent the expression, he certainly gave it wide currency in the law. But there is, I think, a tendency to regard it as a vague description of some kind of divination which mysteriously penetrates beneath the language of the specification. Lord Diplock was in my opinion being much more specific and his intention was to point out that a person may be taken to mean something different when he uses words for one purpose from what he would be taken to mean if he was using them for another. The example in the *Catnic* case was the difference between what a person would reasonably be taken to mean by using the word “vertical” in a mathematical theorem and by using it in a claimed definition of a lintel for use in the building trade. The only point on which I would question the otherwise admirable summary of the law on infringement in the judgment of Jacob LJ in *Rockwater Ltd v Technip France SA* (unreported) [2004] EWCA Civ 381, at paragraph 41, is when he says in sub-paragraph (e) that to be “fair to the patentee” one must use “the widest purpose consistent with his teaching.” This, as it seems to me, is to confuse the purpose of the utterance with what it would be understood to mean. The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one uses to ascertain the meaning. But purpose and meaning are different. If, when speaking of the widest purpose, Jacob LJ meant the widest meaning, I would respectfully disagree. There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.

34. “Purposive construction” does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee’s own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to describe something which, at any rate in his opinion, is new; which has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often.

35. One of the reasons why it will be unusual for the notional skilled man to conclude, after construing the claim purposively in the context of the specification and drawings, that the patentee must nevertheless have meant something different from what he appears to have meant, is that there are necessarily gaps in our knowledge of the background which led him to express himself in that particular way. The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed. One possible explanation is that it does not represent what the patentee really meant to say. But another is that he did mean it, for reasons of his own; such as wanting to avoid arguments with the examiners over enablement or prior art and have his patent granted as soon as possible. This feature of the practical life of a patent agent reduces the scope for a conclusion that the patentee could not have meant what the words appear to be saying. It has been suggested that in the absence of any explanation for a restriction in the extent of protection claimed, it should be presumed that there was some good reason between the patentee and the patent office. I do not think that it is sensible to have presumptions about what people must be taken to have meant but a conclusion that they have departed from conventional usage obviously needs some rational basis.

The Doctrine of Equivalents

36. At the time when the rules about natural and ordinary meanings were more or less rigidly applied, the United Kingdom and American courts showed understandable anxiety about applying a construction which allowed someone to avoid infringement by making an “immaterial variation” in the invention as described in the claims. In England, this led to the development of a doctrine of infringement by use of the “pith and marrow” of the invention (a phrase invented by Lord Cairns in *Clark v Adie* (1877) 2 App Cas 315, 320) as opposed to a “textual infringement.” The pith and marrow doctrine was always a bit vague (“necessary to prevent sharp practice” said Lord Reid in *C Van Der Lely NV v Bamfords Ltd* [1963] RPC 61, 77) and it was unclear whether the courts regarded it as a principle of construction or an extension of protection outside the claims.

37. In the United States, where a similar principle is called the “doctrine of equivalents,” it is frankly acknowledged that it allows the patentee to extend his monopoly beyond the claims. In the leading case of *Graver Tank & Manufacturing Co Inc v Linde Air Products Company* 339 US 605, 607 (1950), Jackson J said that the American courts had recognised:

that to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for — indeed encourage — the unscrupulous copyist to make unimportant and insubstantial changes and sub-

stitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.

38. In similar vein, Learned Hand J (a great patent lawyer) said that the purpose of the doctrine of equivalents was “to temper unsparing logic and prevent an infringer from stealing the benefit of the invention”: *Royal Typewriter Co v Remington Rand Inc* (CA2nd Conn) 168 F2nd 691, 692. The effect of the doctrine is thus to extend protection to something outside the claims which performs substantially the same function in substantially the same way to obtain the same result.

39. However, once the monopoly had been allowed to escape from the terms of the claims, it is not easy to know where its limits should be drawn. In *Warner-Jenkinson Co v Hilton Davis Chemical Co* 520 US 17, 28-29 (1997) the United States Supreme Court expressed some anxiety that the doctrine of equivalents had “taken on a life of its own, unbounded by the patent claims.” It seems to me, however, that once the doctrine is allowed to go beyond the claims, a life of its own is exactly what it is bound to have. The American courts have restricted the scope of the doctrine by what is called prosecution history or file wrapper estoppel, by which equivalence cannot be claimed for integers restricting the monopoly which have been included by amendment during the prosecution of the application in the patent office. The patentee is estopped against the world (who need not have known of or relied upon the amendment) from denying that he intended to surrender that part of the monopoly. File wrapper estoppel means that the true scope of patent protection often cannot be established without an expensive investigation of the patent office file. Furthermore, the difficulties involved in deciding exactly what part of the claim should be taken to have been withdrawn by an amendment drove the Federal Court of Appeals in *Festo Corporation v Shoketsu Kinzoku Kogyo Kabushiki Co Ltd* 234 F3rd 558 (2000) to declare that the law was arbitrary and unworkable. Lourie J said:

The only settled expectation currently existing is the expectation that clever attorneys can argue infringement outside the scope of the claims all the way through this Court of Appeals.

40. In order to restore some certainty, the Court of Appeals laid down a rule that any amendment for reasons of patent validity was an absolute bar to any extension of the monopoly outside the literal meaning of the amended text. But the Supreme Court reversed this retreat to literalism on the ground that the cure was worse than the disease: see *Festo Corporation v Shoketsu Kinzoku Kogyo Kabushiki Co Ltd* (28 May 2002) US Supreme Court.

41. There is often discussion about whether we have a European doctrine of equivalents and, if not, whether we should. It seems to me that both the doctrine of equivalents in the United States and the pith and marrow doctrine in the United Kingdom were born of despair. The courts felt unable to escape from interpretations which “unsparing logic” appeared to require and which prevented them from according the patentee the full extent of the monopoly which the person skilled in the art would reasonably have thought he was claiming. The background was the tendency to literalism which then characterised the approach of the courts to the interpretation of documents generally and the fact that patents are likely to attract the skills of lawyers

seeking to exploit literalism to find loopholes in the monopoly they create. (Similar skills are devoted to revenue statutes).

42. If literalism stands in the way of construing patent claims so as to give fair protection to the patentee, there are two things that you can do. One is to adhere to literalism in construing the claims and evolve a doctrine which supplements the claims by extending protection to equivalents. That is what the Americans have done. The other is to abandon literalism. That is what the House of Lords did in the *Catnic* case, where Lord Diplock said (at [1982] RPC 183, 242:

Both parties to this appeal have tended to treat “textual infringement” and infringement of the “pith and marrow” of an invention as if they were separate causes of action, the existence of the former to be determined as a matter of construction only and of the latter upon some broader principle of colourable evasion. There is, in my view, no such dichotomy; there is but a single cause of action and to treat it otherwise . . . is liable to lead to confusion.

43. The solution, said Lord Diplock, was to adopt a principle of construction which actually gave effect to what the person skilled in the art would have understood the patentee to be claiming.

44. Since the *Catnic* case we have article 69 which, as it seems to me, firmly shuts the door on any doctrine which extends protection outside the claims. I cannot say that I am sorry because the *Festo* litigation suggests, with all respect to the courts of the United States, that American patent litigants pay dearly for results which are no more just or predictable than could be achieved by simply reading the claims.

Is *Catnic* Consistent with the Protocol?

45. In *Improver Corp v Remington Consumer Products Ltd* [1989] RPC 69 the Court of Appeal said that Lord Diplock’s speech in *Catnic* advocated the same approach to construction as is required by the Protocol. (See also *Southco Inc v Dzus Fastener Europe Ltd* [1992] RPC 299.) But in *PLG Research Ltd v Ardon International Ltd* [1995] RPC 287, 309 Millett LJ said:

Lord Diplock was expounding the common law approach to the construction of a patent. This has been replaced by the approach laid down by the Protocol. If the two approaches are the same, reference to Lord Diplock’s formulation is unnecessary, while if they are different it is dangerous.

46. This echoes, perhaps consciously, the famous justification said to have been given by the Caliph Omar for burning the library of Alexandria: “If these writings of the Greeks agree with the Book of God, they are useless and need not be preserved: if they disagree, they are pernicious and ought to be destroyed”—a story which Gibbon dismissed as Christian propaganda. But I think that the Protocol can suffer no harm from a little explanation and I entirely agree with the masterly judgment of Aldous J in *Assidoman Multipack Ltd v The Mead Corporation* [1995] RPC 321, in which he explains why the *Catnic* approach accords with the Protocol.

47. The Protocol, as I have said, is a Protocol for the construction of article 69 and does not expressly lay down any principle for the construction of claims. It does say what principle should not be followed, namely the old English literalism, but otherwise it says only that one should not go outside the claims. It

does however say that the object is to combine a fair protection for the patentee with a reasonable degree of certainty for third parties. How is this to be achieved? The claims must be construed in a way which attempts, so far as is possible in an imperfect world, not to disappoint the reasonable expectations of either side. What principle of interpretation would give fair protection to the patentee? Surely, a principle which would give him the full extent of the monopoly which the person skilled in the art would think he was intending to claim. And what principle would provide a reasonable degree of protection for third parties? Surely again, a principle which would not give the patentee more than the full extent of the monopoly which the person skilled in the art would think that he was intending to claim. Indeed, any other principle would also be unfair to the patentee, because it would unreasonably expose the patent to claims of invalidity on grounds of anticipation or insufficiency.

48. The *Catnic* principle of construction is therefore in my opinion precisely in accordance with the Protocol. It is intended to give the patentee the full extent, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim. Of course it is easy to say this and sometimes more difficult to apply it in practice, although the difficulty should not be exaggerated. The vast majority of patent specifications are perfectly clear about the extent of the monopoly they claim. Disputes over them never come to court. In borderline cases, however, it does happen that an interpretation which strikes one person as fair and reasonable will strike another as unfair to the patentee or unreasonable for third parties. That degree of uncertainty is inherent in any rule which involves the construction of any document. It afflicts the whole of the law of contract, to say nothing of legislation. In principle it is without remedy, although I shall consider in a moment whether uncertainty can be alleviated by guidelines or a “structured” approach to construction.

Equivalents as a Guide to Construction

49. Although article 69 prevents equivalence from extending protection outside the claims, there is no reason why it cannot be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean. That is no more than common sense. It is also expressly provided by the new article 2 added to the Protocol by the Munich Act revising the EPC, dated 29 November 2000 (but which has not yet come into force):

For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.

50. In the *Catnic* case [1982] RPC 183, 243 Lord Diplock offered some observations on the relevance of equivalence to the question of construction:

The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.

The question, of course, does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of publication of the specification it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then-existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked.

51. In *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181, 189 I tried to summarise this guidance:

If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim (“a variant”) was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:

- (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?
- (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes?
- (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class.

52. These questions, which the Court of Appeal in *Wheatly v Drillsafe Ltd* [2001] RPC 133, 142 dubbed “the Protocol questions” have been used by English courts for the past fifteen years as a framework for deciding whether equivalents fall within the scope of the claims. On the whole, the judges appear to have been comfortable with the results, although some of the cases have exposed the limitations of the method. When speaking of the “*Catnic* principle” it is important to distinguish between, on the one hand, the principle of purposive construction which I have said gives effect to the requirements of the Protocol, and on the other hand, the guidelines for applying that principle to equivalents, which are encapsulated in the Protocol questions. The former is the bedrock of patent construction, universally applicable. The latter are only guidelines, more useful in some cases than in others. I am bound to say that the cases show a tendency for counsel to treat the Protocol questions as legal rules rather than guides which will in appropriate

cases help to decide what the skilled man would have understood the patentee to mean.

* * *

69. I shall say in a moment why I agree with the Court of Appeal, but I want first to emphasise a point I have already made about the use of the Protocol questions. The determination of the extent of protection conferred by a European patent is an examination in which there is only one compulsory question, namely that set by article 69 and its Protocol: what would a person skilled in the art have understood the patentee to have used the language of the claim to mean? Everything else, including the Protocol questions, is only guidance to a judge trying to answer that question. But there is no point in going through the motions of answering the Protocol questions when you cannot sensibly do so until you have construed the claim. In such a case—and the present is in my opinion such a case—they simply provide a formal justification for a conclusion which has already been reached on other grounds.

70. I agree with the Court of Appeal that the invention should normally be taken as having been claimed at the same level of generality as that at which it is defined in the claims. It would be unusual for the person skilled in the art to understand a specification to be claiming an invention at a higher level of generality than that chosen by the patentee. That means that once the judge had construed the claims as he did, he had answered the question of infringement. It could only cause confusion to try to answer the Protocol questions as well.

71. No doubt there will be patent lawyers who are dismayed at the notion that the Protocol questions do not provide an answer in every case. They may feel cast adrift on a sea of interpretative uncertainty. But that is the fate of all who have to understand what people mean by using language. The Protocol questions are useful in many cases, but they are not a substitute for trying to understand what the person skilled in the art would have understood the patentee to mean by the language of the claims.

72. This is perhaps an appropriate point at which to mention what may appear to be a difference between the German, United Kingdom and Netherlands approach to these questions. It used to be thought that despite article 69 and the Protocol, there remained serious differences between the approaches to construction of the United Kingdom on the one hand and Germany and the Netherlands on the other. And it is true that in the early years of the EPC, there was a view in the German and Netherlands courts that the Convention had made no difference and that the Protocol entitled the courts of Contracting States to go on deciding the extent of protection exactly as before. The position in the Netherlands is described by Professor Brinkhof in the article *Is there a European Doctrine of Equivalence?* (2002) IIC 911 to which I have already referred.

73. But I do not think that this is any longer true. The highest courts in both Germany (see *Batteriekastenschnur* [1989] GRUR 903, 904) and the Netherlands (see *Ciba-Geigy/Ot Optics* (1995) *Nederlandse Jurisprudentie* 39) have said that the effect of article 69 is to give the claims what the European Patent Office has called a “central role”: see *BAYER/Plant growth regulating agent* [1990] EPOR 257, 261. The Bundesgerichtshof said in the *Batterie-*

kastenschnur case that the claims are no longer merely a point of departure but the decisive basis (massgebliche Grundlage) for determining the extent of protection.

* * *

75. The German courts have their own guidelines for dealing with equivalents, which have some resemblance to the Protocol questions. In the “quintet” of cases before the Bundesgerichtshof (see, for example, *Kunststoffrohrteil* [2002] GRUR 511 and *Schneidemesser 1* [2003] ENPR 12 309) which concerned questions of whether figures or measurements in a claim allow some degree of approximation (and, if so, what degree), the court expressly said that its approach was similar to that adopted in *Catnic*. But there are differences from the Protocol questions which are lucidly explained by Dr Peter Meier-Beck (currently a judge of the 10th Senate) in a paper to be published in the *International Review of Intellectual Property and Competition Law* (IIC). For example, German judges do not ask whether a variant “works in the same way” but whether it solves the problem underlying the invention by means which have the same technical effect. That may be a better way of putting the question because it avoids the ambiguity illustrated by *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 159 over whether “works in the same way” involves an assumption that it works at all. On the other hand, as is illustrated by the present case, everything will depend upon what you regard as “the problem underlying the invention.” It seems to me, however, that the German courts are also approaching the question of equivalents with a view to answering the same ultimate question as that which I have suggested is raised by Article 69, namely what a person skilled in the art would have thought the patentee was using the language of the claim to mean.

The Decision of the Court of Appeal

* * *

77. . . . An invention is a practical product or process, not information about the natural world. That seems to me to accord with the social contract between the state and the inventor which underlies patent law. The state gives the inventor a monopoly in return for an immediate disclosure of all the information necessary to enable performance of the invention. That disclosure is not only to enable other people to perform the invention after the patent has expired. If that were all, the inventor might as well be allowed to keep it secret during the life of the patent. It is also to enable anyone to make immediate use of the information for any purpose which does not infringe the claims. The specifications of valid and subsisting patents are an important source of information for further research, as is abundantly shown by a reading of the sources cited in the specification for the patent in suit. Of course a patentee may in some cases be able to frame his claim to a product or process so broadly that in practice it will be impossible to use the information he has disclosed, even to develop important improvements, in a way which does not infringe. But it cannot be right to give him a monopoly of the use of the information as such.

New Technology

* * *

80. I do not dispute that a claim may, upon its proper construction, cover products or processes which involve the use of technology unknown at the time the claim was drafted. The question is whether the person skilled in the art would understand the description in a way which was sufficiently general to include the new technology. There is no difficulty in principle about construing general terms to include embodiments which were unknown at the time the document was written. One frequently does that in construing legislation, for example, by construing “carriage” in a 19th century statute to include a motor car. In such cases it is particularly important not to be too literal. It may be clear from the language, context and background that the patentee intended to refer in general terms to, for example, every way of achieving a certain result, even though he has used language which is in some respects inappropriate in relation to a new way of achieving that result: compare *Regina (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. In the present case, however, I agree with the Court of Appeal (and with the judge, before he came to apply the Protocol questions) that the man skilled in the art would not have understood the claim as sufficiently general to include gene activation. He would have understood it to be limited to the expression of an exogenous DNA sequence which coded for EPO.

81. The argument over whether the claim can include the new technology is linked to a dispute over the meaning of the second Protocol question. When one asks whether it would have been obvious to the person skilled in the art that the variant worked in the same way as the invention, does one assume that it works? Otherwise, in the case of a technology which was unknown at the priority date, the person skilled in the art would probably say that it was by no means obvious that it would work in the same way because it was not obvious that it would work at all.

82. Some might say, in answer to this question, that it depends on the nature of the invention. For example, in *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 159 the alleged invention was a second medical use for the known drug rapamycin, which was found to have an immuno-suppressive effect. The question was whether a claim to rapamycin should be construed as including derivatives of rapamycin. The evidence was that the person skilled in the art would be unable to say without experimentation that any particular derivative would have an immuno-suppressive effect. In applying the second Protocol question, it would have been absurd to ask whether, assuming that a derivative “worked” in the sense of having an immuno-suppressive effect, it worked “in the same way”. That would really be to beg the question. Neither the product nor the process was new: the whole point of the invention was the newly discovered immuno-suppressive effect.

83. On the other hand, in *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181 the invention was based upon the discovery that an arcuate rod with slits, when rotated at high speed, would take the hair off the skin by means of the opening and closing of the slits. The claim was to a rod in the form of an “helical spring” but the alleged infringer had found that an arcuate rod of vulcanised rubber with slits would do just as well. In answering the

second Protocol question, I said that it did not matter that it would not have been obvious to the person skilled in the art to substitute a rubber rod. The question was whether such a rod would work in the same way as an helical spring. I went on, however, to say (in answer to the third question) that “helical spring” could not be generalised to mean any arcuate rod with slits. It meant an helical spring.

84. So perhaps a better answer to the dispute over the second Protocol question is that new technology is another situation in which the Protocol questions may be unhelpful. On the other hand, if the claim can properly be construed in a way which is sufficiently general to include the new technology, the Protocol questions tend to answer themselves.

Comments

1. **Catnic, “*Purposive Construction*,” and *Equivalents*.** Lord Hoffmann was clear to distinguish between principles of claim construction and the “Protocol questions” relating to non-literal infringement. The *Catnic* principle of purposive construction gives effect to the protocol of Article 69, and is considered a “bedrock of patent construction.” In contrast, the protocol questions of *Improver* and *Catnic* are “only guidelines, more useful in some cases than in others.”

Regarding purposive construction, Lord Hoffmann was clear in his emphasis on the importance of objective interpretation. For him, “[t]here is no window into the mind of the patentee or the author of any other document.” Rather, “[c]onstruction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean.” This approach is similar to the American approach to claim construction and the central role of the person of ordinary skill in the art. One important difference, however, is the effect given to prosecution history estoppel, a prominent doctrine in American patent law. (See Comment 3, below.)

In addition, in discussing equivalents, Lord Hoffmann views Article 69 as “firmly shut[ting] the door on any doctrine which extends protection outside the claims.” He asks how can a rule be constructed that satisfies Article 69’s compromise, namely to “combine fair protection for the patentee with a reasonable degree of certainty for third parties.” As with claim construction, Lord Hoffmann turns to the skilled artisan in his discussion of non-literal infringement. Citing the *Catnic* principle and its accordance with the Protocol, he states the principle is “intended to give the patentee the full extent, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim.”

2. **Language and Context.** The meaning of language and context are extremely important to Lord Hoffmann. For example, in ¶ 29, he states “the attempt to treat the words of the claim as having meanings ‘in themselves’ and without regard to the context in which or the purpose for which they were used was always a highly artificial exercise.” And in ¶ 32, he notes,

What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of and background to the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience.

Of course, the importance of context in understanding linguistic meaning has relevance beyond the law. Indeed, Lord Hoffmann has noted elsewhere his views on interpretation are influenced by the philosophy of language and the work of John Searle and Ludwig Wittgenstein. *See, e.g.,* JOHN R. SEARLE, *THE CONSTRUCTION OF SOCIAL REALITY* (Free Press 1995) and LUDWIG WITTGENSTEIN, *PHILOSOPHICAL INVESTIGATIONS* (G.E.M. Anscombe trans., 1953).

3. ***“Life is Too Short” for the Use of Prosecution History in the U.K.*** Unlike the United States, the U.K. views prosecution history as having little value for purposes of claim interpretation or infringement analysis. According to *Kirin-Amgen*, “[t]here are good reasons” for discouraging the use of prosecution history, namely “the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide.” Indeed, under U.K. law, a party cannot make reference to the prosecution history unless the patentee puts it into evidence and relies on it.
4. ***Article 69 and U.K.-Germany Compromise.*** The U.K. has traditionally placed a great deal of emphasis on the patent claim, which was viewed as a self-contained device that was used “to limit and not to extend the monopoly.” In contrast, the German practice historically used the claim as a “point of departure in determining the extent of protection.” Article 69, and more accurately, its protocol, sought a compromise position between these two views. And, according to *Kirin-Amgen* and Lord Hoffmann, Germany (and The Netherlands) has now trended toward the traditional U.K. position that the claim plays a “central role.”
5. ***Penicillin and the U.K.-Germany Approach to the Value of Patents.*** The divergent views of the U.K. and Germany were not limited to claim interpretation and non-literal infringement. These competing views can be seen in how the countries viewed the value of patents during the first half of the 20th century, as reflected in the history of penicillin. Howard Florey of England and Ernst Chain of Germany (he moved to England when he was 27), two scientists instrumental to the development of penicillin at Oxford, debated whether they should seek a patent. Florey, steeped in the scientific culture of England, “believed it was odious for a scientist to claim a gain as his own.” But Chain was adamant that a patent should be obtained. As Eric Lax writes, “[f]rom his father’s and own experiences as a scientist in Germany, Chain knew firsthand how in the competitive world outside Britain patents leveraged economic advantage.” ERIC LAX, *THE MOLD IN DR. FLOREY’S COAT* 162 (2004). Lax continues that, “[o]ne of the many differences between the German and the British approaches to science in the early twentieth century was the importance of patents. In Germany a patent was a natural and valued part of scientific advance; in Britain it was a repugnant sign of commercialism.” *Id.* at 163. Much to the chagrin of

Chain, a decision was made at Oxford University not to seek patent protection. But Florey, Chain, and Alexander Fleming would go on to receive the Nobel Prize in 1945 for Physiology or Medicine. Consistent with the German view, patents also played an important role in Germany's dominance of the synthetic dye industry in the late 19th and early 20th centuries at the expense of British and American companies. See JOHANN PETER MURMANN, KNOWLEDGE AND COMPETITIVE ADVANTAGE: THE COEVOLUTION OF FIRMS, TECHNOLOGY, AND NATIONAL INSTITUTIONS 86-93, 179-92 (2003).

4. Indirect Infringement

Indirect infringement has, in recent years, assumed great importance in copyright law, particularly in the context of peer-to-peer networks, and it was at the heart of the famous "Betamax case." See *Sony Corp. v. Universal City Studio, Inc.*, 464 U.S. 417 (1984). But indirect infringement is equally important in patent law and has a richer historical presence. (Indeed, *Sony* relied on patent law's indirect infringement jurisprudence.) The doctrine of indirect infringement allows patentees to capture actors who, while not directly infringing, aid and abet the direct infringer by, for example, supplying an individual component of a patent invention (contributing to infringement) or providing instruction that facilitates direct infringement (inducing infringement). The rationale for the doctrine of indirect infringement was aptly described by the Supreme Court in *Dawson Chemical Co. v. Rohm and Haas Company*:

[It] exists to protect patent rights from subversion by those who, without directly infringing the patent themselves, engage in acts designed to facilitate infringement by others. This protection is of particular importance in situations . . . where enforcement against direct infringers would be difficult, and where the technicalities of patent law make it relatively easy to profit from another's invention without risking a charge of direct infringement.

448 F.3d 176, 188 (1980).

The statutory authority for inducement and contributory infringement is in § 271(b) and (c), respectively. In addition to these sections, there are common law requirements that must be satisfied. The principal case, *DSU*, explores both the statutory and common law requirements of inducement and contributory infringement.

DSU MEDICAL CORP. v. JMS CO. LTD

471 F.3d 1293 (Fed. Cir. 2006)

RADER, Circuit Judge.

DSU Medical Corporation (DSU) and Medisystems Corporation (MDS) (collectively DSU) sued JMS Company, Limited (JMS) and JMS North America (collectively JMS) and ITL Corporation Pty, Limited (ITL) for patent infringement, inducement to infringe, and contributory infringement of United States Patent Nos. 5,112,311 ('311) and 5,266,072 ('072). After a six-week jury trial produced a unanimous verdict, the United States District Court for the Northern District of California . . . entered a final judgment, pursuant

to the unanimous verdict, of infringement against JMS and JMS North American on claims 49, 53, and 54 of the '311 patent, and of non-infringement for ITL. Finding no reversible error, this court affirms.

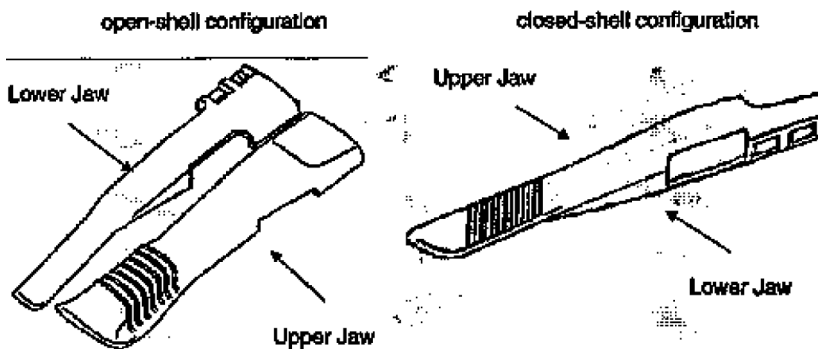
I.

The '311 and '072 patents claim a guarded, winged-needle assembly. The invention reduces the risk of accidental needle-stick injuries. Needle puncture wounds can transmit blood-borne diseases such as Hepatitis B and AIDS. The '311 and '072 patented inventions effectively guard standard winged-needle-sets to prevent needle-stick injuries.

The '311 patent claims a "slotted, locking guard for shielding a needle, and a winged needle assembly including a needle, a winged needle hub, and a slotted, locking guard." This invention includes both "[a] slotted guard for locking a needle in a shielded position as the needle is removed from the patient," and "a guarded winged needle assembly . . . slidably mounted within the guard."

Mr. David Utterberg, a co-inventor of the '311 patent, owns DSU and MDS. DSU owns the '311 patent; MDS has an exclusive license to make and sell the '311 invention for large-bore needles, including Arterial-Venous Fistula (AVF) sets used for dialysis and aphaeresis. MDS markets AVF needles under the brand names "MasterGuard" and "PointGuard."

The alleged infringing device, made by ITL (an Australian company) sells under the name Platypus TM Needle Guard (Platypus). ITL manufactures the Platypus in Malaysia and Singapore. The Platypus needle guard is a "stand-alone" product: a small configured piece of plastic. This plastic guard structure is not attached to any other device. In other words, the Platypus does not include a needle, but only a sheathing structure. Some claims of the '311 patent recite both a slotted guard and a guarded winged needle assembly. Before use, the Platypus resembles an open clamshell (open-shell configuration). During use, the halves of the clam shell close to form the needle guard (closed-shell configuration). The following illustration shows the Platypus in open-and closed-shell configuration:



The Platypus has an upper and a lower "jaw." When closed, the upper jaw extends around and overlaps the inner, lower jaw. During use, a medical technician closes the Platypus and locks it around tubing connected to the winged needle assembly. When the technician removes the needle from a patient, the

worker slides the guard down the tube until the needle assembly's wings meet and pry the jaws apart. The wings and their attached needle assembly slide into and through the guard, forcing the jaws ever wider as the wings make their way into a notched opening at the guard's back. Ultimately the wings slide into the rear opening. At that point, the jaws close around the used needle.

JMS is a large Japanese medical supply business that competes with MDS in the United States market. Beginning in June 1999, JMS purchased Platypus needle guards from ITL, entering into an agreement to distribute the Platypus worldwide (the Supply Agreement). Under the Supply Agreement, JMS bought open-shell configuration Platypus guard units from ITL in Singapore and Malaysia. JMS generally closed the Platypus guards around needle sets before distributing them to customers.

DSU alleges that the Platypus infringes the '311 patent. DSU also alleges that JMS and ITL contributed to and induced each other's infringement. JMS sought to sell ITL's infringing Platypus until it could produce its substitute non-infringing product, the WingEater. ITL offered to supply its infringing Platypus.

II.

The trial court identified the crux of the dispute over "slot" as "whether . . . the slots for the wings should have defined widths closely approximating the wings' thickness." If "slot" limits the size of the opening to accommodate the "minor" thickness of the '311 patent's wings, the Platypus would not infringe because its jaws accommodate any thickness. On the other hand, if "slot" contains no thickness limitation, the Platypus would infringe because it opens to receive a wing of any size.

The claim language recites only "slot." Thus, the claim itself does not incorporate any thickness limitation. Moreover, the specification provided no size limitation on the opening. The trial court found that "as a matter of law, every reasonable jury would find that there is a slot in the [Platypus] closed-shell configuration." Therefore, the trial court held that when sold in the United States in its "closed-shell" configuration, the Platypus literally infringed claims 46-47, 49, and 52-53 of '311 patent, when closed over the tubing of a needle-set.

Viewing the evidence in the light most favorable to the nonmoving party, this court holds that the trial court correctly concluded that the closed-shell configuration of the Platypus does have a slot. As applied to the Platypus, its slot is an opening in a needle guard capable of receiving a wing that projects through the opening. Further, the slot has both an upper edge and a lower edge defined by the sidewall of the guard. The Platypus's slot is also sized relative to the wing and can accommodate the needle wing as it moves through the length of the slot. Furthermore, the Platypus contains the other limitations of claims 46-47, 49, and 52-53 of the '311 patent. Therefore, in its closed-shell configuration, the Platypus does infringe claims 46-47, 49, and 52-53 of the '311 patent. This court affirms the trial court's summary judgment ruling.

III.

The jury found that JMS North America and JMS directly and contributorily infringed, and that JMS additionally induced JMS North America to infringe. However, the jury returned a verdict of non-infringement in favor of ITL. The jury entered a verdict finding that ITL did not engage in con-

tributory infringement or inducement to infringe. The trial court denied DSU's motion for new trial on the jury's verdict that ITL did not contributorily infringe or induce infringement. This court reviews a denial of a motion for a new trial after a jury trial for an abuse of discretion.

A.

On appeal, DSU argues that ITL committed contributory infringement. According to DSU, the Platypus, which ITL sold to JMS, had no substantial noninfringing use. Therefore, DSU argues, ITL committed contributory infringement as a matter of law. ITL responds that it made and sold "most Platypus guards" outside of the United States. ITL also contends that the record contains no evidence that the Platypus was used in an infringing manner in the United States.

The Platypus sets that came into the United States fall within three categories:

- (1) JMS imported into the United States approximately 30 million Platypus guards that, prior to importation into the United States, it had already assembled into the closed-shell configuration, combined with needle sets. These units accounted for the vast majority of Platypus sales in the United States.
- (2) Fresenius purchased approximately 3.5 million Platypus guards, in the open-shell configuration without needle sets. ITL billed JMS for the shipments and shipped them to Fresenius in the United States at JMS's request. Fresenius ultimately decided that guards without needle sets did not meet FDA regulations, and it returned about 3 million.
- (3) ITL sent approximately 15,000 Platypus in the open-shell configuration to JMS in San Francisco. DSU introduced no evidence that those units were ever put into the closed-shell configuration in the United States.

Additionally, the record contained evidence that when instructed to do so by JMS, ITL would ship Platypus guard units F.O.B. into the United States. The record also shows, however, that ITL only sold the Platypus in its open-shell configuration.

Therefore, this court must determine whether the jury's verdict is against the clear weight of the evidence. Under § 271(c):

[w]hoever offers to sell or sells *within the United States* . . . a component of a patented machine, manufacture, combination or composition . . . constituting a material part of the invention, *knowing* the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce *suitable for substantial noninfringing use*, shall be liable as a contributory infringer.

35 U.S.C. § 271(c) (2000) (emphases added). In discussing 35 U.S.C. § 271(c), the Supreme Court stated:

One who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of his acts; he will be presumed to intend that they shall be used in the combination of the patent.

Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd., 545 U.S. 913 (2005). In addition, the patentee always has the burden to show direct infringement for

each instance of indirect infringement. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993) (“Liability for either active inducement of infringement or contributory infringement is dependent upon the existence of direct infringement.”). Thus, to prevail on contributory infringement, DSU must have shown that ITL made and sold the Platypus, that the Platypus has no substantial non-infringing uses in its closed-shell configuration, that ITL engaged in conduct (made sales) within the United States that contributed to another’s direct infringement, and that JMS engaged in an act of direct infringement on those sales that ITL made in the United States.

The trial court properly applied these legal principles. The trial court determined that the record showed that ITL supplied the Platypus, that the Platypus had no substantial non-infringing uses in its closed-shell configuration, and that ITL intended to make the Platypus that resulted in the potential for contributory infringement as a product designed for use in the patented combination. In fact, even beyond the minimal intent requirement for contributory infringement, ITL acted with the knowledge of the ’311 patent and knowledge that the component was especially made or adapted for use in an infringing manner. However, the district court denied the motion for a new trial because the record does not show that “the alleged contributory act ha[d] a direct nexus to a specific act of direct infringement.” In denying the new trial, the court stated:

And while it is true that Plaintiffs introduced evidence that “ITL sold and shipped millions of ‘stand alone’ guards directly to United States customers, including JMS [North America] and end-users like Fresenius,” *there was no direct evidence* at trial establishing that these guards were actually closed and used as an act of direct infringement in the United States.

Id., slip op. at 26.

Upon review of the record, this court perceives, as well, an absence of evidence of direct infringement to which ITL contributed *in* the United States. Under the terms of the ’311 patent, the Platypus only infringes in the closed-shell configuration. When open, the Platypus, for instance, lacks a “slot” as well as other claimed features. ITL only contributed to placing the Platypus into the closed-shell configuration in Malaysia (category 1, above); not in the United States. Section 271(c) has a territorial limitation requiring contributory acts to occur in the United States. Furthermore, this court cannot reverse a jury verdict of non-infringement on mere inferences that the Platypus guard units sold in the United States (i.e., the open-shell configuration in categories 2 and 3, above) were put into the infringing closed-shell configuration. The record does not show that the Platypus guards ITL shipped into the United States in the open-shell configuration were ever put into an infringing configuration, i.e., closed-shell. On categories 2 and 3, above, the record contains no evidence of direct infringement, i.e., that the open-shell Platypus guards imported by ITL were sold or used in their closed-shell configuration. As a result, the trial court did not abuse its discretion in denying DSU’s motion for new trial on ITL’s contributory infringement.

On the issue of induced infringement, DSU argues that ITL induced infringement by inducing JMS to sell the closed-shell configuration in the United States. The district court denied DSU’s motion for a new trial on the ground that, although JMS directly infringed, ITL did not intend JMS to infringe.

B. Resolution of Conflicting Precedent

Section III. B., only, is considered en banc.

Opinion for the en banc court filed by Circuit Judge RADER.

This court addresses Part III. B., of this opinion en banc. This section addresses, in the context of induced infringement, “the required intent . . . to induce the specific acts of [infringement] or additionally to cause an infringement.” *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 n. 4 (Fed. Cir. 2005) This section clarifies that intent requirement by holding en banc that, as was stated in *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990), “[t]he plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.” The requirement that the alleged infringer knew or should have known his actions would induce actual infringement necessarily includes the requirement that he or she knew of the patent.

DSU claims the district court improperly instructed the jury on the state of mind necessary to prove inducement to infringe under 35 U.S.C. § 271(b). This court reviews the legal sufficiency of jury instructions on an issue of patent law without deference to the district court.

Under section 271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they “actively and *knowingly* aid[ed] and abett[ed] another’s direct infringement.” *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (emphasis in original). However, “knowledge of the acts alleged to constitute infringement” is not enough. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003). The “mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.” *Id.* at 1364.

DSU asked the court to instruct the jury, purportedly in accordance with *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464 (Fed. Cir. 1990), that to induce infringement, the inducer need only intend to cause the *acts* of the third party that constitute direct infringement. The trial court gave the following instruction to the jury:

In order to induce infringement, there must first be an act of direct infringement and proof that the defendant knowingly induced infringement with the intent to encourage the infringement. The defendant must have intended to cause the acts that constitute the direct infringement and must have known or should have known that [sic] its action would cause the direct infringement. Unlike direct infringement, which must take place within the United States, induced infringement does not require any activity by the indirect infringer in this country, as long as the direct infringement occurs here.

Thus, the court charged the jury in accordance with *Manville*. The statute does not define whether the purported infringer must intend to induce the infringement or whether the purported infringer must merely intend to engage in the acts that induce the infringement regardless of whether it knows it is causing another to infringe. DSU complains that the instruction is incorrect because it requires that the inducer possess specific intent to encourage

another's infringement, and not merely that the inducer had knowledge of the acts alleged to constitute infringement.

In *Grokster*, which was a copyright case, the Supreme Court cited with approval this court's decision in *Water Technologies* when it discussed inducement of infringement, stating:

The rule on inducement of infringement as developed in the early cases is no different today. Evidence of "active steps . . . taken to encourage direct infringement," such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.

Grokster, 125 S. Ct. at 2779. As a result, if an entity offers a product with the object of promoting its use to infringe, as shown by clear expression or other affirmative steps taken to foster infringement, it is then liable for the resulting acts of infringement by third parties. *Id.* at 2780. "The inducement rule . . . premises liability on purposeful, culpable expression and conduct. . . ." *Id.*

Grokster, thus, validates this court's articulation of the state of mind requirement for inducement. In *Manville*, this court held that the "alleged infringer must be shown . . . to have *knowingly* induced infringement," 917 F.2d at 553, not merely knowingly induced the *acts* that constitute direct infringement. This court explained its "knowing" requirement:

It must be established that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.

Id. at 553. In *Water Technologies*, also cited with approval by the Supreme Court, this court clarified: "While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." 850 F.2d at 668. Although this court stated "that proof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement," *Hewlett-Packard*, 909 F.2d at 1469, *Grokster* has clarified that the intent requirement for inducement requires more than just intent to cause the acts that produce direct infringement. Beyond that threshold knowledge, the inducer must have an affirmative intent to cause direct infringement. In the words of a recent decision, inducement requires "that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *MEMC Elec.*, 420 F.3d at 1378 (Fed. Cir. 2005) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)). Accordingly, inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities. Accordingly, the district court correctly instructed the jury in this case.

C.

The district court denied DSU's motion for a new trial on the issue of inducement to infringe. This court reviews a denial of a motion for a new trial

after a jury trial for abuse of discretion, affirming on any basis that supports the verdict. In denying the motion for new trial, the trial court stated:

Fundamental principles of law hold that it is up to the jury to make determinations of witness credibility, to decide the existence of any factual inferences, and to determine the weight to be attributed to any direct or indirect evidence. Although Plaintiffs introduced circumstantial evidence which permitted inferences of ITL's intentions, it is up to the Jury to decide whether or not to draw any inference and to consider the weight of any such evidence. Assessing competing evidence is what the law asks juries to do, and the Court declines to take over this fundamental role of the Jury.

The jury heard evidence about the commercial transactions between ITL and JMS, including JMS's intention to sell ITL's Platypus to Fresenius until JMS could get its own WingEater approved by the Food and Drug Administration (FDA) and ready for market. The jury also heard evidence that Mr. Utterberg's lawyer informed ITL in January 1997 that the Platypus infringed the '311 patent. Additionally, the jury learned that ITL contacted an Australian attorney, who concluded that its Platypus would not infringe. JMS and ITL then also obtained letters from U.S. patent counsel advising that the Platypus did not infringe. Mr. William Mobbs, one of the owners of ITL who had participated in the design of the Platypus, testified that ITL had no intent to infringe the '311 patent.

Thus, on this record, the jury was well within the law to conclude that ITL did not induce JMS to infringe by purposefully and culpably encouraging JMS's infringement. To the contrary, the record contains evidence that ITL did not believe its Platypus infringed. Therefore, it had no intent to infringe. Accordingly, the record supports the jury's verdict based on the evidence showing a lack of the necessary specific intent. The trial court certainly did not abuse its discretion.

Comments

1. **Contributory Infringement.** The *DSU* case identified four requirements that must obtain before contributory infringement can be found. First, the alleged contributory infringer must have made or sold the component in question. In *DSU*, the patentee had to show ITL made and sold the Platypus. Second, the component (*e.g.*, Platypus) must have no substantial non-infringing uses (the non-staple article requirement). Third, the alleged contributory infringer had knowledge of the non-staple nature of the component. (See Comment 3, below.) And fourth, the alleged contributory infringer (*e.g.*, ITL) engaged in conduct (*e.g.*, sales) within the United States that contributed to another's direct infringement. Direct infringement is a precondition for a finding of indirect infringement.
2. **The Non-Staple Article Requirement.** This requirement goes to the heart of contributory infringement. There can be no contributory infringement if an article is capable of substantial non-infringing use. This requirement is made express in § 271(c), which states the article must be "especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use." The sell of a non-staple article is tantamount to direct infringement because the article has no other plausible use.

In *C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670 (Fed. Cir. 1990), the patentee's contributory infringement claim failed because of the staple article doctrine. In *Bard*, the patentee held a patent on a method for using a catheter in coronary angioplasty. The patentee alleged the defendant's (ACS) sale of catheters for use by surgeons was an act of contributory infringement. The court disagreed because there were three possible ways to use the ACS catheter, only one of which resulted in direct infringement. The catheters were staple articles, capable of substantial non-infringing use. The court stated that "[w]hen a charge of contributory infringement is predicated entirely on the sale of an article of commerce that is used by the purchaser to infringe a patent, the public interest in access to that article is necessarily implicated." In other words, the patentee should not be permitted to impede access to articles that have substantial non-infringing use.

The non-staple requirement was also at issue in *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980), but in the context of the relationship between contributory infringement under § 271(c) and patent misuse under § 271(d). In *Dawson*, Rohm & Haas owned a patent on a method for applying propanil, which was not subject to patent protection. Rohm & Haas agreed to license its patent only to those who also purchased propanil from Rohm & Haas. Propanil was commercially available from other sources, but formed a "material part of the claimed invention" and had "no use except through practice of the patented method." In other words, propanil was a non-staple article, not subject to substantial non-infringing uses. Dawson asserted Rohm & Haas was misusing the patent by conditioning a license on the purchase of propanil. The Court, in a lengthy opinion, disagreed with Dawson based on propanil's non-staple status. According to the court,

The provisions of § 271(d) effectively confer upon the patentee, as a lawful adjunct of his patent rights, a limited power to exclude others from competition in nonstaple goods. A patentee may sell a nonstaple article himself while enjoining others from marketing that same good without his authorization. . . . To be sure, the sum effect of Rohm & Haas' actions is to suppress competition in the market for an unpatented commodity. But . . . this conduct is no different from that which the statute [§ 271(c)] expressly protects. . . . If [Dawson's] argument were accepted, it would force patentees either to grant licenses or to forfeit their statutory protection against contributory infringement.

Id. at 201, 215. (The doctrine of patent misuse is explored in Chapter 8.)

3. **Contributory Infringement's Knowledge Requirement.** Section 271(c) has a knowledge requirement: "[w]hoever offers to sell or sells . . . *knowing* the same to be especially made or especially adapted for use in an infringement of such patent." 35 U.S.C. § 271(c) (2000) (emphases added). Does this requirement mean the alleged infringer intended to make the article that led to direct infringement, or knew of the patent's existence, or had knowledge that the article would be used to infringe? In discussing this requirement, the *DSU* court quoted the Supreme Court's *Grokster* decision relating to peer-to-peer networks:

One who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of

his acts; he will be presumed to intend that they shall be used in the combination of the patent.

Thus, if one makes a non-staple article, knowledge of the article's use to infringe will be presumed, apparently because the article has no other substantial commercial use. Moreover, the *DSU* court stated the district court found that ITL not only intended to make the Platypus that resulted in the potential for contributory infringement, but found that "even beyond the minimal intent requirement for contributory infringement, ITL acted with the knowledge of the '311 patent and knowledge that the component was especially made or adapted for use in an infringing manner." This language suggest knowledge of the patent and use of the article for infringement is not required under § 271(c).

4. **Inducement's Knowledge Requirement.** The nature of the knowledge requirement for active inducement is not without confusion. For instance, in *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1377 (Fed. Cir. 2004), the court conceded "there is a lack of clarity concerning whether the required intent must be merely to induce the specific acts or additionally to cause an infringement." This uncertainly no doubt played a role in the *DSU* court's willingness to sit en banc on this issue.

The *DSU* court concluded inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities. In quoting *Manville*, the "plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements." In other words, "inducement requires 'that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.'" *MEMC Elec.*, 420 F.3d at 1378 (Fed. Cir. 2005) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)).

5. **No Geographic Limitation in § 271(b).** Unlike § 271(c), the active inducement statutory provision does not include a geographic limitation. This means that § 271(b) can apply to inducement activity in the U.S. and abroad. Section 271(c), in contrast, is limited to contributory infringement activity within the United States.

5. Infringement of Means-Plus-Function Claims

Under § 112, ¶ 6, patent claims may be drafted in means-plus-function format—a means for performing a particular function (*e.g.*, means for attaching A to B). This format permits patentees to draft claims using functional language while disclosing structural aspects—that correspond to the "means"—in the specification. A principal advantage of a means-plus-function claim is efficiency because one does not need to recite in the claim every possible means of achieving the claimed function. Although courts have taken a narrow interpretation of means-plus-function claims, they remain useful, particularly for software and electrical inventions. Software programs are typically subdivided into modules each having a specific function that a means-plus-function claim can capture. Electrical (or electronic) devices usually possess functional circuitry that can be constructed in numerous ways and with myriad components, which can be set forth in the specification.

The infringement analysis for means-plus-function claims can be confusing. Infringement of a means-plus-function claim is deemed literal infringement, but § 112, ¶ 6 provides a patentee to capture not only the means disclosed in the specification, but “equivalents thereof.” The courts use the term “literal” infringement because the accused product must perform the identical function of the claim, and “equivalents” are limited to the disclosed structure, not to all possible structures or acts that might perform the claimed function. Identity of function is a threshold requirement, meaning that an analysis of structural equivalence is conditioned on a finding of identical function. Infringement of means-plus-function claims is explored in *Odetics*, the principal case.

ODETICS, INC. v. STORAGE TECHNOLOGY CORP.

185 F.3d 1259 (Fed. Cir. 1999)

CLEVENGER, Circuit Judge.

On March 27, 1998, a jury impaneled in the United States District Court for the Eastern District of Virginia concluded that automated storage library systems manufactured and sold by Storage Technology Corporation, and used by Visa International Service Association, Inc., Visa USA, Inc., and Crestar Bank, Inc. (collectively, “STK”) literally infringed United States Patent No. 4,779,151 (“the ’151 patent”) owned by the plaintiff, Odetics, Inc. (“Odetics”). After initially denying STK’s renewed motion for Judgment as a Matter of Law (“JMOL”), the district court sua sponte reconsidered, granting the JMOL and ordering that judgment be entered in favor of STK. The district court deemed its reconsidered decision to be “mandat[ed]” by “the analytical framework established” by this court’s opinion in *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, Odetics appeals the reconsideration judgment.

Because *Chiuminatta* did not mark a change in the proper infringement analysis under § 112, ¶ 6, and the jury’s verdict is supported by substantial evidence, we reverse the grant of JMOL and order the jury’s verdict reinstated.

I

This patent infringement action concerns robotic tape storage systems, which are typically used to store, organize, and retrieve videotapes or computer data tapes. The storage systems generally consist of a large, generally cylindrical housing with a pivoting retrieval mechanism, such as a robotic arm, located in the center of the housing. Acting on commands to retrieve certain tapes, the robotic arm can selectively grip the desired tape, removing it from its storage shelf and placing it on another shelf or in a tape player/recorder. These systems are highly automated and are especially useful in situations where large quantities of data must be easily and quickly retrieved from storage.

A

At issue are claims 9 and 14 of the ’151 patent. Claim 9 reads as follows (emphasis supplied to highlight disputed limitation):

9. A tape cassette handling system comprising:

a plurality of tape transports;

a housing including a cassette storage library having a plurality of storage bins and at least one cassette access opening for receiving cassettes to be moved to the storage bins or to the tape transports, or for receiving cassettes to be removed from the library or from the tape transports;

a *rotary means* rotatably mounted within the library adjacent the access opening for providing access to the storage library, the rotary means having

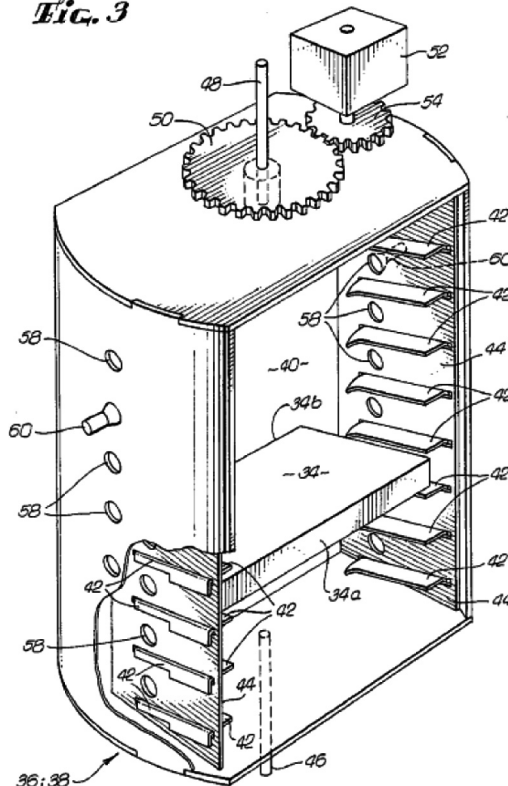
one or more holding bins each having an opening for receiving a cassette, wherein the rotary means is rotatable from a first position in which the opening of at least one holding bin is accessible from outside of the housing to a second position in which the opening of at least one holding bin is accessible from inside of the housing; and

cassette manipulator means located within the housing for selectively moving cassettes between the rotary means, said storage bins and said tape transports.

Claim 14 is identical in all relevant aspects.

The critical “rotary means” claim element is in means-plus-function form, requiring that it “be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” 35 U.S.C. § 112, ¶ 6. In *Odetics II*, this court held that the structure corresponding to the “rotary means” element was “the components that receive the force and rotate as a result of that force (*i.e.*, the rod, gear, and rotary loading and loading mechanisms).” This court noted that this structure could be seen in Fig. 3 of the ’151 patent, except that the structure did not include the motor (52) or its gear (54).

Fig. 3



Thus, the structure corresponding to the “rotary means” element, as depicted in Fig. 3 of the ’151 patent, is a set of tape holders or bins, a rod providing the axis of rotation, and a gear capable of receiving a force sufficient to cause the structure to accomplish the claimed “rotary” function.

STK manufactures and sells Library Storage Modules (“libraries”) to companies, such as Visa and Crestar, that require large quantities of automated data storage. Library systems sold by STK are scaleable: that is, additional libraries may be added to increase the amount of storage space. When libraries are added, STK uses a device known as a “pass-thru port” to link the libraries, allowing data tapes to be passed from library to library. The pass-thru ports bridge the gaps between the libraries using a “bin array”—a box-like set of tape slots or holders—that slides linearly along a short track. As the bin arrays move from library to library, they rotate to allow tapes to be manipulated from within the library housings. This rotation is accomplished by the use of “cam followers,” or pins, that are affixed to the bottom of the bin array. As a bin array moves along its track, the pins come into contact with angled structures, or “cams,” that exert force against the pins, causing the bin array to rotate about a rod that forms its axis. The “bin array” in the accused devices, then, comprises a set of tape holders or bins, a rod, and pins.

* * *

II

* * *

A

Because the district court explicitly premised its grant of STK’s JMOL motion on the “mandate” resulting from its review of the *Chiuminatta* opinion, we must first decide whether, in the words of the district court, *Chiuminatta* “announced a significant change in the proper mode of infringement analysis under § 112, ¶ 6.” Indeed, the crux of the district court’s reading of *Chiuminatta* is that statutory equivalence under § 112, ¶ 6 requires “component by component” equivalence between the relevant structure identified in the patent and the portion of the accused device asserted to be structurally equivalent. This reading of *Chiuminatta* misapprehends § 112, ¶ 6 infringement analysis and is therefore incorrect.

A claim limitation written in means-plus-function form, reciting a function to be performed rather than definite structure, is subject to the requirements of 35 U.S.C. § 112, ¶ 6. As such, the limitation must be construed “to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” *See* 35 U.S.C. § 112, ¶ 6. Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification. Functional identity and either structural identity or equivalence are *both* necessary.

Structural equivalence under § 112, ¶ 6 is, as noted by the Supreme Court, “an application of the doctrine of equivalents . . . in a restrictive role.” *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). As such, “their tests for equivalence are closely related,” *Chiuminatta*, 145 F.3d at 1310, involving “similar analyses of insubstantiality of differences.” *Al-Site* [v. VSI

Int'l, Inc.], 174 F.3d at 1321 (quoting *Chiuminatta*, 145 F.3d at 1310. In the doctrine of equivalents context, the following test is often used: if the “function, way, or result” of the assertedly substitute structure is substantially different from that described by the claim limitation, equivalence is not established. As we have noted, this tripartite test developed for the doctrine of equivalents is not wholly transferable to the § 112, ¶ 6 statutory equivalence context. Instead, the statutory equivalence analysis, while rooted in similar concepts of insubstantial differences as its doctrine of equivalents counterpart, is narrower. This is because, under § 112, ¶ 6 equivalence, functional *identity* is required; thus the equivalence (indeed, identity) of the “function” of the assertedly substitute structure, material, or acts must be first established in order to reach the statutory equivalence analysis. See 35 U.S.C. § 112, ¶ 6. The content of the test for insubstantial differences under § 112, ¶ 6 thus reduces to “way” and “result.” That is, the statutory equivalence analysis requires a determination of whether the “way” the assertedly substitute structure performs the claimed function, and the “result” of that performance, is substantially different from the “way” the claimed function is performed by the “corresponding structure, acts, or materials described in the specification,” or its “result.” Structural equivalence under § 112, ¶ 6 is met only if the differences are insubstantial; that is, if the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification. See 35 U.S.C. § 112, ¶ 6 (means-plus function claim literally covers “the corresponding structure, material, or acts described in the specification *and equivalents thereof*” (emphasis supplied)).

The similar analysis of equivalents under § 112, ¶ 6 and the doctrine of equivalents does not, however, lead to the conclusion that *Pennwalt* and *Warner-Jenkinson* command a component-by-component analysis of structural equivalence under § 112, ¶ 6. It is of course axiomatic that “[e]ach element contained in a patent claim is deemed material to determining the scope of the patented invention.” *Warner-Jenkinson*, 520 U.S. at 29. Thus a claim limitation written in § 112, ¶ 6 form, like all claim limitations, must be met, literally or equivalently, for infringement to lie. As we noted above, such a limitation is literally met by structure, materials, or acts in the accused device that perform the claimed function in substantially the same way to achieve substantially the same result. The individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations. Rather, the claim limitation is the overall structure corresponding to the claimed function. This is why structures with different numbers of parts may still be equivalent under § 112, ¶ 6, thereby meeting the claim limitation. See, e.g., *Al-Site*, 174 F.3d at 1321-22 (upholding jury verdict of § 112, ¶ 6 equivalence between “a mechanically-fastened loop . . . includ[ing] either the rivet fastener or the button and hole fastener” and “holes in the arms [of an eye-glass hanger tag]”). The appropriate degree of specificity is provided by the statute itself; the relevant structure is that which “corresponds” to the claimed function. See, e.g., *Chiuminatta*, 145 F.3d at 1308-09 (structure “unrelated to the recited function” disclosed in the patent is irrelevant to § 112, ¶ 6). Further deconstruction or parsing is incorrect.

Rather than altering this well-worn path of the law, *Chiuminatta* confirms it. After determining that the structure corresponding to the “means . . . for

supporting the surface of the concrete” was a “skid plate” or “generally rectangular strip of metal having rounded ends between which is a flat piece,” the court proceeded to analyze the differences between the skid plate and the assertedly equivalent structure in the accused device, a set of soft rubber wheels. In finding “not insubstantial” differences between the wheels and skid plate, the court noted that the *way* the structures performed the claimed function were substantially different: while the wheels roll or rotate across the surface, the skid plate “skid[s] as the saw moves across the concrete and thus ha[s] a different impact on the concrete.” At no point did the *Chiuminatta* court deconstruct the skid plate structure into component parts in order to analyze equivalence. Instead, *Chiuminatta* simply applied the well-established law of insubstantial differences to the particular structures at issue. The component-by-component analysis used by the district court finds no support in the law.

B

Although we have determined that the premise of the district court’s reconsidered grant of JMOL is incorrect, our inquiry is not at an end. STK argues that the grant of JMOL can be upheld on alternative grounds. We disagree.

First, STK contends that the jury’s verdict of infringement was unsupported by substantial evidence. Whether an accused device infringes a § 112, ¶ 6 claim as an equivalent is a question of fact. STK asserts that Odetics did not present substantial evidence that the “bin array” of the accused device is equivalent to the ’151 patent’s “rotary means” claim element and corresponding structure in the specification. A review of the record, however, overwhelmingly proves otherwise. [T]he jury was instructed that “a rotary means rotatably mounted” could be what is depicted in Figure 3 [of the ’151 patent], less elements 52 and 54, or the equivalent. In other words, [the rotary means structure is] depicted in Figure 3, less elements 52 and 54, that figure, or the equivalent.” [T]he district court noted to the jury that the structure corresponding to the claimed function was “rotatable” as a result of receiving a rotary force. The “bin array” in the accused device contains a rod, bins for holding the cassettes, and pins or “cam followers” protruding from the bottom of the cassette bin. Odetics’s theory of equivalence was to point out the parallels between the claimed and accused structures, noting that rotation is accomplished in the ’151 patent by exerting force against the teeth of the gear, thereby turning the bin about the rod, and that rotation is accomplished in the accused device by exerting force against the cam followers, also turning the bin about the rod. Thus Odetics argued to the jury that the structures were equivalent “rotary means” within the meaning of § 112, ¶ 6. To prove its case, Odetics introduced documentary and testimonial evidence of structural equivalence, including diagrams, claim charts, computer animation sequences, and the opinions of its expert, Dr. John M. McCarthy, whom the parties agree is a specialist in robotics. Dr. McCarthy specifically and clearly testified — on at least eight occasions during the trial — that the “rotary means” structure was equivalent to the “bin array” in the accused devices and why this was so. Indeed, he described the “bin array” structure in the accused devices and the rotary means structure in the ’151 patent as “nearly identical,” possible to “match directly,” “completely equivalent,” having “almost identical correspondence,” “literally equivalent,” and that they “correspond so completely, that I could match every element one-for-one.” When pressed to describe specifically why the presence of pins

or cam followers in the accused devices rather than the gear depicted in the '151 patent did not affect his equivalence analysis, Dr. McCarthy first noted that “you can push on a pin as well as you can push on a gear tooth. . . . For this application, this is completely equivalent, pushing on these pins and pushing on these gear teeth, particularly from [the perspective of] one of ordinary skill in the art.” On cross-examination, Dr. McCarthy further explained that one could “[t]ake that gear off, put those pins on. . . . [The accused “bin array” structure] is completely equivalent, completely identical.”

Given the clear, consistent, and oft-repeated evidence that the “rotary means” structure in the '151 patent and the “bin array” structure in the accused devices were equivalent, the district court, announcing its initial ruling against JMOL, stated: “the jury could find infringement, as it did, based on Dr. McCarthy’s testimony of literal infringement. So STK’s motion for Judgment as a Matter of Law must be denied.” We agree. Odetics introduced substantial evidence that the rotary means and bin array structures were equivalent; a reasonable jury was therefore entitled to find infringement. *See, e.g., Al-Site*, 174 F.3d at 1316, 50 U.S.P.Q.2d at 1165 (expert testimony that an “equivalent fastening means could be a rivet, glue, or staple . . . ’ constitutes sufficient evidence to sustain the jury’s verdict”).

STK’s argument that the testimony of Dr. McCarthy relates only to the functional identity of the two structures—and is thus insufficient to demonstrate structural equivalence—is unavailing. Dr. McCarthy testified repeatedly about the *structural* similarities, noting that, overall, the two structures “match directly,” and that “the entire [bin array] structure surely is equivalent.” Dr. McCarthy also stated that the *way* that the two structures accomplish the claimed “rotary” function, and the *result* of that function, is substantially equivalent: “[the depiction of the rotary means structure] represents the way this system is actuated. That’s the point [at which] the force is applied to rotate[e]. Any equivalent way of rotating, is what’s captured in this drawing.” Therefore, when the question is whether substantial evidence supports the jury verdict, Dr. McCarthy’s testimony answers that question against STK, as the district court correctly noted in the initial denial of the renewed motion for JMOL.

Contrary to STK’s argument, the “bin array” structure (the rod, bin, and pins) is not precluded from being equivalent, under § 112, ¶ 6, to the '151 patent’s “rotary means” structure (the rod, bin, and gear) by the fact that the “bin array” structure would not be able to perform unrelated functions, such as “meshing with a gear motor.” A claim limitation written according to § 112, ¶ 6 recites a function to be performed. *See* 35 U.S.C. § 112, ¶ 6. The scope of that functional limitation is, of course, limited to the “corresponding structure, material, or acts described in the specification and equivalents thereof.” *Id.* The “corresponding” structure is the structure disclosed as performing the function. That two structures may perform unrelated—and, more to the point, unclaimed—functions differently or not at all is simply not pertinent to the measure of § 112, ¶ 6 equivalents. *See Chiuminatta*, 145 F.3d at 1308 (structure that “reduce[s] wobbling” and “support[s] the weight of the cutting blade” is unrelated to the claimed function of “support[ing] the surface of the concrete” and accordingly are not to be read as limiting the scope of the means clause”). In this case, Dr. McCarthy testified that the structural equivalence between the “rotary means” and the “bin array” derives from the capacity of

both structures to perform the identical function in the same way: to receive the force necessary to accomplish the “rotary” function.

* * *

For the reasons stated above, we reverse the grant of JMOL in favor of STK and order the jury’s verdict reinstated.

Comments

1. **Pre-1952 Prohibition.** Prior to the 1952 Patent Act, functionally defined claims were prohibited because of fear of excessive ambiguity and scope. See *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946). The 1952 Act overruled *Halliburton*, “but provided a standard to make the broad claim language more definite” by requiring the applicant to “describe in the patent specification some structure which performs the specified function” and stating “a court must construe the functional claim language ‘to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.’” *Valmont Industries, Inc. v. Reinke Manufacturing Co., Inc.*, 983 F.2d 1039, 1041 (Fed. Cir. 1993).
2. **Infringement under § 112, ¶ 6: Statutory and Common Law Equivalents.** A means-plus-function claim is literally infringed if the accused device performs the identical function set forth in the claim. The infringement is deemed “literal” because the functions are the same. If there is “identity of function,” an equivalents analysis is limited to the structure disclosed in the specification.

As *Odetics* discusses, § 112, ¶ 6 statutory equivalence is essentially a common law equivalence analysis (*i.e.*, insubstantial differences) in a limited role because the identity of function is a prerequisite to application of a statutory equivalence analysis to determine if the accused structure and disclosed structure are equivalent. Interestingly, § 112, ¶ 6 says nothing about structural equivalence. The statute states the “claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” This view is reflected in *de Graffenried*, 20 Cl. Ct. 458, 479-80 (1980) (noting the “defendant interprets Section 112 too narrowly when it defines the term ‘equivalent’ to include only equivalents in physical structure. . . . [T]he term ‘equivalent’ in Section 112 should not be interpreted as being limited to structures that are ‘equivalent’ to the physical structure of the ‘means’ disclosed in a patent. The literal wording of Section 112 contains no such requirement. The statute merely refers to structures ‘described in the specification and equivalents thereof.’ It does not state that the only possible ‘equivalents’ to the structures described in the specification are devices with equivalent physical structures, *i.e.*, it does not provide structures ‘described in the specification and *structural* equivalents thereof”).

Because infringement under § 112, ¶6 is deemed literal infringement, the structural equivalent must exist at the time the patent issued. (Recall, literal infringement is measured at the time of issuance and does not apply to after-arising technology.) In contrast, under the common law DOE, equivalents is measured at the time of infringement, and therefore, applies to after-arising technology. In both instances, an equivalency analysis will apply, but whether

the resulting infringement (assuming there is infringement) is called literal or non-literal depends on when the accused equivalent became available. This temporal distinction was discussed in *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1321 n.2 (Fed. Cir. 1999):

A proposed equivalent must have arisen at a definite period in time, i.e., either before or after patent issuance. If before, a § 112, ¶6 structural equivalents analysis applies and any analysis for equivalent structure under the doctrine of equivalents collapses into the § 112, ¶6 analysis. If after, a non-textual infringement analysis proceeds under the doctrine of equivalents. Patent policy supports application of the doctrine of equivalents to a claim element expressed in means-plus-function form in the case of “after-arising” technology because a patent draftsman has no way to anticipate and account for later developed substitutes for a claim element. Therefore, the doctrine of equivalents appropriately allows marginally broader coverage than § 112, ¶6.

One final point: if the accused structure does not literally perform the claimed function, possess the “§ 112, ¶6 plays no role in determining whether an equivalent function is performed by the accused device under the doctrine of equivalents.” *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc).

3. **Constructing a § 112, ¶ 6 Claim.** The easiest way to invoke § 112, ¶ 6 is to use “means for” language. The use of the word “means” creates a rebuttable presumption that § 112, ¶ 6 applies; conversely, the failure to use “means” invokes a presumption that § 112, ¶ 6 does not apply. See *CCS Fitness v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002). But use of the word “means” does not guarantee ¶ 6 will apply; nor is it necessary to use “means” to qualify for a means-plus-function claim. The key is not to recite a definite structure that performs the described function. See *Apex, Inc. v. Ravitan Computer, Inc.*, 325 F.3d 1364, 1373 (Fed. Cir. 2003). See also *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996) (“We do not mean to suggest that section 112(6) is triggered only if the claim uses the word ‘means.’ . . . Nonetheless, the use of the term ‘means’ has come to be so closely associated with ‘means-plus-function’ claiming that it is fair to say that the use of the term ‘means’ (particularly as used in the phrase ‘means for’) generally invokes section 112(6) and that the use of a different formulation generally does not.”).

C. DEFINING THE GEOGRAPHIC SCOPE OF THE PATENT RIGHT

Territoriality is a fundamental principle of American patent law. As the Supreme Court stated at the beginning of the twentieth century, “[t]he right conferred by a patent under our law is confined to the United States and its territories . . . and infringement of this right cannot be predicated of acts wholly done in a foreign country.” *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 650 (1915). The territoriality principle, however, has been altered by statute to capture certain forms of export and import activity. See § 271(f) and (g) and the principal cases of *Microsoft* and *Eli Lilly*. But before export and import issues are addressed, we must first understand the geographic scope of infringement that occurs “within the United States,” under § 271(a).

1. The Parameters of § 271(a): Defining “Within the United States”

Section 271(a) of title 35 sets forth the requirements for a claim of direct infringement of a patent. It provides:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, *within the United States or imports into the United States* any patented invention during the term of the patent therefor, infringes the patent.

Section 154(a)(1) grants a patentee the right to exclude others from making, using, offering for sale, or selling the claimed invention “within the United States” or importing the invention “into” the United States. Thus, activity in a foreign country, *in and of itself*, does not constitute an infringing act. But the statutory term “within the United States” is not as straightforward as initially appears, as illustrated by *NTP, Inc. v. Research in Motion*, the well-known BlackBerry® case.

NTP, INC. v. RESEARCH IN MOTION LTD.

418 F.3d 1282 (Fed. Cir. 2005)

LINN, Circuit Judge.

Research In Motion, Ltd. (“RIM”) appeals from a judgment of the U.S. District Court for the Eastern District of Virginia (“district court”) entered in favor of NTP, Inc. (“NTP”) following a jury verdict that RIM’s BlackBerry TM system infringed NTP’s patents . . . and awarding damages to NTP in the amount of \$53,704,322.69. The court, in a final order also appealed by RIM, permanently enjoined any further infringement by RIM, but stayed the injunction pending this appeal. . . .

I. BACKGROUND

The technology at issue relates to systems for integrating existing electronic mail systems (“wireline” systems) with radio frequency (“RF”) wireless communication networks, to enable a mobile user to receive email over a wireless network.

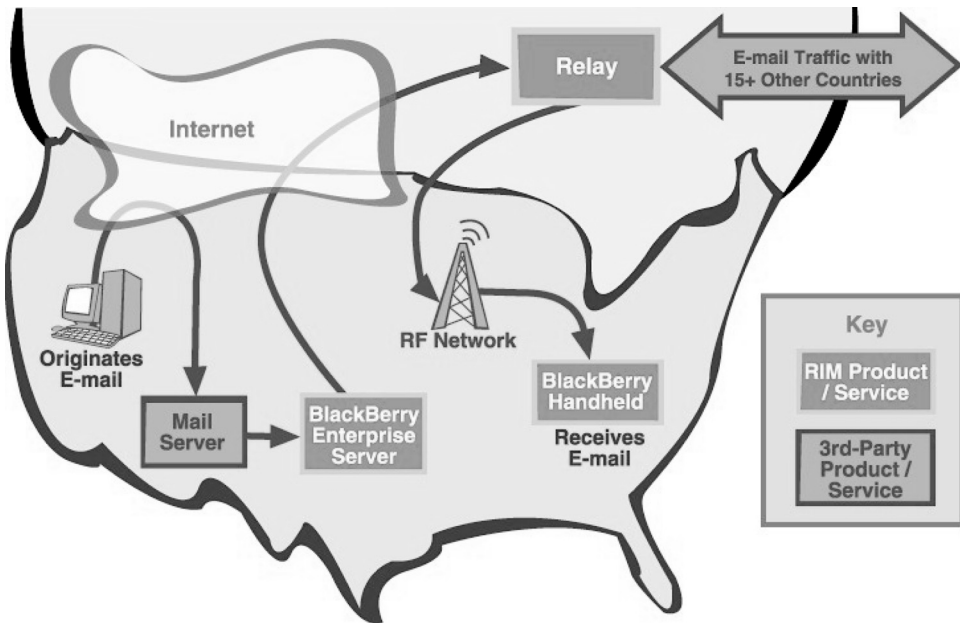
* * *

C. The Patents-in-Suit

Inventors Thomas J. Campana, Jr.; Michael P. Ponschke; and Gary F. Thelen (collectively “Campana”) developed an electronic mail system that was claimed in the ’960, ’670, ’172, ’451, and ’592 patents. . . .

Campana’s particular innovation was to integrate existing electronic mail systems with RF wireless communications networks. In simplified terms, the Campana invention operates in the following manner: A message originating in an electronic mail system may be transmitted not only by wireline but also via RF, in which case it is received by the user and stored on his or her mobile RF receiver. The user can view the message on the RF receiver and, at some later point, connect the RF receiver to a fixed destination processor, *i.e.*, his or

her personal desktop computer, and transfer the stored message. Intermediate transmission to the RF receiver is advantageous because it “eliminat[es] the requirement that the destination processor [be] turned on and carried with the user” to receive messages. Instead, a user can access his or her email stored on the RF receiver and “review . . . its content without interaction with the destination processor,” while reserving the ability to transfer the stored messages automatically to the destination processor. The patents-in-suit do not disclose a method for composing and sending messages from the RF receiver. [The graphic below illustrates the above description.]*



D. The Accused System

RIM is a Canadian corporation with its principal place of business in Waterloo, Ontario. RIM sells the accused BlackBerry system, which allows out-of-office users to continue to receive and send electronic mail, or “email” communications, using a small wireless device. The system utilizes the following components: (1) the BlackBerry handheld unit (also referred to as the “BlackBerry Pager”); (2) email redirector software (such as the BlackBerry Enterprise Server (“BES”), the Desktop Redirector, or the Internet Redirector); and (3) access to a nationwide wireless network (such as Mobitex, DataTAC, or GPRS).

The BlackBerry system uses “push” email technology to route messages to the user’s handheld device without a user-initiated connection. There are multiple BlackBerry email “solutions” that interface with different levels of the

*[This graphic appeared in RIM’s brief before the Federal Circuit and is reproduced here with permission from RIM’s counsel. — Ed.]

user's email system. In the Desktop solution, the BlackBerry email redirector software, the Desktop Redirector, is installed on the user's personal computer. In the Corporate solution, different BlackBerry email redirector software, the BES program, is installed on the organizational user's mail server, where it can function for the benefit of the multiple users of that server. Also at issue in this case is RIM's Internet solution of the BlackBerry system. The Internet solution operates in a manner similar to the Corporate solution, but it executes a different email redirector software, Internet Redirector. In either version, the BlackBerry email redirector software merges seamlessly with the user's existing email system. The operation of the email redirector software is transparent to the user's desktop email client and the organizational user's mail server. That is, the user's email system does not recognize or incorporate the BlackBerry wireless system into its operation. No modification of the underlying email system is required to run RIM's wireless email extension. When new mail is detected in the Desktop solution, the Desktop Redirector is notified and retrieves the message from the mail server. It then copies, encrypts, and routes the message to the BlackBerry "Relay" component of RIM's wireless network, which is located in Canada. In the Corporate solution, the BES software performs this same function but intercepts the email before the message reaches the individual user's personal computer. The individual user's personal computer need not be turned on for the BES software to properly redirect the user's emails. However, the user retains some control over message forwarding by using the BlackBerry "Desktop Manager." This additional software permits the user to specify his or her email redirection preferences. In both systems, the message travels through the BlackBerry Relay, where it is translated and routed from the processors in the user's email system to a partner wireless network. That partner network delivers the message to the user's BlackBerry handheld, and the user is "notified virtually instantly" of new email messages. *White Paper* at 6. This process, accomplished without any command from the BlackBerry user, is an example of "push" email architecture. *Id.* There are significant advantages to "push" email architecture. Most importantly, the user is no longer required to initiate a connection with the mail server to determine if he or she has new email. As RIM's technical literature explains, "[b]y having the desktop connect to the user, time spent dialing-up and connecting to the desktop (possibly to find that there is no new email) is eliminated as users . . . are notified virtually instantly of important messages, enabling the user to respond immediately." *Id.*

RIM's system also permits users to send email messages over the wireless network from their handhelds. This functionality is achieved through the integration of an RF transmitter and a processor in the BlackBerry handheld unit. The processor allows the user to manipulate, view, and respond to email on his or her BlackBerry handheld. Sending a message from the handheld requires the same steps as the process for receiving email, only in reverse. When the user composes a message on his or her handheld, it is sent back to that user's desktop machine over the partner and BlackBerry wireless networks. The BlackBerry email redirector software then retrieves the outgoing message from the user's mail server and places it in the user's desktop email software, where it is dispersed through normal channels. In this way, messages sent from the BlackBerry handheld are identical to messages sent from the

user's desktop email—they originate from the same address and also appear in the “sent mail” folder of the user's email client.

* * *

II. ANALYSIS

* * *

B. Infringement

... RIM contends that because the BlackBerry Relay is located in Canada, as a matter of law RIM cannot be held liable for infringement under 35 U.S.C. § 271.

* * *

2. Section 271(a)

Section 271(a) of title 35 sets forth the requirements for a claim of direct infringement of a patent. It provides:

Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

35 U.S.C. § 271(a) (2000). The territorial reach of section 271 is limited. Section 271(a) is only actionable against patent infringement that occurs within the United States. See *Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1117 (Fed. Cir. 2004) (“[As] the U.S. Supreme Court explained nearly 150 years ago in *Brown v. Duchesne*, the U.S. patent laws ‘do not, and were not intended to, operate beyond the limits of the United States.’”).

Ordinarily, whether an infringing activity under section 271(a) occurs within the United States can be determined without difficulty. This case presents an added degree of complexity, however, in that: (1) the “patented invention” is not one single device, but rather a system comprising multiple distinct components or a method with multiple distinct steps; and (2) the nature of those components or steps permits their function and use to be separated from their physical location.

In its complaint, NTP alleged that RIM had infringed its patents by “making, using, selling, offering to sell and importing into the United States products and services, including the Defendant's BlackBerry™ products and their related software. . . .” NTP's theory of infringement tracks the language of section 271(a). In the district court, RIM moved for summary judgment of non-infringement, arguing that it could not be held liable as a direct infringer under section 271(a). According to RIM, the statutory requirement that the allegedly infringing activity occur “within the United States” was not satisfied because the BlackBerry Relay component of the accused system is located in Canada. The Relay component is alleged to meet the “interface” or the “interface switch” limitation in the '960, '670, '172, and '451 patents. RIM's argument based on the location of its Relay outside the United States does not apply to the asserted claims of the '592 patent (claims 40, 150, 278, 287, 653,

and 654) because those claims do not include the “interface” or “interface switch” limitation.

[D]uring trial, the court . . . held that “the fact that the BlackBerry relay is located in Canada is not a bar to infringement in this matter.” The court therefore instructed the jury that “the location of RIM’s Relay in Canada does not preclude infringement.” In the district court, the jury found direct, induced, and contributory infringement by RIM on all asserted claims. The asserted claims included both systems and methods for transmitting an email message between an originating processor and a destination processor. By holding RIM liable for contributory infringement and inducing infringement, the jury necessarily found that its customers are direct infringers of the claimed systems and methods.

On appeal, RIM argues that the district court erred in its interpretation of the infringement statute. RIM does not appeal the jury’s finding that its customers use, *i.e.*, put into service, its systems and methods for transmitting email messages. RIM has, however, appealed whether any direct infringement, by it or its customers, can be considered “within the United States” for purposes of section 271(a). Citing the Supreme Court’s decision in *Deepsouth*, RIM contends that an action for infringement under section 271(a) may lie only if the allegedly infringing activity occurs within the United States. RIM urges that, in this case, that standard is not met because the BlackBerry Relay component, described by RIM as the “control point” of the accused system, is housed in Canada. For section 271(a) to apply, RIM asserts that the entire accused system and method must be contained or conducted within the territorial bounds of the United States. RIM thus contends that there can be no direct infringement as a matter of law because the location of RIM’s Relay outside the United States precludes a finding of an infringing act occurring within the United States.

The question before us is whether the using, offering to sell, or selling of a patented invention is an infringement under section 271(a) if a component or step of the patented invention is located or performed abroad. Pursuant to section 271(a), whoever without authority “uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent.” 35 U.S.C. § 271(a). The grammatical structure of the statute indicates that “within the United States” is a separate requirement from the infringing acts clause. Thus, it is unclear from the statutory language how the territoriality requirement limits direct infringement where the location of at least a part of the “patented invention” is not the same as the location of the infringing act.

RIM argues that *Deepsouth* answers this question. However, *Deepsouth* did not address this issue. In *Deepsouth*, the Supreme Court considered whether section 271(a) prevented, as direct infringement, the domestic production of all component parts of a patented combination for export, assembly, and use abroad. The Court held that the export of unassembled components of an invention could not infringe the patent. The Court said that it could not “endorse the view that the ‘substantial manufacture of the constituent parts of a machine’ constitutes direct infringement when we have so often held that a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts.” *Id.* at 528. Thus, the Court concluded that the complete manufacture of the operable assembly of the whole within

the United States was required for infringement by making under section 271(a). In that case, however, both the act of making and the resulting patented invention were wholly outside the United States. By contrast, this case involves a system that is partly within and partly outside the United States and relates to acts that may be occurring within or outside the United States.

Although *Deepsouth* does not resolve these issues, our predecessor court's decision in *Decca Ltd. v. United States*, 544 F.2d 1070 (1976), is instructive. In *Decca*, the plaintiff sued the United States for use and manufacture of its patented invention under 28 U.S.C. § 1498. The claimed invention was a radio navigation system requiring stations transmitting signals that are received by a receiver, which then calculates position by the time difference in the signals. At the time of the suit, the United States was operating three such transmitting stations, one of which was located in Norway and thus was outside the territorial limits of the United States. Only asserted claim 11 required three transmitting stations. Thus, in considering infringement of claim 11, the court considered the extraterritorial reach of the patent laws as applied to a system in which a component was located outside the United States. The court recognized that *Deepsouth* did not address this issue. In analyzing whether such a system was "made" in the United States, however, the court focused on the "operable assembly of the whole" language from *Deepsouth* and concluded that "[t]he plain fact is that one of the claimed elements is outside of the United States so that the combination, as an operable assembly, simply is not to be found solely within the territorial limits of this country." *Id.* at 1082. The court recognized that what was located within the United States was as much of the system as was possible, but the court reached no clear resolution of whether the accused system was "made" within the United States. Nevertheless, the court said, "[a]nalyzed from the standpoint of a use instead of a making by the United States, a somewhat clearer picture emerges." *Id.* The court concluded that "it is obvious that, although the Norwegian station is located on Norwegian soil, a navigator employing signals from that station is, in fact, 'using' that station and such use occurs wherever the signals are received and used in the manner claimed." *Id.* at 1083. In reaching its decision, the court found particularly significant "the ownership of the equipment by the United States, the control of the equipment from the United States and . . . the actual beneficial use of the system within the United States." *Id.* Although *Decca* was decided within the context of section 1498, which raises questions of use *by* the United States, the question of use *within* the United States also was implicated because direct infringement under section 271(a) is a necessary predicate for government liability under section 1498.

Decca provides a legal framework for analyzing this case. As our predecessor court concluded, infringement under section 271(a) is not necessarily precluded even though a component of a patented system is located outside the United States. However, as is also evident from *Decca*, the effect of the extraterritorial component may be different for different infringing acts. In *Decca*, the court found it difficult to conclude that the system had been made within the United States but concluded that the system had been used in the United States even though one of the claim limitations was only met by including a component located in Norway. Not only will the analysis differ for different types of infringing acts, it will also differ as the result of differences between different types of claims. Because the analytical frameworks differ, we

will separately analyze the alleged infringing acts, considering first the system claims and then the claimed methods.

a. “uses . . . within the United States”

The situs of the infringement “is wherever an offending act [of infringement] is committed.” *N. Am. Philips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994) (“[Section 271] on its face clearly suggests the conception that the ‘tort’ of patent infringement occurs where the offending act is committed and not where the injury is felt.”). The situs of the infringing act is a “purely physical occurrence[.]” *Id.* In terms of the infringing act of “use,” courts have interpreted the term “use” broadly. In *Bauer & Cie v. O'Donnell*, 229 U.S. 1 (1913), the Supreme Court stated that “use,” as used in a predecessor to title 35, is a “comprehensive term and embraces within its meaning the right to put into service any given invention.” *Id.* at 10-11. The ordinary meaning of “use” is to “put into action or service.” *Webster's Third New International Dictionary* 2523 (1993).

The use of a claimed system under section 271(a) is the place at which the system as a whole is put into service, *i.e.*, the place where control of the system is exercised and beneficial use of the system obtained. Based on this interpretation of section 271(a), it was proper for the jury to have found that use of NTP's asserted system claims occurred within the United States. RIM's customers located within the United States controlled the transmission of the originated information and also benefited from such an exchange of information. Thus, the location of the Relay in Canada did not, as a matter of law, preclude infringement of the asserted system claims in this case.

RIM argues that the BlackBerry system is distinguishable from the system in *Decca* because the RIM Relay, which controls the accused systems and is necessary for the other components of the system to function properly, is not located within the United States. While this distinction recognizes technical differences between the two systems, it fails to appreciate the way in which the claimed NTP system is actually used by RIM's customers. When RIM's United States customers send and receive messages by manipulating the handheld devices in their possession in the United States, the location of the use of the communication system as a whole occurs in the United States. This satisfactorily establishes that the situs of the “use” of RIM's system by RIM's United States customers for purposes of section 271(a) is the United States. Therefore, we conclude that the jury was properly presented with questions of infringement as to NTP's system claims containing the “interface” or “interface switch” limitation; namely, claim 15 of the '960 patent; claim 8 of the '670 patent; and claims 28 and 248 of the '451 patent.

We reach a different conclusion as to NTP's asserted method claims. Under section 271(a), the concept of “use” of a patented method or process is fundamentally different from the use of a patented system or device. *See In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (recognizing “the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps. . . . [A process] consists of doing something, and therefore has to be carried out or performed.”). Although the Supreme Court focused on the whole operable assembly of a system claim for infringement in *Deepsouth*, there is no corresponding whole operable assembly of a process claim. A method or process

consists of one or more operative steps, and, accordingly, “[i]t is well established that a patent for a method or process is not infringed unless all steps or stages of the claimed process are utilized.” *Roberts Dairy Co. v. United States*, 530 F.2d 1342, 1354 (1976).

Because a process is nothing more than the sequence of actions of which it is comprised, the use of a process necessarily involves doing or performing each of the steps recited. This is unlike use of a system as a whole, in which the components are used collectively, not individually. We therefore hold that a process cannot be used “within” the United States as required by section 271(a) unless each of the steps is performed within this country. In the present case, each of the asserted method claims of the ’960, ’172, and ’451 patents recites a step that utilizes an “interface” or “interface switch,” which is only satisfied by the use of RIM’s Relay located in Canada. Therefore, as a matter of law, these claimed methods could not be infringed by use of RIM’s system.

Thus, we agree with RIM that a finding of direct infringement by RIM’s customers under section 271(a) of the method claims reciting an “interface switch” or an “interface” is precluded by the location of RIM’s Relay in Canada. As a consequence, RIM cannot be liable for induced or contributory infringement of the asserted method claims, as a matter of law.

b. “offers to sell, or sells”

Because we conclude that RIM’s customers could not have infringed the asserted method claims of the ’960, ’172, and ’451 patents under the “use” prong of section 271(a), and thus, could not have provided the necessary predicate for the charges of induced or contributory infringement of those claims, we must consider whether RIM could have directly infringed the method claims under the “sell” or “offer to sell” prongs of section 271(a). The cases cited by RIM are concerned primarily with the “use” and “make” prongs of section 271(a) and do not directly address the issue of whether a method claim may be infringed by selling or offering to sell within the meaning of section 271(a).

Because the relevant precedent does not address the issue of whether a sale of a claimed method can occur in the United States, even though the contemplated performance of that method would not be wholly within the United States, the issue is one of first impression. We begin with the language of the statute. Section 271(a) does not define “sells” or “offers to sell,” nor does the statute specify which infringing acts apply to which types of claims. Section 271(a) was merely a codification of the common law of infringement that had developed up to the time of passage of the 1952 Patent Act. It was not meant to change the law of infringement. A claim directed to a method or process, although somewhat controversial in the Nineteenth Century, is now a well-established form of claiming. Nevertheless, the precise contours of infringement of a method claim have not been clearly established.

In *Enercon GmbH v. International Trade Commission*, 151 F.3d 1376 (Fed. Cir. 1998), this court considered the meaning of the phrase “sale for importation” in the International Trade Commission’s governing statute, 19 U.S.C. § 1337. Because the term “sale” was not defined in the statute, we assumed that Congress intended to give the term its ordinary meaning. In considering the ordinary meaning, we looked to dictionaries and to the Uniform Commercial Code. We employ a similar methodology here, looking to the ordinary

meaning of the term “sale.” The definition of “sale” is: “1. The transfer of property or title for a price. 2. The agreement by which such a transfer takes place. The four elements are (1) parties competent to contract, (2) mutual assent, (3) a thing capable of being transferred, and (4) a price in money paid or promised.” *Black’s Law Dictionary* 1337 (7th ed. 1999). Thus, the ordinary meaning of a sale includes the concept of a transfer of title or property. The definition also requires as the third element “a thing capable of being transferred.” It is difficult to apply this concept to a method claim consisting of a series of acts. It is difficult to envision what property is transferred merely by one party performing the steps of a method claim in exchange for payment by another party. Moreover, performance of a method does not necessarily require anything that is capable of being transferred.

Congress has consistently expressed the view that it understands infringement of method claims under section 271(a) to be limited to use. The committee reports surrounding the passage of the Process Patents Amendments Act of 1987 indicate that Congress did not understand all of the infringing acts in section 271(a) to apply to method claims. The Senate Report explains, “Under our current patent laws, a patent on a process gives the patentholder the right to exclude others from using that process in the United States without authorization from the patentholder. The other two standard aspects of the patent right—the exclusive right to make or sell the invention—are not directly applicable to a patented process.” S. Rep. No. 100-83, at 30 (1987). The House Report expresses a similar view: “With respect to process patents, courts have reasoned that the only act of infringement is the act of making through the use of a patented process. . . .” H.R. Rep. No. 99-807, at 5 (1986). Although this issue has not been directly addressed, this court expressed a similar view in *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770 (Fed. Cir. 1993). In that case, we said, “A method claim is *directly* infringed only by one practicing the patented method.” *Id.* at 775.

In 1994, Congress passed legislation to implement the Uruguay Round of the General Agreement on Tariffs and Trade. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994). That legislation modified section 271(a) to include the infringing acts of offering to sell and importing into the United States. *Id.* § 533, 108 Stat. at 4988. The portion of the Uruguay Round being implemented in the modification of section 271(a) was the Agreement on Trade-Related Aspects of Intellectual Property Rights. That agreement clearly spells out the rights to be protected. It states:

1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 28, H.R. Doc. No. 103-316, at 1634 (1994) (footnote omitted). The agreement makes clear that claimed processes are to be directly protected

only from “the act of using the process.” The joint committee report from the Senate reflects the same understanding: “The list of exclusive rights granted to patent owners is expanded to preclude others from offering to sell or importing products covered by a U.S. patent or offering to sell the products of patented processes.” S. Rep. 103-412, at 230 (1994), U.S. Code Cong. & Admin. News 1994 at pp. 3773, 4002. Thus, the legislative history of section 271(a) indicates Congress’s understanding that method claims could only be directly infringed by use.

In the context of the on sale bar, we have held that a method claim may be invalid if an offer to perform the method was made prior to the critical date. Nevertheless, we have previously “decline[d] to import the authority construing the ‘on sale’ bar of § 102(b) into the ‘offer to sell’ provision of § 271(a).” *3D Sys., Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1379 n. 4 (Fed. Cir. 1998). As the Supreme Court cautioned in *Deepsouth*, 406 U.S. at 531: “We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argues that the beachhead of privilege is wider, and the area of public use narrower, than courts had previously thought.” The indication we have from Congress on infringement by selling or offering to sell method claims shows that it believes the beachhead is narrow.

In this case, we conclude that the jury could not have found that RIM infringed the asserted method claims under the “sells” or “offers to sell” prongs of section 271(a). We need not and do not hold that method claims may not be infringed under the “sells” and “offers to sell” prongs of section 271(a). Rather, we conclude only that RIM’s performance of at least some of the recited steps of the asserted method claims as a service for its customers cannot be considered to be selling or offering to sell the invention covered by the asserted method claims. The sale or offer to sell handheld devices is not, in and of itself, enough. Thus, we conclude as a matter of law that RIM did not sell or offer to sell the invention covered by NTP’s method claims within the United States.

Comments

1. **“Control” and “Beneficial Use.”** The following passage in *NTP* reflects the expansive approach the court took in interpreting § 271(a):

The use of a claimed system under section 271(a) is the place at which the system as a whole is put into service, *i.e.*, the place where *control* of the system is exercised and *beneficial use* of the system obtained. Based on this interpretation of section 271(a), it was proper for the jury to have found that use of NTP’s asserted system claims occurred within the United States. RIM’s customers located within the United States controlled the transmission of the originated information and also benefited from such an exchange of information. Thus, the location of the Relay in Canada did not, as a matter of law, preclude infringement of the asserted system claims in this case.

(emphasis added). The *NTP* court held that the geographic test for infringement was whether “control and beneficial use” of RIM’s system was within the United States; not whether the actual infringement occurs in the United States. Some commentators have suggested *NTP* and *Decca*—which *NTP* relied on—have embraced a “locus of infringement” posture

when interpreting § 271(a). See Mark Lemley, David O'Brien, Ryan M. Kent, Ashok Ramani & Robert Van Nest, *Divided Infringement Claims*, 33 AIPLA Q.J. 255, 269 (stating *NTP* and *Decca* "have adopted a 'locus of infringement' approach, under which the invention is deemed to exist in the country with the strongest connection to the invention").

2. **Deepsouth and Congress' Response.** The *RIM* court discussed the *Deepsouth* case and rejected *RIM*'s reliance on *Deepsouth*'s holding. The court distinguished *Deepsouth* because in *RIM* "the location of the infringement is within United States territory, not abroad as in *Deepsouth*." In *Deepsouth*, the defendant made the components of the patented device and transported them to foreign-based customers. The components were thereafter assembled outside of the United States. The Supreme Court held for the accused infringer, noting "a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts." 406 U.S. 518, 528. While one who manufactures unassembled components may be liable of contributory infringement, there must first be direct infringement. Activity that would otherwise constitute direct infringement if done in the U.S. (*e.g.*, making and using), is not direct infringement if performed abroad.

Several years after *Deepsouth*, Congress responded with § 271(f), which was enacted in 1984. Under this statutory provision, one who supplies unassembled parts of a patented device is an infringer. The policies underlying § 271(f) are explained in the legislative history:

The . . . change . . . will prevent copiers from avoiding U.S. patents by supplying components of a patented product in this country so that the assembly of the components may be completed abroad. This proposal responds to the United States Supreme Court decision in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), concerning the need for a legislative solution to close a loophole in patent law.

In this regard, section 101 adds a new subsection 271(f) to the patent law. Subsection 271(f) makes it an infringement to supply components of a patented invention, or to cause components to be supplied, that are to be combined outside the United States. In order to be liable as an infringer under paragraph (f)(1), one must supply or cause to be supplied "all or a substantial portion" of the components in a manner that would infringe the patent if such a combination occurred in the United States. The term "actively induce" is drawn from existing subsection 271(b) of the patent law, which provides that whoever actively induces patent infringement is liable as an infringer.

Under paragraph (f)(1) the components may be staple articles or commodities of commerce which are also suitable for substantial non-infringing use, but under paragraph (f)(2) the components must be especially made or adapted for use in the invention. The passage in paragraph (f)(2) reading "especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use" comes from existing section 271(c) of the patent law, which governs contributory infringement. Paragraph (f)(2), like existing subsection 271(c), requires the infringer to have knowledge that the component is especially made or adapted. Paragraph (f)(2) also contains a further requirement that infringers

must have an intent that the components will be combined outside of the United States in a manner that would infringe if the combination occurred within the United States.

“Section-by-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984,” Congressional Record, Oct. 1, 1984, H10525-26. *DeepSouth* is also explored in the next principal case, immediately below.

2. The Parameters of § 271(f): Export Activity

It is axiomatic that someone who makes and uses a patented invention in the United States without permission of the patent owner engages in patent infringement. But what about a situation where a third party makes an incomplete version of the patented product in the U.S. for export or only makes a component of a patented machine and thereafter exports it for assembly abroad with other components that ultimately form the patented device? There is no infringement under § 271(a) because the assembly was outside the U.S. But there may be infringement under § 271(f), which was drafted with this type of scenario in mind. The principal case of *Microsoft v. AT&T* explores the reach and parameters of § 271(f).

MICROSOFT CORP. v. AT&T CORP.

127 S. Ct. 1746 (2007)

Justice GINSBURG delivered the opinion of the Court.

It is the general rule under United States patent law that no infringement occurs when a patented product is made and sold in another country. There is an exception. Section 271(f) of the Patent Act, adopted in 1984, provides that infringement does occur when one “supplies . . . from the United States,” for “combination” abroad, a patented invention’s “components.” 35 U.S.C. § 271(f)(1). This case concerns the applicability of § 271(f) to computer software first sent from the United States to a foreign manufacturer on a master disk, or by electronic transmission, then copied by the foreign recipient for installation on computers made and sold abroad.

AT&T holds a patent on an apparatus for digitally encoding and compressing recorded speech. Microsoft’s Windows operating system, it is conceded, has the potential to infringe AT&T’s patent, because Windows incorporates software code that, when installed, enables a computer to process speech in the manner claimed by that patent. It bears emphasis, however, that uninstalled Windows software does not infringe AT&T’s patent any more than a computer standing alone does; instead, the patent is infringed only when a computer is loaded with Windows and is thereby rendered capable of performing as the patented speech processor. The question before us: Does Microsoft’s liability extend to computers made in another country when loaded with Windows software copied abroad from a master disk or electronic transmission dispatched by Microsoft from the United States? Our answer is “No.”

The master disk or electronic transmission Microsoft sends from the United States is never installed on any of the foreign-made computers in question. Instead, copies made abroad are used for installation. Because Microsoft does

not export from the United States the copies actually installed, it does not “suppl[y] . . . from the United States” “components” of the relevant computers, and therefore is not liable under § 271(f) as currently written.

Plausible arguments can be made for and against extending § 271(f) to the conduct charged in this case as infringing AT&T’s patent. Recognizing that § 271(f) is an exception to the general rule that our patent law does not apply extraterritorially, we resist giving the language in which Congress cast § 271(f) an expansive interpretation. Our decision leaves to Congress’ informed judgment any adjustment of § 271(f) it deems necessary or proper.

I

Our decision some 35 years ago in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972), a case about a shrimp deveining machine, led Congress to enact § 271(f). In that case, Laitram, holder of a patent on the time-and-expense-saving machine, sued Deepsouth, manufacturer of an infringing deveiner. Deepsouth conceded that the Patent Act barred it from making and selling its deveining machine in the United States, but sought to salvage a portion of its business: Nothing in United States patent law, Deepsouth urged, stopped it from making in the United States the *parts* of its deveiner, as opposed to the machine itself, and selling those *parts* to foreign buyers for assembly and use abroad. *Id.*, at 522-524.¹ We agreed.

Interpreting our patent law as then written, we reiterated in *Deepsouth* that it was “not an infringement to make or use a patented product outside of the United States.” *Id.*, at 527; see 35 U.S.C. § 271(a) (1970 ed.) (“[W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.”). Deepsouth’s foreign buyers did not infringe Laitram’s patent, we held, because they assembled and used the deveining machines outside the United States. Deepsouth, we therefore concluded, could not be charged with inducing or contributing to an infringement. Nor could Deepsouth be held liable as a direct infringer, for it did not make, sell, or use the patented invention—the fully assembled deveining machine—within the United States. The parts of the machine were not themselves patented, we noted, hence export of those parts, unassembled, did not rank as an infringement of Laitram’s patent.

Laitram had argued in *Deepsouth* that resistance to extension of the patent privilege to cover exported parts “derived from too narrow and technical an interpretation of the [Patent Act].” *Id.*, at 529. Rejecting that argument, we referred to prior decisions holding that “a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts.” *Id.*, at 528. Congress’ codification of patent law, we said, signaled no intention to broaden the scope of the privilege. *Id.*, at 530 (“When, as here, the Constitution is permissive, the sign of how far Congress has chosen to go can come only from Congress.”). And we again emphasized that

1. Deepsouth shipped its deveining equipment “to foreign customers in three separate boxes, each containing only parts of the 1-ton machines, yet the whole [was] assemblable in less than one hour.” *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 524 (1972).

[o]ur patent system makes no claim to extraterritorial effect; these acts of Congress do not, and were not intended to, operate beyond the limits of the United States; and we correspondingly reject the claims of others to such control over our markets.

Id., at 531 (quoting *Brown v. Duchesne*, 19 How. 183, 195 (1857)).

Absent “a clear congressional indication of intent,” we stated, courts had no warrant to stop the manufacture and sale of the parts of patented inventions for assembly and use abroad. 406 U.S., at 532.

Focusing its attention on *DeepSouth*, Congress enacted § 271(f).³ The provision expands the definition of infringement to include supplying from the United States a patented invention’s components:

(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

35 U.S.C. § 271(f).

II

Windows is designed, authored, and tested at Microsoft’s Redmond, Washington, headquarters. Microsoft sells Windows to end users and computer manufacturers, both foreign and domestic. Purchasing manufacturers install the software onto the computers they sell. Microsoft sends to each of the foreign manufacturers a master version of Windows, either on a disk or via encrypted electronic transmission. The manufacturer uses the master version to generate copies. Those copies, not the master sent by Microsoft, are installed on the foreign manufacturer’s computers. Once assembly is complete, the foreign-made computers are sold to users abroad.

AT&T’s patent (’580 patent) is for an apparatus (as relevant here, a computer) capable of digitally encoding and compressing recorded speech. Windows, the parties agree, contains software that enables a computer to process speech in the manner claimed by the ’580 patent. In 2001, AT&T filed an infringement suit in the United States District Court for the Southern

3. See also, *e.g.*, Patent Law Amendments of 1984, S. Rep. No. 98-663, pp. 2-3 (1984) (describing § 271(f) as “a response to the Supreme Court’s 1972 *DeepSouth* decision which interpreted the patent law not to make it infringement where the final assembly and sale is abroad”); Section-by-Section Analysis of H.R. 6286, 130 Cong. Rec. 28069 (1984) (“This proposal responds to the United States Supreme Court decision in *DeepSouth* . . . concerning the need for a legislative solution to close a loophole in [the] patent law.”).

District of New York, charging Microsoft with liability for domestic and foreign installations of Windows.

Neither Windows software (*e.g.*, in a box on the shelf) nor a computer standing alone (*i.e.*, without Windows installed) infringes AT&T's patent. Infringement occurs only when Windows is installed on a computer, thereby rendering it capable of performing as the patented speech processor. Microsoft stipulated that by installing Windows on its own computers during the software development process, it directly infringed the '580 patent. Microsoft further acknowledged that by licensing copies of Windows to manufacturers of computers sold in the United States, it induced infringement of AT&T's patent.

Microsoft denied, however, any liability based on the master disks and electronic transmissions it dispatched to foreign manufacturers, thus joining issue with AT&T. By sending Windows to foreign manufacturers, AT&T contended, Microsoft "supplie[d] . . . from the United States," for "combination" abroad, "components" of AT&T's patented speech processor; accordingly, AT&T urged, Microsoft was liable under § 271(f). Microsoft responded that unincorporated software, because it is intangible information, cannot be typed a "component" of an invention under § 271(f). In any event, Microsoft urged, the foreign-generated copies of Windows actually installed abroad were not "supplie[d] . . . from the United States." Rejecting these responses, the District Court held Microsoft liable under § 271(f). On appeal, a divided panel of the Court of Appeals for the Federal Circuit affirmed. We granted certiorari, and now reverse.

III

A

This case poses two questions: First, when, or in what form, does software qualify as a "component" under § 271(f)? Second, were "components" of the foreign-made computers involved in this case "supplie[d]" by Microsoft "from the United States"?⁷

As to the first question, no one in this litigation argues that software can *never* rank as a "component" under § 271(f). The parties disagree, however, over the stage at which software becomes a component. Software, the "set of instructions, known as code, that directs a computer to perform specified functions or operations," *Fantasy Sports Properties, Inc. v. Sportsline.com, Inc.*, 287 F. 3d 1108, 1118 (CA Fed. 2002), can be conceptualized in (at least) two ways. One can speak of software in the abstract: the instructions themselves detached from any medium. (An analogy: The notes of Beethoven's Ninth Symphony.) One can alternatively envision a tangible "copy" of software, the instructions encoded on a medium such as a CD-ROM. (Sheet music for Beethoven's Ninth.) AT&T argues that software in the abstract, not simply a particular copy of software, qualifies as a "component" under § 271(f).

7. The record leaves unclear which paragraph of § 271(f) AT&T's claim invokes. While there are differences between § 271(f)(1) and (f)(2), the parties do not suggest that those differences are outcome determinative. Cf. *infra*, at 14-15, n.16 (explaining why both paragraphs yield the same result). For clarity's sake, we focus our analysis on the text of § 271(f)(1).

Microsoft and the United States argue that only a copy of software, not software in the abstract, can be a component.⁸

The significance of these diverse views becomes apparent when we turn to the second question: Were components of the foreign-made computers involved in this case “supplie[d]” by Microsoft “from the United States”? If the relevant components are the copies of Windows actually installed on the foreign computers, AT&T could not persuasively argue that those components, though generated abroad, were “supplie[d] . . . from the United States” as § 271(f) requires for liability to attach.⁹ If, on the other hand, Windows in the abstract qualifies as a component within § 271(f)’s compass, it would not matter that the master copies of Windows software dispatched from the United States were not themselves installed abroad as working parts of the foreign computers.¹⁰

With this explanation of the relationship between the two questions in view, we further consider the twin inquiries.

B

First, when, or in what form, does software become a “component” under § 271(f)? We construe § 271(f)’s terms “in accordance with [their] ordinary or natural meaning.” *FDIC v. Meyer*, 510 U. S. 471, 476 (1994). Section 271(f) applies to the supply abroad of the “components of a patented invention, where *such components* are uncombined in whole or in part, in such manner as to actively induce the combination of *such components*.” § 271(f)(1) (emphasis added). The provision thus applies only to “such components”¹¹ as are combined to form the “patented invention” at issue. The patented invention here is AT&T’s speech-processing computer.

Until it is expressed as a computer-readable “copy,” *e.g.*, on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable. It cannot be inserted into a CD-ROM drive or downloaded from the Internet; it cannot be installed or executed on a computer. Abstract software code is an idea without physical embodiment, and as such, it does not match § 271(f)’s categorization: “components” amenable to “combination.” Windows abstracted from a tangible copy no doubt is information—a detailed set of instructions—and thus might be compared to a

8. Microsoft and the United States stress that to count as a component, the copy of software must be expressed as “object code.” “Software in the form in which it is written and understood by humans is called ‘source code.’ To be functional, however, software must be converted (or ‘compiled’) into its machine-usable version,” a sequence of binary number instructions typed “object code.” It is stipulated that object code was on the master disks and electronic transmissions Microsoft dispatched from the United States.

9. On this view of “component,” the copies of Windows on the master disks and electronic transmissions that Microsoft sent from the United States could not themselves serve as a basis for liability, because those copies were not installed on the foreign manufacturers’ computers. See § 271(f)(1) (encompassing only those components “combin[ed] . . . outside of the United States in a manner that would infringe the patent if such combination occurred within the United States”).

10. The Federal Circuit panel in this case, relying on that court’s prior decision in *Eolas Technologies Inc. v. Microsoft Corp.*, 399 F. 3d 1325 (2005), held that software qualifies as a component under § 271(f). We are unable to determine, however, whether the Federal Circuit panels regarded as a component software in the abstract, or a copy of software.

11. “Component” is commonly defined as “a constituent part,” “element,” or “ingredient.” Webster’s Third New International Dictionary of the English Language 466 (1981).

blueprint (or anything containing design information, *e.g.*, a schematic, template, or prototype). A blueprint may contain precise instructions for the construction and combination of the components of a patented device, but it is not itself a combinable component of that device. AT&T and its *amici* do not suggest otherwise. Cf. *Pellegrini v. Analog Devices, Inc.*, 375 F. 3d 1113, 1117-1119 (CA Fed. 2004) (transmission abroad of instructions for production of patented computer chips not covered by § 271(f)).

AT&T urges that software, at least when expressed as machine-readable object code, is distinguishable from design information presented in a blueprint. Software, unlike a blueprint, is “modular”; it is a stand-alone product developed and marketed “for use on many different types of computer hardware and in conjunction with many other types of software.” Software’s modularity persists even after installation; it can be updated or removed (deleted) without affecting the hardware on which it is installed. Software, unlike a blueprint, is also “dynamic.” After a device has been built according to a blueprint’s instructions, the blueprint’s work is done (as AT&T puts it, the blueprint’s instructions have been “exhausted.”). Software’s instructions, in contrast, are contained in and continuously performed by a computer. See also *Eolas Technologies Inc. v. Microsoft Corp.*, 399 F. 3d 1325, 1339 (CA Fed. 2005) (“[S]oftware code . . . drives the functional nucleus of the finished computer product.”)

The distinctions advanced by AT&T do not persuade us to characterize software, uncoupled from a medium, as a combinable component. Blueprints too, or any design information for that matter, can be independently developed, bought, and sold. If the point of AT&T’s argument is that we do not see blueprints lining stores’ shelves, the same observation may be made about software in the abstract: What retailers sell, and consumers buy, are *copies* of software. Likewise, before software can be contained in and continuously performed by a computer, before it can be updated or deleted, an actual, physical copy of the software must be delivered by CD-ROM or some other means capable of interfacing with the computer.¹²

Because it is so easy to encode software’s instructions onto a medium that can be read by a computer, AT&T intimates, that extra step should not play a decisive role under § 271(f). But the extra step is what renders the software a usable, combinable part of a computer; easy or not, the copy-producing step is essential. Moreover, many tools may be used easily and inexpensively to generate the parts of a device. A machine for making sprockets might be used by a manufacturer to produce tens of thousands of sprockets an hour. That does not make the machine a “component” of the tens of thousands of devices in which the sprockets are incorporated, at least not under any ordinary understanding of the term “component.” Congress, of course, might have included within § 271(f)’s compass, for example, not only combinable “components” of a patented invention, but also “information, instructions, or

12. The dissent, embracing AT&T’s argument, contends that, “unlike a blueprint that merely instructs a user how to do something, software actually causes infringing conduct to occur.” (Stevens, J., dissenting). We have emphasized, however, that Windows can “caus[e] infringing conduct to occur”—*i.e.*, function as part of AT&T’s speech-processing computer-only when expressed as a computer-readable copy. Abstracted from a usable copy, Windows code is intangible, uncombinable information, more like notes of music in the head of a composer than “a roller that causes a player piano to produce sound.” *Ibid.*

tools from which those components readily may be generated.” It did not. In sum, a copy of Windows, not Windows in the abstract, qualifies as a “component” under § 271(f).

C

The next question, has Microsoft “supplie[d] . . . from the United States” components of the computers here involved? Under a conventional reading of § 271(f)’s text, the answer would be “No,” for the foreign-made copies of Windows actually installed on the computers were “supplie[d]” from places outside the United States. The Federal Circuit majority concluded, however, that “for software ‘components,’ the act of copying is subsumed in the act of ‘supplying.’” 414 F. 3d, at 1370. A master sent abroad, the majority observed, differs not at all from the exact copies, easily, inexpensively, and swiftly generated from the master; hence “sending a single copy abroad with the intent that it be replicated invokes § 271(f) liability for th[e] foreign-made copies.” *Ibid.*; cf. (Stevens, J., dissenting) (“[A] master disk is the functional equivalent of a warehouse of components . . . that Microsoft fully expects to be incorporated into foreign-manufactured computers.”).

Judge Rader, dissenting, noted that “supplying” is ordinarily understood to mean an activity separate and distinct from any subsequent “copying, replicating, or reproducing-in effect manufacturing.” 414 F. 3d, at 1372-1373 (“[C]opying and supplying are separate acts with different consequences—particularly when the ‘supplying’ occurs in the United States and the copying occurs in Dusseldorf or Tokyo. As a matter of logic, one cannot supply one hundred components of a patented invention without first making one hundred copies of the component. . . .”). He further observed: “The only true difference between making and supplying software components and physical components [of other patented inventions] is that copies of software components are easier to make and transport.” *Id.*, at 1374. But nothing in § 271(f)’s text, Judge Rader maintained, renders ease of copying a relevant, no less decisive, factor in triggering liability for infringement. See *ibid.* We agree.

Section 271(f) prohibits the supply of components “from the United States . . . in such manner as to actively induce the combination of *such components*.” § 271(f)(1) (emphasis added). Under this formulation, the very components supplied from the United States, and not copies thereof, trigger § 271(f) liability when combined abroad to form the patented invention at issue. Here, as we have repeatedly noted, the copies of Windows actually installed on the foreign computers were not themselves supplied from the United States. Indeed, those copies did not exist until they were generated by third parties outside the United States. Copying software abroad, all might agree, is indeed easy and inexpensive. But the same could be said of other items: “Keys or machine parts might be copied from a master; chemical or biological substances might be created by reproduction; and paper products might be made by electronic copying and printing.” Section 271(f) contains no instruction to gauge when duplication is easy and cheap enough to deem a copy in fact made abroad nevertheless “supplie[d] . . . from the United States.” The absence of anything addressing copying in the statutory text weighs against a judicial determination that replication abroad of a master dispatched

from the United States “supplies” the foreign-made copies from the United States within the intendment of § 271(f).

D

Any doubt that Microsoft’s conduct falls outside § 271(f)’s compass would be resolved by the presumption against extraterritoriality, on which we have already touched. The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law. The traditional understanding that our patent law “operate[s] only domestically and d[oes] not extend to foreign activities,” is embedded in the Patent Act itself, which provides that a patent confers exclusive rights in an invention within the United States. 35 U.S.C. § 154(a)(1) (patentee’s rights over invention apply to manufacture, use, or sale “throughout the United States” and to importation “into the United States”). See *Deepsouth*, 406 U.S., at 531 (“Our patent system makes no claim to extraterritorial effect”; our legislation “d[oes] not, and [was] not intended to, operate beyond the limits of the United States, and we correspondingly reject the claims of others to such control over our markets.” (quoting *Brown*, 19 How., at 195)).

As a principle of general application, moreover, we have stated that courts should “assume that legislators take account of the legitimate sovereign interests of other nations when they write American laws.” *F. Hoffmann-La Roche Ltd v. Empagran S. A.*, 542 U.S. 155, 164 (2004). Thus, the United States accurately conveyed in this case: “Foreign conduct is [generally] the domain of foreign law,” and in the area here involved, in particular, foreign law “may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inventions.” Applied to this case, the presumption tugs strongly against construction of § 271(f) to encompass as a “component” not only a physical copy of software, but also software’s intangible code, and to render “supplie[d] . . . from the United States” not only exported copies of software, but also duplicates made abroad.

AT&T argues that the presumption is inapplicable because Congress enacted § 271(f) specifically to extend the reach of United States patent law to cover certain activity abroad. But as this Court has explained, “the presumption is not defeated . . . just because [a statute] specifically addresses [an] issue of extraterritorial application,” *Smith v. United States*, 507 U.S. 197, 204 (1993); it remains instructive in determining the *extent* of the statutory exception. See *Empagran*, 542 U.S., at 161-162, 164-165.

AT&T alternately contends that the presumption holds no sway here given that § 271(f), by its terms, applies only to domestic conduct, *i.e.*, to the supply of a patented invention’s components “from the United States.” § 271(f)(1). AT&T’s reading, however, “converts a single act of supply from the United States into a springboard for liability each time a copy of the software is subsequently made [abroad] and combined with computer hardware [abroad] for sale [abroad.]” Brief for United States as *Amicus Curiae* 29; see 414 F. 3d, at 1373, 1375 (Rader, J., dissenting). In short, foreign law alone, not United States law, currently governs the manufacture and sale of components of patented inventions in foreign countries. If AT&T desires to prevent copying in foreign countries, its remedy today lies in obtaining and enforcing foreign patents.

IV

AT&T urges that reading § 271(f) to cover only those copies of software actually dispatched from the United States creates a “loophole” for software makers. Liability for infringing a United States patent could be avoided, as Microsoft’s practice shows, by an easily arranged circumvention: Instead of making installation copies of software in the United States, the copies can be made abroad, swiftly and at small cost, by generating them from a master supplied from the United States. The Federal Circuit majority found AT&T’s plea compelling:

Were we to hold that Microsoft’s supply by exportation of the master versions of the Windows software—specifically for the purpose of foreign replication—avoids infringement, we would be subverting the remedial nature of § 271(f), permitting a technical avoidance of the statute by ignoring the advances in a field of technology-and its associated industry practices-that developed after the enactment of § 271(f). . . . Section § 271(f), if it is to remain effective, must therefore be interpreted in a manner that is appropriate to the nature of the technology at issue. 414 F. 3d, at 1371.

While the majority’s concern is understandable, we are not persuaded that dynamic judicial interpretation of § 271(f) is in order. The “loophole,” in our judgment, is properly left for Congress to consider, and to close if it finds such action warranted.

There is no dispute, we note again, that § 271(f) is inapplicable to the export of design tools—blueprints, schematics, templates, and prototypes—all of which may provide the information required to construct and combine overseas the components of inventions patented under United States law. We have no license to attribute to Congress an unstated intention to place the information Microsoft dispatched from the United States in a separate category.

Section 271(f) was a direct response to a gap in our patent law revealed by this Court’s *Deepsouth* decision. The facts of that case were undeniably at the fore when § 271(f) was in the congressional hopper. In *Deepsouth*, the items exported were kits containing all the physical, readily assemblable parts of a shrimp deveining machine (not an intangible set of instructions), and those parts themselves (not foreign-made copies of them) would be combined abroad by foreign buyers. Having attended to the gap made evident in *Deepsouth*, Congress did not address other arguable gaps: Section 271(f) does not identify as an infringing act conduct in the United States that facilitates making a component of a patented invention outside the United States; nor does the provision check “suppl[ying] . . . from the United States” information, instructions, or other materials needed to make copies abroad. Given that Congress did not home in on the loophole AT&T describes, and in view of the expanded extraterritorial thrust AT&T’s reading of § 271(f) entails, our precedent leads us to leave in Congress’ court the patent-protective determination AT&T seeks.

Congress is doubtless aware of the ease with which software (and other electronic media) can be copied, and has not left the matter untouched. In 1998, Congress addressed “the ease with which pirates could copy and distribute a copyrightable work in digital form.” *Universal City Studios, Inc. v. Corley*, 273 F. 3d 429, 435 (CA2 2001). The resulting measure, the Digital Millennium Copyright Act, 17 U.S.C. § 1201 *et seq.*, “backed with legal

sanctions the efforts of copyright owners to protect their works from piracy behind digital walls such as encryption codes or password protections.” *Universal City Studios*, 273 F. 3d, at 435. If the patent law is to be adjusted better “to account for the realities of software distribution,” 414 F. 3d, at 1370, the alteration should be made after focused legislative consideration, and not by the Judiciary forecasting Congress’ likely disposition.

For the reasons stated, the judgment of the Court of Appeals for the Federal Circuit is reversed.

Justice STEVENS, dissenting.

As the Court acknowledges, “[p]lausible arguments can be made for and against extending § 271(f) to the conduct charged in this case as infringing AT&T’s patent.” Strong policy considerations, buttressed by the presumption against the application of domestic patent law in foreign markets, support Microsoft Corporation’s position. I am, however, persuaded that an affirmation of the Court of Appeals’ judgment is more faithful to the intent of the Congress that enacted § 271(f) than a reversal.

The provision was a response to our decision in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U. S. 518 (1972), holding that a patent on a shrimp deveining machine had not been infringed by the export of components for assembly abroad. Paragraph (1) of § 271(f) would have been sufficient on its own to overrule *Deepsouth*, but it is paragraph (2) that best supports AT&T’s position here. It provides:

Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

§ 271(f)(2).

Under this provision, the export of a specially designed knife that has no use other than as a part of a patented deveining machine would constitute infringement. It follows that § 271(f)(2) would cover the export of an inventory of such knives to be warehoused until used to complete the assembly of an infringing machine.

The relevant component in this case is not a physical item like a knife. Both Microsoft and the Court think that means it cannot be a “component.” But if a disk with software inscribed on it is a “component,” I find it difficult to understand why the most important ingredient of that component is not also a component. Indeed, the master disk is the functional equivalent of a warehouse of components—components that Microsoft fully expects to be incorporated into foreign-manufactured computers. Put somewhat differently: On the Court’s view, Microsoft could be liable under § 271(f) only if it sends individual copies of its software directly from the United States with the intent that each copy would be incorporated into a separate infringing computer. But it seems to me that an indirect transmission via a master disk warehouse is likewise covered by § 271(f).

I disagree with the Court's suggestion that because software is analogous to an abstract set of instructions, it cannot be regarded as a "component" within the meaning of § 271(f). Whether attached or detached from any medium, software plainly satisfies the dictionary definition of that word. See *ante*, at 9, n. 11 (observing that "[c]omponent" is commonly defined as 'a constituent part,' 'element,' or 'ingredient'). And unlike a blueprint that merely instructs a user how to do something, software actually causes infringing conduct to occur. It is more like a roller that causes a player piano to produce sound than sheet music that tells a pianist what to do. Moreover, it is surely not "a staple article or commodity of commerce suitable for substantial noninfringing use" as that term is used in § 271(f)(2). On the contrary, its sole intended use is an infringing use.

I would therefore affirm the judgment of the Court of Appeals.

Comments

1. ***Patent Rights Are Territorial.*** There is no such thing as a worldwide patent. To say that patent rights are territorial means that "the right conferred by a patent under [U.S.] is confined to the United States and its Territories." Accordingly, "infringement of this right cannot be predicated [on] acts wholly done in a foreign country." *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 650 (1915). The *Microsoft* Court placed particular emphasis on the territoriality aspect of patent rights:

Any doubt that Microsoft's conduct falls outside § 271(f)'s compass would be resolved by the presumption against extraterritoriality. . . . The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law. The traditional understanding that our patent law "operate[s] only domestically and d[oes] not extend to foreign activities," is embedded in the Patent Act itself, which provides that a patent confers exclusive rights in an invention within the United States. 35 U. S. C. § 154(a)(1).

2. ***Federal Circuit's View of § 271(f) Prior to Microsoft.*** In recent years, § 271(f) has been the subject of a small, but important group of cases. In *Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113 (Fed. Cir. 2004), for example, the patent related to brushless motor drive circuits that used integrated circuit chips. It was undisputed that the accused infringer, Analog, manufactured and sold the circuit chips outside the United States. The chips in question—the ADCMC chips—were manufactured in Ireland by two independent contractors hired by Analog in Taiwan. Also, most of the chips were shipped and sold to customers outside the U.S. Pellegrini sued Analog for direct and indirect infringement, asserting that certain claims of its patent read on a combination of ADCMC chips and other components in brushless motors. The district court granted Analog's motion for summary judgment of non-infringement because U.S. patent laws do not have extraterritorial effect. The court rejected Pellegrini's argument that, because Analog's headquarters are located in the United States and instructions for the production and disposition of the ADCMC chips emanate from the United States, the chips should be regarded

as having been “supplie[d] or cause[d] to be supplied in or from the United States” and Analog should be liable as an infringer under 35 U.S.C. § 271(f)(1).

The Federal Circuit affirmed the district court, and characterized the issue—one of first impression—as “whether components that are manufactured outside the United States and never physically shipped to or from the United States may nonetheless be “supplie[d] or cause[d] to be supplied in or from the United States” within the meaning of 35 U.S.C. § 271(f)(1) if those components are designed within the United States and the instructions for their manufacture and disposition are transmitted from within the United States.” *Id.* at 1115-16. According to the court, § 271(f) was inapplicable because “Analog did not make, use, sell, or offer to sell ADMC products in the United States, and it did not import ADMC products into the United States. Analog also does not supply ADMC chips in or from the United States, and does not cause ADMC chips to be supplied in or from the United States.” *Id.* at 1118. The court wrote:

§ 271(f) applies only where components of a patent invention are physically present in the United States and then either sold or exported “in such a manner as to actively induce the combination of such components outside the United States in a manner that would infringe the patent if such combination occurred within the United States.” . . . The plain language of § 271(f)(1) focuses on the location of the accused components, not the accused infringer. Pellegrini contends that it is irrelevant that the chips within the scope of the partial summary judgment never enter the United States, because to impose a location requirement would lead to a “seemingly contradictory construction of § 271(f)(1).” According to Pellegrini, “it is difficult to understand how the combination of such components outside the United States can occur if they are inside the United States.” However, the language of § 271(f) clearly contemplates that there must be an intervening sale or exportation; there can be no liability under § 271(f)(1) unless components are shipped from the United States for assembly.

Id. at 1117.

Pellegrini was distinguished in *Eolas Techs., Inc. v. Microsoft Corp.*, 399 F.3d 1325 (Fed. Cir. 2005), which seemingly eliminated the physicality requirement under § 271(f) as interpreted by *Pellegrini*. The *Eolas* case is factually similar to *Microsoft v. AT&T*. In *Eolas*, the licensee sued Microsoft under § 271(f)(1) based on Microsoft’s export to foreign manufactures of its “golden master” disks that contained code for Windows. The code was replicated by the foreign manufactures outside of the U.S. and, as in *AT&T*, the master disk did not form a physical part of infringing product. The court held Microsoft infringed. The court stated “*Pellegrini* requires only that components are physically *supplied* from the United States,” implying that what is actually shipped (*i.e.*, the components themselves) need not be tangible or physical. Needless to say, the reasoning and holding in *Eolas* is now dubious in the light of *Microsoft v. AT&T*.

The *Eolas* case was applied in *Union Carbide v. Shell*, 425 F.3d 1366 (Fed. Cir. 2005). In *Union Carbide*, Federal Circuit held that Shell’s exportation of a catalyst used outside the United States to facilitate the practice of Union Carbide’s patented process was an infringing act under § 271(f). The court was again had to interpret “any component of a patented

invention” in § 271(f) and decide whether this phrase applies “to components used in the performance of patented process/method inventions.” *Id.* at 1378-79. The court held that it does, noting § 271(f) “makes no distinction between patentable method/process inventions and other forms of patentable inventions.” *Id.* at 1379. As in *Eolas*, the court interpreted the statutory language “any component of a patented invention” to mean “every component of every form of invention deserves the protection of 35 U.S.C. § 271(f); *i.e.*, that “components” and “patented inventions” under § 271(f) are not limited to physical machines.” *Id.* (emphasis in original). Indeed, the court found *Eolas* directly on point:

In *Eolas*, Microsoft exported a master computer disc with program code that caused a computer to perform various method steps. Thus, both this case and *Eolas* feature the exportation of a component (*i.e.*, a computer disc with program code in *Eolas* and a catalyst in this case) used in the performance of a patented process or method (*i.e.*, the method steps executed by the computer in response to the computer readable program code in *Eolas* and the commercial production of EO in this case). In that setting, *Eolas* applied § 271(f) to Microsoft’s exported component. Similarly, § 271(f) applies to Shell’s exportation of catalysts (*i.e.*, a “component”) used in the commercial production of EO abroad (*i.e.*, a “patented invention”).

The facts in *Union Carbide* provided a stronger basis for application of § 271(f) than in *Eolas*, because in *Union Carbide* Shell supplied all of its catalysts from the United States directly to foreign affiliates, and these affiliates did not copy the catalysts and use the copies in a foreign process; instead the catalysts supplied by Shell were used directly in their processes. Recall, Microsoft’s golden master disk did not end up as a physical part of an infringing product.

The *Union Carbide* court also discussed the *RIM* case, and explained why § 271(f) did not apply to RIM’s activities. The court stated that “it is clear that RIM’s supply of the BlackBerry handheld devices and Redirector products to its customers in the United States is not the statutory ‘supply’ of any ‘component’ steps for combination into NTP’s patented methods.” 418 F.3d at 1322. Unlike Shell, RIM did not supply any component to a foreign affiliate. Thus, according to the court, “NTP is different from [*Union Carbide*] because Shell supplies catalysts from the United States directly to foreign customers,” and therefore, because “Shell supplies these catalysts directly to its foreign affiliates, this court does not face another situation involving the domestic sale of a component being used, in part, outside the United States.”

3. **§ 271(f) at the Supreme Court.** The Supreme Court addressed two questions in *Microsoft v. AT&T*: Was the software a “component” under § 271(f), and, were “components” of a foreign-made computer “supplied” by Microsoft “from the United States.”

In interpreting the term “components” in § 271, the Court noted that the statute refers to components that are combined to form the patented invention, which is AT&T’s speech-processing computer. As such, “[u]ntil [the software] is expressed as a computer-readable ‘copy,’ *e.g.*, on a CD-ROM, Windows software—indeed any software detached from an activating medium—remains uncombinable.” The Court also rejected

AT&T's argument that "[b]ecause it is so easy to encode software's instructions onto a medium that can be read by a computer, that extra step should not play a decisive role under § 271(f)." But, wrote the Court, the extra step is what renders the software a usable, combinable part of a computer; easy or not." In short, "copy-producing step is essential." Justice Stevens, in his dissent, was not persuaded of the importance of "copy-producing step." For him, "if a disk with software inscribed on it is a 'component,' I find it difficult to understand why the most important ingredient of that component is not also a component." That the majority opinion was too formalistic was implicit in Justice Stevens's dissent. As he wrote, liability under § 271(f) would attached only if Microsoft "sends individual copies of its software directly from the United States with the intent that each copy would be incorporated into a separate infringing computer."

In addressing whether Microsoft "supplied" components, the Court refused to read § 271(f) expansively. For example, the Court expressly rejected the "easy" to copy argument, stating "[s]ection 271(f) contains no instruction to gauge when duplication is easy and cheap enough to deem a copy in fact made abroad nevertheless 'supplie[d]' . . . from the United States." This reasoning eschews, absent Congressional intervention, a technology-specific approach to patent law, at least with regard to § 271(f). In an exercise of judicial restraint, the Court stated "[o]ur decision leaves to Congress' informed judgment any adjustment of § 271(f) it deems necessary or proper."

The Court's reading of § 271(f) permits a U.S. producer to evade liability by shipping components abroad to have them copied, and thereafter have the copies used or installed by a foreign entity to create another product. But lurking behind the legal issues and questions of statutory construction, was whether an affirmation of the Federal Circuit would induce software companies (and companies in other industries) to move their manufacturing facilities outside the United States. This argument was raised in the briefs, including amici briefs. In addition, *Microsoft* also highlights the importance of obtaining foreign patent protection; § 271(f) can be circumvented if the actual production occurs abroad, even though the product design occurred in the U.S. or if instructions on how to produce the product were shipped from the United States. Perhaps the lack of patent protection in Europe reflects the less than sympathetic environment in Europe vis-à-vis the United States for software patents.

4. **§ 271(f)'s Structure.** Sections 271(f)(1) and (2) mirror the inducement and contributory infringement provisions of § 271(b) and (c), respectively. For example, § 271(f)(1) reads, in relevant part, "[w]hoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention . . . in such a manner as to actively induce the combination of such components" resulting in infringement "shall be liable as an infringer." And § 271(f)(2) reads, in relevant part, "[w]hoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention that is especially made or especially adapted for use in the invention and not a staple article . . . suitable for substantial non-infringement use . . . knowing that such component is so

made or adapted and intending that such component will be combined outside the United States” resulting in infringement “shall be liable as an infringer.” Thus, § 271(f)(2), like § 271(c), has an intent component.

Section 271(f), as discussed in *Microsoft*, was a direct response to the Supreme Court case of *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972). See Comment 2 after the *RIM* case on page 539. But contributory infringement can be found only if there is direct infringement, which did not exist in *Deepsouth* because the manufacture and use was outside the United States.

3. The Parameters of § 271(g): Import Activity

It is an act of infringement to import a patented product into the United States. Under § 271(g), it is also an act of infringement to import an unpatented product into the United States if that product was “made by” a patented process—even though the process was practiced outside of the United States. This form of importation became an infringing act only after the enactment of the Patent Process Amendments Act of 1988, which became effective of February 23, 1989. There are important conditions associated with this right. For instance, the imported, unpatented product must be “made by” the patented process. According to § 271(g), “[a] product which is made by a patented process will . . . not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.” The *Eli Lilly* case explores the phrase “materially changed.”

ELI LILLY & CO. v. AMERICAN CYANAMID CO.

82 F.3d 1568 (Fed. Cir. 1996)

BRYSON, Circuit Judge.

The ongoing struggle between “pioneer” drug manufacturers and generic drug distributors has once more come before our court. Eli Lilly and Company (Lilly), the “pioneer” drug manufacturer in this case, has filed suit for patent infringement against the appellees, who are involved in various ways in the distribution of a particular generic drug. Lilly sought a preliminary injunction, arguing that the importation and sale of the generic drug in this country infringed Lilly’s patent on a process for making a related compound. After a hearing, the United States District Court for the Southern District of Indiana denied Lilly’s request for a preliminary injunction. The court found that Lilly had failed to show that it was likely to prevail on the merits of its infringement claim and had failed to show that it would suffer irreparable harm in the absence of preliminary injunctive relief. *Eli Lilly & Co. v. American Cyanamid Co.* Because Lilly has failed to overcome the substantial hurdle faced by a party seeking to overturn the denial of a preliminary injunction, we affirm.

I

The pharmaceutical product at issue in this case is a broad-spectrum antibiotic known as “cefactor.” Cefactor is a member of the class of cephalosporin

antibiotics, all of which are based on the cephem nucleus. Although there are many different cephem compounds, only a few have utility as antibiotic drugs. Each of the known commercial methods for producing cefaclor requires the production of an intermediate cephem compound known as an enol. Once the desired enol cephem intermediate is obtained, it is then subjected to several processing steps in order to produce cefaclor.

A

Lilly developed cefaclor and patented it in 1975. Until recently, Lilly has been the exclusive manufacturer and distributor of cefaclor in this country. In addition to its product patent on cefaclor, Lilly obtained several patents covering different aspects of the manufacture of cefaclor, including processes for producing enol cephem intermediates. Many of those patents have now expired.

In 1995, Lilly purchased the patent at issue in this case, U.S. Patent No. 4,160,085 (the '085 patent). Claim 5 of that patent defines a method of producing enol cephem compounds, including what is called "compound 6," an enol cephem similar to the one Lilly uses in its process for manufacturing cefaclor. The '085 patent will expire on July 3, 1996.

Compound 6 differs from cefaclor in three respects. Although both compound 6 and cefaclor are based on the cephem nucleus, compound 6 has a hydroxy group at the 3-position on the cephem nucleus, a para-nitrobenzyl carboxylate ester at the 4-position, and a phenylacetyl group at the 7-position. Cefaclor has different groups at each of those positions: it has a chlorine atom at the 3-position, a free carboxyl group at the 4-position, and a phenylglycyl group at the 7-position. Each of those differences between compound 6 and cefaclor contributes to the effectiveness of cefaclor as an orally administered antibiotic drug. The free carboxyl group at the 4-position is believed important for antibacterial activity; the chlorine increases cefaclor's antibiotic potency; and the phenylglycyl group enables cefaclor to be effective when taken orally.

To produce cefaclor from compound 6 requires four distinct steps. First, the hydroxy group is removed from the 3-position and is replaced by a chlorine atom, which results in the creation of "compound 7." Second, compound 7 is subjected to a reaction that removes the phenylacetyl group at the 7-position, which results in the creation of "compound 8." Third, a phenylglycyl group is added at the 7-position, which results in the creation of "compound 9." Fourth, the para-nitrobenzyl carboxylate ester is removed from the 4-position, which results in the creation of cefaclor.

B

On April 27, 1995, defendants Zenith Laboratories, Inc. (Zenith) and American Cyanamid Company (Cyanamid) obtained permission from the Food and Drug Administration to distribute cefaclor in this country. Defendant Biocraft Laboratories, Inc. (Biocraft) had applied for FDA approval to manufacture and sell cefaclor in the United States but had not yet obtained that approval. All three have obtained large quantities of cefaclor that were manufactured in Italy by defendant Biochimica Opos, S.p.A. (Opos).

On the same day that Zenith and Cyanamid obtained FDA approval to sell cefaclor in this country, Lilly obtained the rights to the '085 patent and filed suit against Zenith, Cyanamid, Biocraft, and Opos. In its complaint, Lilly sought a declaration that the domestic defendants' importation of cefaclor manufactured by Opos infringed Lilly's rights under several patents, including the '085 patent. Lilly also requested a preliminary injunction, based on the alleged infringement of claim 5 of the '085 patent, to bar the defendants from importing or inducing the importation of cefaclor manufactured by Opos.

The district court held a three-day hearing on the motion for a preliminary injunction. Following the hearing, the court denied the motion in a comprehensive opinion. The court devoted most of its attention to the question whether Lilly had met its burden of showing that it was likely to prevail on the merits of its claim that the defendants were liable for infringing claim 5 of the '085 patent.

Based on the evidence presented at the hearing, the district court concluded that Lilly had shown that it was likely to prevail on the issue of the validity of the '085 patent. With respect to the infringement issue, however, the court held that Lilly had not met its burden of showing that it was likely to prevail.

The district court correctly framed the issue as whether, under the Process Patent Amendments Act of 1988, Pub. L. No. 100-418, §§ 9001-07, the importers of cefaclor infringed claim 5 of the '085 patent, which granted U.S. patent protection to the process that Opos used to make compound 6. The Process Patent Amendments Act makes it an act of infringement to import, sell, offer to sell, or use in this country a product that was made abroad by a process protected by a U.S. patent. 35 U.S.C. § 271(g). The Act, however, does not apply if the product made by the patented process is "materially changed by subsequent processes" before it is imported. 35 U.S.C. § 271(g)(1).

The district court found that compound 6 and cefaclor differ significantly in their structure and properties, including their biological activity. Citing the Senate Report on the Process Patent Amendments Act, the district court found that, because the processing steps necessary to convert compound 6 to cefaclor "change the physical or chemical properties of the product in a manner which changes the basic utility of the product," 896 F. Supp. at 857 (citing S. Rep. No. 83, 100th Cong., 1st Sess. 50 (1987)), Lilly was not likely to succeed on its claim that the defendants infringed Lilly's rights under claim 5 of the '085 patent by importing and selling cefaclor.

The district court also found that Lilly had failed to prove that it would suffer irreparable harm in the absence of a preliminary injunction. The presumption of irreparable harm that is available when a patentee makes a strong showing of likelihood of success on the merits was not available here, the court held, because of Lilly's failure to make such a showing on the issue of infringement. In addition, the court was not persuaded by Lilly's arguments that it faced irreparable economic injury if it were not granted immediate equitable relief. Under the circumstances of this case, the district court found that an award of money damages would be an adequate remedy in the event that Lilly ultimately proves that the importation of cefaclor made by the Opos process infringes the '085 patent. In light of Lilly's failure to establish either a

likelihood of success on the merits or irreparable harm, the court found it unnecessary to articulate findings regarding the other factors bearing on the propriety of preliminary injunctive relief—the balance of the hardships and the effect of the court’s action on the public interest.

II

The Process Patent Amendments Act of 1988 was enacted to close a perceived loophole in the statutory scheme for protecting owners of United States patents. Prior to the enactment of the 1988 statute, a patentee holding a process patent could sue for infringement if others used the process in this country, but had no cause of action if such persons used the patented process abroad to manufacture products, and then imported, used, or sold the products in this country. In that setting, the process patent owner’s only legal recourse was to seek an exclusion order for such products from the International Trade Commission under section 337a of the Tariff Act of 1930, 19 U.S.C. § 1337a (1982). By enacting the Process Patent Amendments Act, the principal portion of which is codified as 35 U.S.C. § 271(g), Congress changed the law by making it an act of infringement to import into the United States, or to sell or use within the United States “a product which is made by a process patented in the United States . . . if the importation, sale, or use of the product occurs during the term of such process patent.”

A concern raised during Congress’s consideration of the process patent legislation was whether and to what extent the new legislation would affect products other than the direct and unaltered products of patented processes—that is, whether the new statute would apply when a product was produced abroad by a patented process but then modified or incorporated into other products before being imported into this country. Congress addressed that issue by providing that a product that is “made by” a patented process within the meaning of the statute “will . . . not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.” 35 U.S.C. § 271(g).

That language, unfortunately, is not very precise. Whether the product of a patented process is a “trivial and nonessential component” of another product is necessarily a question of degree. Even less well defined is the question whether the product of a patented process has been “materially changed” before its importation into this country. While applying that statutory language may be relatively easy in extreme cases, it is not at all easy in a closer case such as this one.

A

Lilly argues that the “materially changed” clause of section 271(g) must be construed in light of its underlying purpose, which is to protect the economic value of U.S. process patents to their owners. Prior to the enactment of the Process Patent Amendments Act, the value of a U.S. process patent could be undermined by a manufacturer who used the process abroad and then imported the product into this country. Because the purpose of the process patent legislation was to protect against such subversion of protected economic rights, Lilly argues that the statute should be read to apply to any such

scheme that undercuts the commercial value of a U.S. process patent. In Lilly's view, the product of a patented process therefore should not be considered "materially changed" if the principal commercial use of that product lies in its conversion into the product that is the subject of the infringement charge. Because cefaclor is the only product of compound 6 that is sold in the United States market, Lilly argues, the change in compound 6 that results in cefaclor—no matter how significant as a matter of chemical properties or molecular structure—is not a "material change" for purposes of section 271(g).

Although we are not prepared to embrace Lilly's argument, we acknowledge that it has considerable appeal. Congress was concerned with the problem of the overseas use of patented processes followed by the importation of the products of those processes, and a grudging construction of the statute could significantly limit the statute's effectiveness in addressing the problem Congress targeted. That is especially true with respect to chemical products, as to which simple, routine reactions can often produce dramatic changes in the products' structure and properties.

Nonetheless, while the general purpose of the statute informs the construction of the language Congress chose, purpose cannot displace language, and we cannot stretch the term "materially changed" as far as Lilly's argument would require. The problem is that the language of the statute refers to changes in the product; the statute permits the importation of an item that is derived from a product made by a patented process as long as that product is "materially changed" in the course of its conversion into the imported item. The reference to a "changed" product is very hard to square with Lilly's proposed test, which turns on the quite different question of whether the use or sale of the imported item impairs the economic value of the process patent.

The facts of this case demonstrate how far Lilly's test strays from the statutory text. While Lilly notes that there are only four steps between compound 6 and cefaclor, and that all four steps involve relatively routine chemical reactions, Lilly does not suggest any limiting principle based on the structure of the intermediate product or the nature of the steps necessary to produce the imported product. Thus, even if there were ten complex chemical reactions that separated compound 6 from cefaclor, Lilly's test would characterize the two compounds as not "materially" different as long as the primary commercial use of compound 6 in this country was to produce cefaclor.

Besides not responding to the natural meaning of the term "changed," Lilly's construction of the "materially changed" clause would create a curious anomaly. Lilly's value-based construction of the clause turns in large measure on Lilly's contention that the only commercial use for compound 6 in this country is to produce cefaclor; that is, Lilly views compound 6 and cefaclor as essentially the same product because compound 6 has no commercial use in the U.S. market except to produce cefaclor. Under that approach, however, the question whether compound 6 was "materially changed" in the course of its conversion to cefaclor would depend on whether and to what extent other derivative products of compound 6 are marketed in this country. Thus, under Lilly's theory compound 6 would become materially different from cefaclor if and when compound 6 came to have other commercial uses in the United States, even though the respective structures and properties of the two compounds remained unchanged.

That is asking the statutory language to do too much work. We cannot accept the argument that the question whether one compound is “materially changed” in the course of its conversion into another depends on whether there are other products of the first compound that have economic value. We therefore do not adopt Lilly’s proposed construction of section 271(g). We look instead to the substantiality of the change between the product of the patented process and the product that is being imported.

In the chemical context, a “material” change in a compound is most naturally viewed as a significant change in the compound’s structure and properties. Without attempting to define with precision what classes of changes would be material and what would not, we share the district court’s view that a change in chemical structure and properties as significant as the change between compound 6 and cefaclor cannot lightly be dismissed as immaterial. Although compound 6 and cefaclor share the basic cephem nucleus, which is the ultimate source of the antibiotic potential of all cephalosporins, the cephem nucleus is common to thousands of compounds, many of which have antibiotic activity, and many of which are dramatically different from others within the cephem family. Beyond the cephem nucleus that they have in common, compound 6 and cefaclor are different in four important structural respects, corresponding to the four discrete chemical steps between the two compounds. While the addition or removal of a protective group, standing alone, might not be sufficient to constitute a “material change” between two compounds (even though it could dramatically affect certain of their properties), the conversion process between compound 6 and cefaclor involves considerably more than the removal of a protective group. We therefore conclude that the statutory text of section 271(g) does not support Lilly’s contention that it is likely to prevail on the merits of its infringement claim.

B

In aid of their differing approaches to the issue of statutory construction, both sides in this dispute seek support for their positions in the legislative history of the 1988 statute. As is often the case, there is something in the legislative history for each side. On Lilly’s side, for example, are characterizations of the legislation as creating process patent protection that is “meaningful and not easily evaded,” H.R. Rep. No. 60, 100th Cong., 1st Sess. 13 (1987), and as excluding products only if they “cease to have a reasonable nexus with the patented process,” S. Rep. No. 83, 100th Cong., 1st Sess. 36 (1987). On the other side are directions for applying the statute to chemical intermediates—directions that suggest a narrower construction of the statute than Lilly proposes. On balance, while we do not find the legislative history dispositive, we conclude that it does not unequivocally favor Lilly’s position and thus does not raise doubts about the district court’s statutory analysis as applied to the facts of this case.

* * *

RADER, Circuit Judge, concurring.

I depart from the court’s reasoning and conclusion about the “material change” standard under 35 U.S.C. § 271(g).

I

The court's majority places great emphasis on the legislative history to resolve the meaning of "material change"—a curious approach given its recognition that the legislative history contains "something . . . for each side." The enactment history is far from dispositive in this case. The record of the enactment of this provision evinces a bitter battle between the pharmaceutical industry and its generic industry competitors.

* * *

II

Sadly this decision will create another massive loophole in the protection of patented processes. This decision will, in effect, deny protection to holders of process patents on intermediates as opposed to "final" products. This decision denies protection to a patented process anytime it is not the only way to make an intermediate, even if it is the most economically efficient way to produce the intermediate.

In view of the purpose of the statute, compound 6 and cefaclor are essentially the same product. Compound 6 has no commercial use in the U.S. market except to make cefaclor. The patented process is thus in use to make compound 6—a product only four simple, well-known steps from cefaclor. The record shows no other current commercial use of compound 6. Rather than attempting to distill an elixir from this intoxicating witches brew of enactment history, this court should interpret "material change" consistent with the overriding purpose of the Act—to provide protection to process patent holders. With its eye firmly fixed on the purpose of the Act, this court would avoid eliminating processes for intermediates from the protections of the 1988 Act.

Comment

1. *Why Was the PPAA Needed?* Process patents—particularly in certain industries such as biotechnology and pharmaceutical—are not without economic value. This fact was reflected in the following memorandum, which also nicely captures the rationale for enacting the PPAA:

The extension (to product of the process) seems to be an exception to the principle that the protection conferred by a patent or another title of protection for an invention is defined by the object of the invention. In the case of a process invention, a strict application of the said principle would mean that the owner of a process patent could only exclude others from using the patented process. The legal provisions which extend process protection to products obtained by the patented process are based on practical economic considerations. A process which leads to a specific product presents an economic value only through the product. However, it is not always possible to obtain a patent for the product; for example, the product may not be new or may—although new—lack inventive step [i.e., the invention is obvious]. The invention of a new and inventive process for the production of such a product which is not patentable constitutes an important technological advance but the reward granted through a process patent is not important because—without an extension to the product—the process patent would be difficult to enforce (since infringement of the process is difficult to prove) and could even

be circumvented by use of the process in another country where the process is not protected. In order to make patent protection of a process meaningful, it is therefore necessary to consider the patented process and the resulting product as a whole, with the consequence that process protection is automatically extended to the resulting product even if the said product has not been claimed.

S. Rep. No.100-83, at 30-31.

D. JURISDICTION, VENUE, AND STANDING

1. Federal Circuit Subject Matter Jurisdiction

The jurisdiction of the Federal Circuit is governed by two statutes, 28 U.S.C. §§ 1295 and 1338. The latter applies to district court jurisdiction, and states (emphasis added):

The district courts shall have original jurisdiction of *any civil action arising under any Act of Congress relating to patents*, plant variety protection, copyrights and trade-marks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

Section 1295 vests the Federal Circuit with jurisdiction over an appeal from a district court “if the jurisdiction of [the district court] was based, in whole or in part, on Section 1338.” Thus, the Federal Circuit’s jurisdiction depends upon the district court’s jurisdiction. *See Atari, Inc. v. JS & A Group, Inc.*, 747 F.2d 1422, 1430 (Fed. Cir. 1984) (stating Federal Circuit’s jurisdiction “is defined by the basis of the district court jurisdiction”) (emphasis in original).

Not every dispute involving a patent is an action “arising under” the patent laws. *Id.* at 1429 (noting “a mere allegation that patent law is involved will not give [the Federal Circuit] jurisdiction when that of the district court did not rest at least in part on a continuing claim arising under” the patent laws). Therefore, the question is: When does a civil action arise under an “Act of Congress relating to patents” as set forth in § 1338? The principal case of *Holmes Group* addresses this question.

HOLMES GROUP, INC. v. VORNADO AIR CIRCULATION SYSTEMS, INC.

535 U.S. 826 (2002)

Justice SCALIA delivered the opinion of the Court.

In this case, we address whether the Court of Appeals for the Federal Circuit has appellate jurisdiction over a case in which the complaint does not allege a claim arising under federal patent law, but the answer contains a patent-law counterclaim.

I

Respondent, Vornado Air Circulation Systems, Inc., is a manufacturer of patented fans and heaters. In late 1992, respondent sued a competitor,

Duracraft Corp., claiming that Duracraft's use of a "spiral grill design" in its fans infringed respondent's trade dress. The Court of Appeals for the Tenth Circuit found for Duracraft, holding that Vornado had no protectable trade-dress rights in the grill design.

Nevertheless, on November 26, 1999, respondent lodged a complaint with the United States International Trade Commission against petitioner, The Holmes Group, Inc., claiming that petitioner's sale of fans and heaters with a spiral grill design infringed respondent's patent and the same trade dress held unprotectable in *Vornado I*. Several weeks later, petitioner filed this action against respondent in the United States District Court for the District of Kansas, seeking, *inter alia*, a declaratory judgment that its products did not infringe respondent's trade dress and an injunction restraining respondent from accusing it of trade-dress infringement in promotional materials. Respondent's answer asserted a compulsory counterclaim alleging patent infringement.

The District Court granted petitioner the declaratory judgment and injunction it sought. [The court] rejected respondent's contention that an intervening Federal Circuit case, *Midwest Industries, Inc. v. Karavan Trailers, Inc.*, which disagreed with the Tenth Circuit's reasoning in *Vornado I*. The court also stayed all proceedings related to respondent's counterclaim, adding that the counterclaim would be dismissed if the declaratory judgment and injunction entered in favor of petitioner were affirmed on appeal.

Respondent appealed to the Court of Appeals for the Federal Circuit. Notwithstanding petitioner's challenge to its jurisdiction, the Federal Circuit vacated the District Court's judgment.

We granted certiorari to consider whether the Federal Circuit properly asserted jurisdiction over the appeal.

II

Congress vested the Federal Circuit with exclusive jurisdiction over "an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on [28 U.S.C. §] 1338. . . ." 28 U.S.C. § 1295(a)(1) (emphasis added). Section 1338(a), in turn, provides in relevant part that "[t]he district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . ." Thus, the Federal Circuit's jurisdiction is fixed with reference to that of the district court, and turns on whether the action arises under federal patent law.¹

Section 1338(a) uses the same operative language as 28 U.S.C. § 1331, the statute conferring general federal-question jurisdiction, which gives the district courts "original jurisdiction of all civil actions *arising under* the Constitution, laws, or treaties of the United States." (Emphasis added.) We said in *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 808 (1988), that "[l]inguistic consistency" requires us to apply the same test to determine whether a case arises under § 1338(a) as under § 1331.

1. Like *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 814-815 (1988), this case does not call upon us to decide whether the Federal Circuit's jurisdiction is fixed with reference to the complaint as initially filed or whether an actual or constructive amendment to the complaint raising a patent-law claim can provide the foundation for the Federal Circuit's jurisdiction.

The well-pleaded-complaint rule has long governed whether a case “arises under” federal law for purposes of § 1331. As “appropriately adapted to § 1338(a),” the well-pleaded-complaint rule provides that whether a case “arises under” patent law “must be determined from what necessarily appears in the plaintiff’s statement of his own claim in the bill or declaration. . . .” *Christianson*, 486 U.S., at 809. The plaintiff’s well-pleaded complaint must “establis[h] either that federal patent law creates the cause of action or that the plaintiff’s right to relief necessarily depends on resolution of a substantial question of federal patent law. . . .” *Ibid.* Here, it is undisputed that petitioner’s well-pleaded complaint did not assert any claim arising under federal patent law. The Federal Circuit therefore erred in asserting jurisdiction over this appeal.

A

Respondent argues that the well-pleaded-complaint rule, properly understood, allows a counterclaim to serve as the basis for a district court’s “arising under” jurisdiction. We disagree.

Admittedly, our prior cases have only required us to address whether a federal defense, rather than a federal counterclaim, can establish “arising under” jurisdiction. Nevertheless, those cases were decided on the principle that federal jurisdiction generally exists “only when a federal question is presented on the face of the *plaintiff’s* properly pleaded complaint.” *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987) (emphasis added). As we said in *The Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913), whether a case arises under federal patent law “cannot depend upon the answer.” Moreover, we have declined to adopt proposals that “the answer as well as the complaint . . . be consulted before a determination [is] made whether the case ‘ar[ises] under’ federal law. . . .” *Franchise Tax Bd. of Cal. v. Construction Laborers Vacation Trust for Southern Cal.*, 463 U.S. 1, 10-11, n. 9 (1983). It follows that a counterclaim—which appears as part of the defendant’s answer, not as part of the plaintiff’s complaint—cannot serve as the basis for “arising under” jurisdiction.

Allowing a counterclaim to establish “arising under” jurisdiction would also contravene the longstanding policies underlying our precedents. First, since the plaintiff is “the master of the complaint,” the well-pleaded-complaint rule enables him, “by eschewing claims based on federal law, . . . to have the cause heard in state court.” *Caterpillar Inc.*, *supra*, at 398-399. The rule proposed by respondent, in contrast, would leave acceptance or rejection of a state forum to the master of the counterclaim. It would allow a defendant to remove a case brought in state court under state law, thereby defeating a plaintiff’s choice of forum, simply by raising a federal counterclaim. Second, conferring this power upon the defendant would radically expand the class of removable cases, contrary to the “[d]ue regard for the rightful independence of state governments” that our cases addressing removal require. See *Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100, 109 (1941). And finally, allowing responsive pleadings by the defendant to establish “arising under” jurisdiction would undermine the clarity and ease of administration of the well-pleaded-complaint doctrine, which serves as a “quick rule of thumb” for resolving jurisdictional conflicts. See *Franchise Tax Bd.*, *supra*, at 11.

For these reasons, we decline to transform the longstanding well-pleaded-complaint rule into the “well-pleaded-complaint-or-counterclaim rule” urged by respondent.

B

Respondent argues, in the alternative, that even if a counterclaim generally cannot establish the original “arising under” jurisdiction of a district court, we should interpret the phrase “arising under” differently in ascertaining the Federal Circuit’s jurisdiction. In respondent’s view, effectuating Congress’s goal of “promoting the uniformity of patent law,” requires us to interpret §§ 1295(a)(1) and 1338(a) to confer exclusive appellate jurisdiction on the Federal Circuit whenever a patent-law counterclaim is raised.³

We do not think this option is available. Our task here is not to determine what would further Congress’s goal of ensuring patent-law uniformity, but to determine what the words of the statute must fairly be understood to mean. It would be difficult enough to give “arising under” the meaning urged by respondent if that phrase appeared in § 1295(a)(1)—the jurisdiction-conferring statute—*itself*. Even then the phrase would not be some neologism that might justify our adverting to the general purpose of the legislation, but rather a term familiar to all law students as invoking the well-pleaded-complaint rule. But the present case is even weaker than that, since § 1295(a)(1) does not itself *use* the term, but rather refers to jurisdiction under § 1338, where it is well established that “arising under any Act of Congress relating to patents” invokes, specifically, the well-pleaded-complaint rule. It would be an unprecedented feat of interpretive necromancy to say that § 1338(a)’s “arising under” language means one thing (the well-pleaded-complaint rule) in its own right, but something quite different (respondent’s complaint-or-counterclaim rule) when referred to by § 1295(a)(1).

Not all cases involving a patent-law claim fall within the Federal Circuit’s jurisdiction. By limiting the Federal Circuit’s jurisdiction to cases in which district courts would have jurisdiction under § 1338, Congress referred to a well-established body of law that requires courts to consider whether a patent-law claim appears on the face of the plaintiff’s well-pleaded complaint. Because petitioner’s complaint did not include any claim based on patent law, we vacate the judgment of the Federal Circuit and remand the case with instructions to transfer the case to the Court of Appeals for the Tenth Circuit. *See* 28 U.S.C. § 1631.

Justice STEVENS, concurring in part and concurring in the judgment.

I . . . do not agree with the Court’s statement that an interpretation of the “in whole or in part” language of § 1295(a)(1) to encompass patent claims alleged in a compulsory counterclaim providing an independent basis for the district court’s jurisdiction would be a “neologism” that would involve “an

3. Echoing a variant of this argument, Justice Ginsburg contends that “giv[ing] effect” to Congress’s intention “to eliminate forum shopping and to advance uniformity in . . . patent law” requires that the Federal Circuit have exclusive jurisdiction whenever a patent claim was “actually adjudicated.” We rejected precisely this argument in *Christianson*, viz., the suggestion that the Federal Circuit’s jurisdiction is “fixed ‘by reference to the case actually litigated.’” 486 U.S., at 813. We held that the Federal Circuit’s jurisdiction, like that of the district court, “is determined by reference to the well-pleaded complaint, not the well-tried case.” 486 U.S., at 814.

unprecedented feat of interpretive necromancy.” For there is well-reasoned precedent supporting precisely that conclusion. I am nevertheless persuaded that a correct interpretation of § 1295(a)(1) limits the Federal Circuit’s exclusive jurisdiction to those cases in which the patent claim is alleged in either the original complaint or an amended pleading filed by the plaintiff. In my judgment, each of the three policies that the Court has identified as supporting the “well-pleaded-complaint” rule governing district court jurisdiction points in the same direction with respect to appellate jurisdiction.

First, the interest in preserving the plaintiff’s choice of forum includes not only the court that will conduct the trial but the appellate court as well. A plaintiff who has a legitimate interest in litigating in a circuit whose precedents support its theory of the case might omit a patent claim in order to avoid review in the Federal Circuit. In some cases that interest would be defeated by a rule that allowed a patent counterclaim to determine the appellate forum.

Second, although I doubt that a rule that enabled the counterclaimant to be the occasional master of the appellate forum “would radically expand” the number of cases heard by the Federal Circuit, we must recognize that the exclusive jurisdiction of the Federal Circuit defined in § 1295(a)(1) does not comprise claims arising under the trademark and copyright laws, which are included in the district court’s grant of jurisdiction under § 1338(a). As the instant litigation demonstrates, claims sounding in these other areas of intellectual property law are not infrequently bound up with patent counterclaims. The potential number of cases in which a counterclaim might direct to the Federal Circuit appeals that Congress specifically chose not to place within its exclusive jurisdiction is therefore significant.

Third, the interest in maintaining clarity and simplicity in rules governing appellate jurisdiction will be served by limiting the number of pleadings that will mandate review in the Federal Circuit. In his opinion in *Aerojet*, Chief Judge Markey merely held that a counterclaim for patent infringement that was “compulsory” and not “frivolous” or “insubstantial” sufficed to establish jurisdiction; he made a point of noting that there was no assertion in the case that the patent counterclaim at issue had been filed “to manipulate the jurisdiction of [the Federal Circuit].” 895 F.2d 736, 738 [Fed. Cir. 1990]. The text of the statute, however, would not seem to distinguish between that counterclaim and those that are permissive, insubstantial, or manipulative, and there is very good reason not to make the choice of appellate forum turn on such distinctions. Requiring assessment of a defendant’s motive in raising a patent counterclaim or the counterclaim’s relative strength wastes judicial resources by inviting “unhappy interactions between jurisdiction and the merits.” *Kennedy v. Wright*, 851 F.2d 963, 968 (C.A.7 1988).

There is, of course, a countervailing interest in directing appeals in patent cases to the specialized court that was created, in part, to promote uniformity in the development of this area of the law. But we have already decided that the Federal Circuit does not have exclusive jurisdiction over all cases raising patent issues. Necessarily, therefore, other circuits will have some role to play in the development of this area of the law. An occasional conflict in decisions may be useful in identifying questions that merit this Court’s attention. Moreover, occasional decisions by courts with broader jurisdiction will provide

an antidote to the risk that the specialized court may develop an institutional bias.

Justice GINSBURG, with whom Justice O'CONNOR joins, concurring in the judgment.

For reasons stated by Chief Judge Markey, writing for a unanimous en banc Federal Circuit in *Aerojet-General Corp. v. Machine Tool Works, Oerlikon-Buehrle Ltd.*, 895 F.2d 736 (1990), I conclude that, when the claim stated in a compulsory counterclaim “aris[es] under” federal patent law and is adjudicated on the merits by a federal district court, the Federal Circuit has exclusive appellate jurisdiction over that adjudication and other determinations made in the same case.

The question now before this Court bears not at all on a plaintiff's choice of trial forum. The sole question presented here concerns Congress' allocation of adjudicatory authority among the federal courts of appeals. At that appellate level, Congress sought to eliminate forum shopping and to advance uniformity in the interpretation and application of federal patent law.

The Court's opinion dwells on district court authority. But, all agree, Congress left that authority entirely untouched. I would attend, instead, to the unique context at issue, and give effect to Congress' endeavor to grant the Federal Circuit exclusive appellate jurisdiction at least over district court adjudications of patent claims.

In the instant case, however, no patent claim was actually adjudicated. For that sole reason, I join the Court's judgment.

Comments

1. ***The Return of the Regional Circuits to the Law of Patents.*** The *Vornado* court applied the well-pleaded complain rule of *Christianson v. Colt* in holding the Federal Circuit does not have jurisdiction to hear patent law counterclaims. The natural result is that regional circuit courts may have more opportunities to rule on patent-related issues. Some welcome this result. For instance, in his concurrence, Justice Stevens wrote, “[a]n occasional conflict in decisions may be useful in identifying questions that merit this Court's attention,” and “occasional decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias.” Indeed, some commentators have argued for greater regional circuit participation in patent law. See Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619 (forthcoming 2007). Cf. S. Jay Plager & Lynne E. Pettigrew, *Rethinking Patent Law's Uniformity Principle: A Response to Nard and Duffy*, 101 NW. U. L. REV. 1735 (forthcoming 2007). Justice Ginsburg, in contrast, viewed the majority's decision as jeopardizing Congressional desire “to advance uniformity in the interpretation and application of federal patent law.” This may be particularly true if regional circuit courts do not apply Federal Circuit law, which is an open question. Several commentators have criticized *Vornado*. See, e.g., Larry D. Thompson, *Adrift on a Sea of Uncertainty: Preserving Uniformity in Patent Law Post-Vornado Through Deference to the Federal Circuit*, 92 GEO. L.J. 523 (2004) (criticizing

Vornado); Christopher A. Cotropia, *Counterclaims, the Well-Pleaded Complaint, and Federal Jurisdiction*, 33 HOFSTRA L. REV. 1 (2004); Janice M. Mueller, "Interpretive Necromancy" or Prudent Patent Policy? *The Supreme Court's "Arising Under" Blunder in Holmes Group v. Vornado*, 2 J. MARSHALL REV. INTELL. PROP. L. 57 (2002). Another result of *Holmes* may be that patentees file suit sooner than later so as not to position themselves as a defendant (in a non-patent suit) forced, under the rules of compulsory counterclaim, to assert patent infringement in a counterclaim.

2. **Forum Shopping and the Creation of the Federal Circuit.** One of the oft-cited reasons for the creation of the Federal Circuit was negative effects on the patent system due to rampant forum shopping by patent litigants. See H. R. Rep. No. 312, 97th Cong., 1st Sess. 20-22 (1981) ("Patent litigation long has been identified as a problem area, characterized by undue forum-shopping and unsettling inconsistency in adjudications."). And forum-shopping, like disuniformity, is generally seen as undesirable, leading to inconsistency and unpredictability. Justice Ginsburg was particularly concerned about new forum shopping opportunities in the light of *Vornado*. But is forum shopping necessarily an undesirable feature of the patent system? Justice Stevens emphasized the positive aspects of forum shopping, namely the power of competition and diversity of voices as an "antidote" to "institutional bias." Moreover, allowing litigants to shop within a more decentralized appellate framework may engender a healthy competition of rationales and provide a mechanism for testing legal innovations.

Interestingly, some commentators have expressed skepticism of the view that forum shopping was problematic during the 1970s. See Scott Atkinson, Alan C. Marco & John L. Turner, *The Economics of a Centralized Judiciary: Uniformity, Forum Shopping, and the Federal Circuit*, <http://ssrn.com/abstract=961035> (econometric study finding "strong evidence that forum shopping on the basis of validity rates ceased several years prior to the" Federal Circuit's creation); Cecil D. Quillen, *Innovation and the U.S. Patent System*, 1 VA. L. & BUS. REV. 207, 228 (2006) (asserting forum shopping and outcome variability were not problematic during the 1970s); Testimony of James W. Geriak, Hearings before the Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice on H.R. 2405 (April 1981), 709 (stating that claims of forum shopping are "seriously exaggerated"). And despite the creation of the Federal Circuit, recent empirical scholarship as shown that "choice of forum continues to play a critical role in the outcome of patent litigation." Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. REV. 889, 892 (2001) (identifying 10 district courts with most active patent dockets).

3. **Federal Circuit Jurisdiction Over Foreign Patents.** Do the federal courts have the power to exercise jurisdiction over foreign-issued patents? The Federal Circuit answered in the negative in *Voda v. Cordis Corp.*, 476 F.3d 887 (Fed. Cir. 2006). There, the Federal Circuit held the district court erred in asserting supplemental jurisdiction under 28 U.S.C. § 1367(c) over Dr. Voda's claims that Cordis was infringing Voda's foreign patents covering catheters used in angioplasty. (Dr. Voda also asserted infringement of three American patents.) The court stated "considerations of comity, judicial economy, convenience, fairness, and other exceptional

circumstances constitute compelling reasons to decline jurisdiction under § 1367(c).” *Id.* at 898. The court was also concerned with American treaty obligations, noting “[b]ased on the international treaties that the United States has joined and ratified as the ‘supreme law of the land,’ a district court’s exercise of supplemental jurisdiction could undermine the obligations of the United States under such treaties.” *Id.* at 900. Moreover, for several reasons, the court was not persuaded by notions of comity:

First, *Voda* has not identified any international duty, and we have found none, that would require our judicial system to adjudicate foreign patent infringement claims. . . . [W]hile the United States has entered into the Paris Convention, the PCT, and the Agreement on TRIPS, nothing in those treaties contemplates or allows one jurisdiction to adjudicate the patents of another. Second, *Voda* has not shown that it would be more convenient for our courts to assume the supplemental jurisdiction at issue. Third, with respect to the rights of our citizens, *Voda* has not shown that foreign courts will inadequately protect his foreign patent rights. Indeed, we see no reason why American courts should supplant British, Canadian, French, or German courts in interpreting and enforcing British, Canadian, European, French, or German patents. Fourth, assuming jurisdiction over *Voda*’s foreign patent infringement claims could prejudice the rights of the foreign governments. None of the parties or amicus curiae have demonstrated that the British, Canadian, French, or German governments are willing to have our courts exercise jurisdiction over infringement claims based on their patents.

Id. at 901.

Judge Newman filed a dissent, arguing that American courts routinely determine and apply foreign law. *Id.* at 906. In addition, Newman asserted the majority “makes no mention of the common nucleus of operative facts among *Voda*’s United States and foreign patent issues.” Citing *eBay Inc. v. MercExchange L.L.C.*, 126 S. Ct. 1837 (2006), she wrote the Supreme Court “discouraged the carving out of an exception uniquely for patent cases, and required that the equitable discretion of the district court be as available in patent cases as in other cases.” In short, the “panel majority strays from precedent, policy, and prudence, in ruling that the discretionary authority of the district court cannot or should not be exercised to resolve foreign patent disputes between parties properly before the court.” *Id.* at 910.

2. Venue

Venue is a distinct concept from jurisdiction, but closely related. Venue is simply the place of trial, whereas jurisdiction is a Constitutional requirement that focuses on the authority of a court to hear a particular case. The general venue statute is found in 28 U.S.C. § 1391. But patent law has a specific venue statute, 28 U.S.C. § 1400(b). The principal case, *VE Holding*, explores the contours of § 1400(b) and its relationship to § 1391.

VE HOLDING CORP. v. JOHNSON GAS APPLIANCE CO.

917 F.2d 1574 (Fed. Cir. 1990)

PLAGER, Circuit Judge.

For almost one hundred years, a specific statutory provision, currently section 1400(b) of chapter 87, title 28, U.S. Code, has set forth the bases for establishing venue in patent infringement actions. Where the defendant ‘resides’ is one of those bases. Supreme Court decisions, with one exception, have maintained that that provision is unaffected by other statutory provisions governing venue.

In 1988 Congress adopted a new definition of ‘reside’ as it applies to venue for corporate defendants. This case requires us to decide whether, by that amendment to § 1391(c) of chapter 87, Congress meant to apply that definition to the term as it is used in § 1400(b), and thus change this long-standing interpretation of the patent venue statute. The district courts addressing this question have arrived at conflicting results.

This is a case of first impression. We hold that Congress by its 1988 amendment of 28 U.S.C. § 1391(c) meant what it said; the meaning of the term ‘resides’ in § 1400(b) has changed.

* * *

II.

Venue, which connotes locality, serves the purpose of protecting a defendant from the inconvenience of having to defend an action in a trial court that is either remote from the defendant’s residence or from the place where the acts underlying the controversy occurred. The venue statutes achieve this by limiting a plaintiff’s choice of forum to only certain courts from among all those which might otherwise acquire personal jurisdiction over the defendant.

The Judiciary Act of 1789 included a general venue provision governing all civil suits cognizable in the federal courts. The general venue statutes are found today in chapter 87, title 28, U.S. Code. The first statute specifically addressed to venue in patent infringement suits was enacted a century later, in 1897. The current version of this Act is found in § 1400(b) of the venue chapter (chapter 87 of title 28). Section 1400(b), which has been in its present form since 1948, reads:

(b) Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.

Act of June 25, 1948, ch. 646, 62 Stat. 869, 936.

Patent law is not alone in having a particular venue statute that differs in its terms from the general venue provisions applicable to other federal causes of action. For example, in addition to sections dealing with venue in diversity jurisdiction cases, federal question cases, and venue regarding suits against aliens, the venue chapter contains provisions for suits in certain cases by a national banking association, for suits for collection of internal revenue taxes, for suits regarding Interstate Commerce Commission orders, and for stockholder’s derivative actions.

In all of these areas in which particular venue statutes apply, the question can be raised—to what extent do the general venue provisions of chapter 87 supplement what is contained in the special provision, whether that special provision is contained in chapter 87 or elsewhere. The issue appears to arise infrequently; the few decisions suggest that the answer depends very much on

the precise language of the relevant statutes along with, in appropriate cases, other evidence of Congressional intent. Facially, there is little consistency from area to area.

In the Jones Act and antitrust areas, for example, the courts have read the general venue provisions into the special provisions. In applying these particular venue provisions, courts have concluded that the Congressional intent was to ‘enlarge’ the plaintiff’s choice of forum by reading the special venue provisions as supplemental to, rather than superseding, the general venue provisions.

In the patent field, that has not been the case. The Supreme Court in 1942 and again in 1957 took a restrictive view of venue in patent infringement cases, holding in effect that the meaning of the terms used in § 1400(b) was not to be altered or supplemented by other provisions found in the venue statutes. *Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222 (1957); *Stonite Prods Co. v. Melvin Lloyd Co.*, 315 U.S. 561 (1942).

As written, section 1400(b) dictates that venue is proper when either of two tests is satisfied: (1) the defendant resides in the judicial district, or (2) the defendant has committed acts of infringement and has a regular and established place of business in the judicial district. The Supreme Court in *Fourco* confirmed that for defendants that are corporations, ‘resides’ meant the state of incorporation only. Section 1391(c), the general venue section which addressed the question of where corporations may be sued, and which contained language about the residence of corporations, did not supplement the specific provisions of § 1400(b). *Id.* 353 U.S. at 229.

At the time the Supreme Court’s decision in *Fourco* was handed down, § 1391(c) consisted of one sentence which read:

(c) A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes.

The first clause (up to the comma) established venue for corporations. The second clause either was surplusage since the term ‘residence’ was not used in the first clause as one of the bases for venue or, if it applied to plaintiffs as well as defendants was at best confusing.

In response to pressure from the bar and the courts, in 1988 Congress amended § 1391(c). The former one sentence subsection now consists of two sentences. The new second sentence of subsection (c) applies when a defendant corporation is amenable to federal jurisdiction in a state having several judicial districts. It prescribes which of them shall be the proper venue, and is not at issue in this case.

The new first sentence of amended § 1391(c) reads:

(c) *For purposes of venue under this chapter*, a defendant that is a corporation shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced.

28 U.S.C. § 1391(c) (1988) (emphasis added). The phrase “this chapter” refers to chapter 87 of title 28, which encompasses §§ 1391-1412, and thus includes § 1400(b). On its face, § 1391(c) clearly applies to § 1400(b), and thus redefines the meaning of the term ‘resides’ in that section.

However, one familiar with the judicial history of § 1400(b) may be tempted to disregard the clear language of § 1391(c) and maintain the independence of that section from § 1400(b). The lack of express legislative history indicating that the 1988 amendment of § 1391(c) was intended to change the scope of venue in patent infringement cases, and the fact that such a conclusion would seem to fly in the face of thirty years of Supreme Court law, strengthens the temptation.

In *Fourco*, the Supreme Court addressed the same question presently before this court. “The question is . . . whether § 1391(c) supplements § 1400(b), or, in other words, whether the latter is complete, independent and alone in controlling in its sphere as was held in *Stonite*, or is, in some measure, dependent for its force upon the former.” *Fourco*, 353 U.S. at 228. In deciding that it was not so intended, the Supreme Court stated:

We think it is clear that § 1391(c) is a general corporation venue statute, whereas § 1400(b) is a special venue statute applicable, specifically, to *all* defendants in a particular type of actions, *i.e.*, patent infringement actions. In these circumstances the law is settled that “However inclusive may be the general language of a statute, it ‘will not be held to apply to a matter specifically dealt with in another part of the same enactment. . . . Specific terms prevail over the general in the same or another statute which otherwise might be controlling.’

Fourco, 353 U.S. at 228-29 (emphasis in original).

III.

The Supreme Court’s decision in *Fourco* is generally viewed as holding that § 1400(b) is the ‘exclusive’ venue statute in patent infringement actions. Thus it is sometimes said that, since *Fourco*, the only way to change the way that venue in patent infringement actions is determined is to change § 1400(b). This argument fails, however, because the Supreme Court, in *Brunette*, refused to impose such a disablement upon the Congress’ ability to enact or amend legislation. The issue in *Brunette* was whether § 400(b) governed venue in a patent suit involving a foreign corporation, or whether the general venue provision applicable to aliens, 28 U.S.C. § 1391(d), governed. The Court held § 1391(d) applied, and that § 1400(b) was supplemented by the provision governing suits against aliens. *Fourco* and *Stonite* were distinguished.

The specific question in *Fourco* was whether the statutory language previously enacted by the Congress as § 1391(c) supported a conclusion that Congress intended to have §§ 1391(c) and 1400(b) read together. On the basis of the nonspecific language of § 1391(c) and prior history as the Court read it, the Court concluded the answer was no.

Section 1391(c) as it was in *Fourco* is no longer. We now have exact and classic language of incorporation: “For purposes of venue under this chapter. . . .” Congress could readily have added “except for section 1400(b),” if that exception, which we can presume was well known to the Congress, was intended to be maintained. Certainly it would not be sensible to require Congress to say, “For purposes of this chapter, *and we mean everything in this chapter . . .*,” in order to ensure that it has covered everything in a chapter of the statutes.

The issue, then, is not whether the prior cases, including Supreme Court cases, determined that under different statutory language Congress’ intent was that § 1400(b) stood alone. The issue is, what, as a matter of first impression, should we conclude the Congress *now* intends by this new language in the venue act.

It is axiomatic that statutory interpretation begins with the language of the statute. If, in a given case, the words of the statute do not provide an answer, then a court has no choice but to fill in the interstices. If, on the other hand, the language is clear and fits the case, the plain meaning of the statute will be regarded as conclusive. In the case before us, the language of the statute is clear and its meaning is unambiguous. Absent extraordinary circumstances, our inquiry must end here. Section 1391(c) applies to all of chapter 87 of title 28, and thus to § 1400(b), as expressed by the words “For purposes of venue under this chapter.” There can be no mistake about that.

It is true that § 1391(c) is a general venue statute and that § 1400(b) is a specific one. But the general rule that a specific statute is not controlled or nullified by a general statute regardless of priority of enactment, absent a clear intention otherwise, does not govern the present situation. This is for two reasons. First, in this case the general statute, § 1391(c), expressly reads itself into the specific statute, § 1400(b). Second, § 1391(c) only operates to define a term in § 1400(b)—it neither alone governs patent venue nor establishes a patent venue rule separate and apart from that provided under § 1400(b). Nor does it conflict with § 1400(b). Furthermore, even were the rule applicable to the issue at hand, the language of the statute would reveal “a clear intention” that § 1391(c) is to supplement § 1400(b).

* * *

VI.

[T]he first test for venue under § 1400(b) with respect to a defendant that is a corporation, in light of the 1988 amendment to § 1391(c), is whether the defendant was subject to personal jurisdiction in the district of suit at the time the action was commenced. 28 U.S.C. §§ 1391(c) & 1400(b) (1988). Since Johnson has conceded that VE obtained personal jurisdiction over it in the Northern District of California, Johnson “resides” in that district, within the meaning of the first test of § 1400(b), and venue properly lies in the Northern District of California. The District Court’s determination that venue with regard to Johnson did not lie in the Northern District of California was error.

Comment

Prior to the 1988 amendments to Title 28, § 1400(b) was deemed independent and separate from § 1391. See *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222 (1957). But in 1988 Congress modified § 1391 so that for purposes of venue, a corporation “resides” in any district where the corporation is subject to personal jurisdiction. The Federal Circuit, in *VE Holding*, interpreted this change to mean that corporate alleged infringers may be sued in a multitude of districts. Thus, § 1400(b) is no longer the exclusive venue provision for patent infringement cases, and now corporate infringers are subject to venues beyond their state of incorporation and where they have regular and established businesses and engaged in the alleged act of infringement. DJ actions brought by alleged infringers are also governed by §§ 1391 and 1400.

3. Standing

The patentee's right to a remedy is governed by the patent statute, which states "[a] patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281. A patentee is one who owns legal title to the patent at the time infringement occurs. Thus, the patentee can be the inventor or a joint inventor. (Absent a contractual obligation to the contrary, ownership of the patent right vests in the inventor.) The patentee can also be a successor-in-title to the inventor such as an assignee, that is, the person to whom full or partial legal title was conveyed by the inventor. In addition, while a "bare licensee" does not have standing, an exclusive licensee or a licensee who has a sufficient interest in the patent *may* have standing to bring suit alone. Of course, a court may require joinder of the patentee even if the license is exclusive. The *Propat* court explores these issues.

PROPAT INTERNATIONAL CORP. v. RPOST, INC.

473 F.3d 1187 (Fed. Cir. 2007)

BRYSON, Circuit Judge.

This "patent standing" case calls on us to decide once again whether a party has a sufficient ownership interest in a patent to be entitled to sue for infringement. The plaintiff, Propat International Corporation, sued RPost, Inc. in the United States District Court for the Central District of California. Propat charged RPost with infringing U.S. Patent No. 6,182,219 ("the '219 patent"). That patent was assigned to Authenticational Technologies Ltd. ("Authentix") by the inventors. After the district court resolved several issues relating to the merits of the lawsuit, the parties filed cross-motions addressing the question whether Propat had standing to bring the action in its own name.

The district court issued an opinion holding that Propat is not the owner of the patent and thus does not have standing to sue. Focusing on a May 2002 agreement between Propat and Authentix, the court ruled that the agreement does not transfer all substantial rights in the patent to Propat but instead merely makes Propat a bare licensee under the patent. Because Propat has no proprietary interest in the patent, the court held that Propat lacks standing to sue infringers even with the patent owner, Authentix, joined as a party-plaintiff.

We affirm the district court's decision that Propat lacks standing to sue for infringement of the '219 patent even with Authentix as an additional party to the action.

I

We have addressed the issue of standing in patent cases on a number of occasions. The governing principles are now reasonably clear. The Patent Act provides that "[a] patentee" is entitled to bring a civil action "for infringement of his patent." 35 U.S.C. § 281. The term "patentee" includes "not only the patentee to whom the patent was issued but also the successors in title to the patentee." *Id.* § 100(d). Those provisions of the Patent Act have been interpreted to require that a suit for infringement of patent rights ordinarily be brought by a party holding legal title to the patent.

Even if the patentee does not transfer formal legal title, the patentee may effect a transfer of ownership for standing purposes if it conveys all substantial rights in the patent to the transferee. In that event, the transferee is treated as the patentee and has standing to sue in its own name.

A

Propat first argues that the May 2002 agreement grants it a sufficient interest in the patent to entitle it to sue for infringement in its own name, without naming Authentix as a co-plaintiff. Because it is undisputed that Authentix is the party with legal title to the patent, Propat is entitled to sue in its own name alone, without Authentix's participation, only if Authentix has transferred to Propat all substantial rights in the patent. In order to determine whether Authentix has done so, we must look to the agreement between the parties and analyze the respective rights allocated to each party under that agreement.

In relevant summary, the agreement between Propat and Authentix gives Propat the responsibility to license the patent to third parties, to enforce the licensing agreements, and to sue infringers. In exchange, the agreement gives Propat a defined percentage share of the proceeds of the licensing royalties and of any judgment or settlement arising out of litigation. As part of the agreement, Propat undertakes "to consult with and obtain prior approval" from Authentix for the selection of any potential targets for licensing or suit, although the agreement provides that Authentix may not unreasonably withhold or delay such approval. The agreement further provides that Authentix may terminate the agreement if Propat breaches the agreement, becomes bankrupt or insolvent, fails to obtain certain levels of income from the patent, or ceases to be actively engaged in licensing or litigation efforts. The agreement forbids Propat from assigning its rights and obligations under the agreement without the consent of Authentix, which consent Authentix may freely withhold. Finally, the agreement provides that Authentix will consent to be joined as a party to any action brought by Propat if a court requires it to be joined, although in such a case Propat must provide counsel for Authentix and defray all the expenses Authentix may incur in connection with its involvement in the litigation.

The agreement contemplates that Propat will be engaged in licensing and litigation. It does not explicitly address whether Propat enjoys a license to practice the patent. Similarly, it does not explicitly state whether Authentix retains the right to practice the patent.

The parties take diametrically opposing views of the consequences of the agreement for purposes of determining Propat's standing as a plaintiff in this case. Propat argues that the district court was wrong to dismiss the action, because the agreement gives Propat all substantial rights in the patent and thus is the functional equivalent of an assignment of the patent from Authentix. Accordingly, Propat contends that it should be treated as the "patentee" and that it is therefore entitled to bring this action without naming Authentix as a co-plaintiff. RPost, on the other hand, argues not only that Propat is not the "patentee," but also that Propat has no proprietary rights in the patent at all and instead is only a bare licensee. For that reason, RPost argues, Propat has no right to participate in this action as a plaintiff and the district court properly dismissed the action for lack of jurisdiction.

The district court first found that the agreement does not assign to Propat the right to make, use, and sell the patented invention. Instead, the court concluded, Propat “merely has a right to enforce or license other parties to use, manufacture, or sell” the invention. Second, the court concluded that the right granted to Propat with respect to the invention is not exclusive, because Authentix retains the right to seek new patents on the underlying invention and therefore retains an implicit right to use the invention. Finally, the court found that Propat’s power to assign its rights under the agreement is entirely subject to Authentix’s consent, which “Authentix can withhold . . . even arbitrarily.” In light of the various rights retained by Authentix, the court found that Propat “was not transferred all substantial rights and, as such, has no standing to sue on its own behalf.”

We agree with the district court. Authentix retains sufficient rights in the patent that it cannot be said to have assigned “all substantial rights” in the patent to Propat. To begin with, the agreement expressly provides that Authentix is, and will continue to be, the owner of the patent. The agreement identifies Authentix as the “owner of various technology,” including the ’219 patent. Moreover, the agreement provides that Authentix is responsible to “maintain any . . . patents [it] owns or controls . . . each for its full term,” a provision that clearly includes the ’219 patent. The responsibility to maintain a patent is one of the obligations that has been recognized by this court as an indication that the party with that obligation has retained an ownership interest in the patent.

In addition, Authentix retains an economic interest in the patent and a substantial measure of control over decisions affecting the patent rights. It enjoys an equity interest in the proceeds of licensing and litigation activities, a right to notice of licensing and litigation decisions and the right to veto such decisions as long as the veto power was not exercised unreasonably, and the unrestricted power to bar Propat from transferring its interest in the patent to a third party. In no case has this court held that a patentee who retains such broad and wide-ranging powers with respect to a patent has nonetheless transferred “all substantial rights” in the patent.

To be sure, the fact that a patent owner has retained a right to a portion of the proceeds of the commercial exploitation of the patent, as Authentix has done in this case, does not necessarily defeat what would otherwise be a transfer of all substantial rights in the patent. Nonetheless, the fact that Authentix retains a substantial share of the proceeds is consistent with Authentix’s retaining ownership rights in the patent, while allocating to Propat the duty to provide licensing and enforcement services.

Authentix’s right to veto licensing and litigation decisions also constitutes a significant restriction on Propat’s interest in the patent. Although Authentix may decline to consent to Propat’s decisions only if it does so reasonably, Propat’s obligation to notify Authentix as to the selection of all targets for licensing or suit and to obtain Authentix’s consent to all such decisions indicates that Authentix retains substantial ongoing control of the sort typically associated with the retention of an ownership interest in the patent.

Authentix’s right to veto any transfer of Propat’s rights under the agreement is particularly significant, the more so because the agreement expressly indicates that Authentix is free to veto any such transfer decision, even if it does so “arbitrarily.” The right to dispose of an asset is an important incident

of ownership, and such a restriction on that right is a strong indicator that the agreement does not grant Propat all substantial rights under the patent. In fact, the court in *Sicom Systems* referred to the restraint on transferability of the rights under the agreement as “fatal” to the argument that the agreement transferred all substantial rights in the patent. 427 F.3d at 979.

Finally, if Propat fails to meet certain specified benchmarks in its efforts to exploit the patent, Authentix is free to terminate the contract, at which point all of Propat’s rights with respect to the patent come to an end. Authentix’s power to terminate the agreement and end all of Propat’s rights in the patent if Propat fails to perform up to the specified benchmarks, although not dispositive, is yet another indication that Authentix retains a significant ownership interest in the patent.

The rights allocated to Propat under the agreement are not sufficiently substantial to make Propat in effect the assignee of the patent. It has long been held that a “right to sue” clause in a contract, unaccompanied by the transfer of other incidents of ownership, does not constitute an assignment of the patent rights that entitles the transferee to sue in its own name. That principle sensibly reflects that a patent owner may give another responsibility to select targets for suit—a power of attorney, in effect—without surrendering ownership of the patent. The same principle applies to Propat’s right to select licensees. While the rights to sue and grant licenses accord Propat broad authority to act as Authentix’s agent for purposes of licensing and litigation, they do not transfer ownership of Authentix’s patent.

Propat relies heavily on two of this court’s decisions, *Vaupel* and *Speedplay*. In those cases, the court held that the agreements in question effected the transfer of all substantial rights in the patent at issue. Each of those cases, however, is distinguishable. In *Vaupel*, the patentee did not retain any rights to control the licensee’s exercise of its right to sue; the patentee retained only the right to be informed of the course of litigation on the patent. In *Speedplay*, the exclusive licensee had complete effective control over litigation decisions, and the patentee did not have the right to veto the licensee’s decision to transfer its rights under the agreement. In this case, by contrast, the patentee must be consulted about and consent to licensing and litigation decisions, and it retains an absolute right to prevent assignment of the licensee’s interests.

The facts of this case are closer to those in *Intellectual Property Development, Inc. v. TCI Cablevision of California, Inc.*, 248 F.3d 1333 (Fed. Cir. 2001), in which we held that the agreement between a patentee and an exclusive licensee did not transfer all substantial rights in the patent and therefore did not confer on the exclusive licensee the right to sue on the patent in its own name alone. In that case, the patentee granted the plaintiff an exclusive license and the right to sue infringers, but it retained certain rights in the patent. Those retained rights included the right in certain circumstances to require the exclusive licensee to obtain the patentee’s consent to sue; the right in other cases to be informed of, and consulted about, litigation; the right to consent to settlements of litigation (which consent could not be unreasonably withheld); the right to a 50 percent share of the proceeds of litigation; and the right to prevent the exclusive licensee from assigning its rights under the agreement. Those rights are similar to the rights retained by Authentix, except that in this case there was no conveyance of an exclusive license to make, use, and sell the invention. Accordingly, as in *Intellectual Property Development*,

we hold that the district court was correct to conclude that Authentix has not conveyed all substantial rights in the patent to Propat. For that reason, Propat lacks standing to sue for infringement in the absence of Authentix.

B

In the alternative, Propat argues that even if it is not the owner of all substantial rights in the '219 patent, the trial court should not have dismissed the complaint, but instead should have granted its request to add Authentix as a party and then permitted the action to continue. The district court, however, concluded that Propat lacks a sufficient interest in the patent to give it standing to sue even as a co-plaintiff and therefore dismissed the action without acting on Propat's request to join Authentix. The court reasoned that Propat's status is that of a bare licensee with no ownership interest in the patent and no right to participate in the infringement action.

A party that is neither the legal owner of the patent nor the transferee of all substantial rights in the patent still has standing to sue for infringement if that party has a legally protected interest in the patent created by the Patent Act, so that it can be said to suffer legal injury from an act of infringement. *See Intellectual Prop. Dev.*, 248 F.3d at 1345-46. An exclusive licensee is considered to have such an interest. Unlike the patentee or the transferee of all substantial rights in the patent, however, an exclusive licensee ordinarily may not sue in its own name alone, but must join the patent owner in an action brought against an accused infringer.

In *Independent Wireless*, the Supreme Court explained the rule regarding exclusive licensees as follows:

The owner of a patent, who grants to another the exclusive right to make, use, or vend the invention, which does not constitute a statutory assignment, holds the title to the patent in trust for such a licensee, to the extent that he must allow the use of his name as plaintiff in any action brought at the instance of the licensee in law or in equity to obtain damages for the injury to his exclusive right by an infringer.

269 U.S. at 469. This court has characterized the rule in *Independent Wireless* as meaning that an exclusive licensee has a sufficient interest in the patent to have standing to sue under Article III of the Constitution. We explained that the requirement that the exclusive licensee must normally join the patent owner in any suit on the patent is a "prudential" requirement, not a constitutional requirement based on Article III limitations, and that an action brought by the exclusive licensee alone may be maintained as long as the licensee joins the patent owner in the course of the litigation.

By contrast, a bare licensee, i.e., a party with only a covenant from the patentee that it will not be sued for infringing the patent rights, lacks standing to sue third parties for infringement of the patent. Thus, an infringement action brought by a bare licensee must be dismissed. A bare licensee cannot cure its lack of standing by joining the patentee as a party.

This case does not fit neatly within either of those two categories. As noted, it appears from the agreement that the parties did not envision that Propat would practice the patent, but instead contemplated that Propat would be involved only in licensing and litigation. The agreement is accordingly silent as to Propat's rights to practice the patent, whether exclusively or otherwise,

and focuses instead on Propat's rights to license the patent and sue for its infringement.

In this setting, we look for guidance to the Supreme Court's decision in *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24 (1923). There, a patent owner sought to assign to another party the right to sue a competitor for infringement of the patent. The Court, however, refused to recognize an assignment of the right to sue on a patent separate from the conveyance of a proprietary interest in the patent. *Id.* at 34-36. The Court explained that if it were permissible for the patentee to retain ownership of the patent but to assign to others the right to sue infringers, "it would give the patentee an opportunity without expense to himself to stir up litigation by third persons." *Id.* at 39. Because the attempted assignment of the right to sue for infringement "carried no part of the title to the patent or interest in it," the Court held that it "conferred no right to sue for damages for infringement of the patent after execution of the [assignment]." *Id.*

It is true that Propat has more rights with respect to the patent than did the assignee in *Crown Die*. Unlike the assignee in *Crown Die*, Propat's right to sue is not limited to a particular infringer, and Propat also has an express right to license the patent, albeit one that is subject to Authentix's consent. But the principles underlying the Court's analysis in *Crown Die* are equally applicable here and dictate the same result. The Court in *Crown Die* refused to permit the right to sue to be segregated from formal ownership of the patent, with the very narrow exceptions previously recognized, including the right accorded to exclusive licensees. In this case, Propat lacks important indicia of a true ownership interest in the patent, such as the right to transfer its interest. Under the May 2002 agreement, Propat is not allowed to assign its interests under the agreement without Authentix's consent, which can be withheld on any ground. Moreover, as noted, Propat must provide Authentix with notice and obtain Authentix's consent to its selection of targets for licensing and suit. And the agreement requires Propat to "use reasonable efforts consistent with prudent business practices" in its licensing and enforcement efforts, a provision that is more consistent with the status of an agent than a co-owner. We therefore agree with the district court that Propat's rights created by the May 2002 agreement did not accord it rights in the patent sufficient to give it standing to sue, even with Authentix named as a co-plaintiff. Accordingly, we uphold the district court's decision dismissing Propat's action without prejudice for lack of jurisdiction.

Comments

1. **Transferring Legal Title or "All Substantial Rights."** An owner of a patent has standing to bring an action for patent infringement under § 281 of the Patent Act, which states "[a] patentee shall have remedy by civil action for infringement of his patent." Under § 100(d), a "patentee" includes not only the patentee to whom the patent was issued but also "the successors in title to the patentee." Thus, because patents "have the attributes of personal property" under § 261, ownership subsist either through issuance of the patent or transfer of patent rights (*i.e.*, an assignment). The Federal Circuit has identified three ways to transfer legal title. A transfer can be (1) "of the

entire patent”; (2) “an undivided part or share of the entire patent”; or (3) “all rights under the patent in a specified geographical region of the United States.” *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1551-52 (Fed. Cir. 1995) (en banc). The court noted that “[a] transfer of less than one of these three interests is a license, not an assignment of legal title, and it gives the licensee no right to sue for infringement in the licensee’s own name.” *Id.* See also *Jim Arnold Corp. v. Hydrotech Systems, Inc.*, 109 F.3d 1567, 1577 (Fed. Cir. 1997). Importantly, “[w]hether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effect of its provisions.” *Waterman v. MacKenzie*, 138 U.S. 252, 256 (1891). Certainly, there are situations where a licensee may have sufficient interest in the patent to have standing, as Comment 2 discusses.

2. **Standing and Licensees.** In the context of standing, there is a fundamental difference between an exclusive and non-exclusive licensee. The latter does not have standing. See *Waterman*, 138 U.S. at 255 (“In equity, as at law, when the transfer amounts to a license only, the title remains in the owner of the patent; and suit must be brought in his name, and never in the name of the licensee alone”); *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 40 (1923) (“[T]he plaintiff in a [patent infringement] action . . . must be the person or persons in whom the legal title to the patent resided at the time of the infringement.”). While it is true that a non-exclusive licensee suffers economic harm, this alone is not enough to confer standing. To have standing, “a licensee must hold some of the proprietary sticks from the bundle of patent rights.” *Ortho Pharmaceutical Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026, 1031 (Fed. Cir. 1995). In addition, as Judge Learned Hand has stated, the non-exclusive licensee’s economic injury is outweighed by the “interest of the infringer to be immune from a second suit by the owner of the patent; and also the interest of the patent owner to be free to choose his forum.” *A.L. Smith Iron Co. v. Dickson*, 141 F.2d 3, 6 (2d Cir. 1944).

In contrast, an exclusive licensee has standing, although it is not uncommon for the patentee to join the suit voluntarily or be required to join as a “prudential” matter. See *Independent Wireless Telegraph Co. v. Radio Corp. of America*, 269 U.S. 459 (1926); *Intellectual Property Development, Inc. v. TCI Cablevision of California, Inc.*, 248 F.3d 1333, 1347 (Fed. Cir. 2001) (“As a general rule, in accordance with *Independent Wireless*, this court adheres to the principle that a patent owner should be joined, either voluntarily or involuntarily, in any patent infringement suit brought by the exclusive licensee.”); *Prima Tek II, LLC v. A-Roo, Inc.*, 222 F.3d 1372, 1377 (Fed. Cir. 2000) (noting “*Independent Wireless* was incorporated into the Federal Rules of Civil Procedure in 1937 with the adoption of Rule 19”). The distinction between an exclusive licensee and non-exclusive licensee is based on the fact that an exclusive licensee—by definition—can preclude the patentee from granting additional licenses to third parties. See *Textile Productions, Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998) (stating “[t]o qualify as an exclusive license, an agreement must clearly manifest the patentee’s promise to refrain from granting to anyone else a license in the area of exclusivity”). Accordingly, the exclusive licensee arguably has an equitable proprietary interest in the patent and the accompanying right to

exclude, whether the exclusion is in a geographic area, temporal, or some form of field-of-use restriction. As the *Rite-Hite* court stated,

[t]o be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee's express or implied promise that others shall be excluded from practicing the invention within that territory as well. . . . If the party has not received an express or implied promise of exclusivity under the patent, *i.e.*, the right to exclude others from making, using or selling the patented invention, the party has a 'bare license.'

See also *Ortho Pharm.*, 52 F.3d at 1032 (Fed. Cir. 1995) (stating "a licensee with proprietary rights in the patent is generally called an 'exclusive' licensee. But it is the licensee's beneficial ownership of a right to prevent others from making, using or selling the patented technology that provides the foundation for co-plaintiff standing, not simply that the word 'exclusive' may or may not appear in the license"); *Intellectual Prop. Dev.*, 248 F.3d at 1345 (stating "[a]n exclusive licensee receives more substantial rights in a patent than a nonexclusive licensee, but receives fewer rights than an assignee of all substantial rights. For example, an exclusive licensee could receive the exclusive right to practice an invention within a given limited territory").

With these principles in mind, let's return to the *Propat* case. Unlike the *Vaupel* and *Speedplay* decisions, the court in *Propat* identified several factors that supported its conclusion that the agreement between Authentix and Propat fell short of transferring "all substantial rights" to Propat. First, Authentix was named as the "owner of various technology," including the patent-in-suit, and Authentix was responsible to "maintain any . . . patents [it] owns or controls . . . each for its full term," which also included the '219 patent. The court noted that the responsibility to maintain a patent is an indication that Authentix has retained an ownership interest in the patent.

Moreover, Authentix retained an economic interest in the patent. For instance, Authentix had an equity interest in the proceeds of licensing and litigation activities. Authentix also retained a great deal of control over the patent rights, namely the right to notice of licensing and litigation decisions and the right to veto such decisions. In addition, under the agreement Authentix could prevent Propat from transferring its interest in the patent to a third party. Lastly, Authentix had the power to terminate the contract, in which case Propat's rights in the patent would be lost.

3. **Co-Owners and Standing.** Patent law allows multiple owners of a patent, each with an undivided interest in the entire patent. In this situation, a co-owner must join all other co-owners to establish standing. See *Israel Bio-Engineering Project v. Amgen, Inc.*, 401 F.3d 1299, 1305 (Fed. Cir. 2005). Thus, "one co-owner has the right to impede the other co-owner's ability to sue infringers by refusing to voluntarily join" in the law suit. *Schering Corp. v. Roussel-UCLAF SA*, 104 F.3d 341, 345 (Fed. Cir. 1997). Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing.

CHAPTER

8

Defenses to Patent Infringement

INTRODUCTION

This chapter explores defenses that are available to alleged infringers. The most common defenses are non-infringement and invalidity, both of which have a statutory basis. *See* 35 U.S.C. § 282.¹ As issues of infringement and validity were previously covered, however, the following materials are devoted to other defenses, including (A) the patent exhaustion doctrine, repair-reconstruction, and defenses related to the role of contract in exploiting patent rights, namely patent misuse; (B) antitrust counterclaims; (C) inequitable conduct; (D) experimental use; (E) inventorship; and (F) pre-emption.

A. THE RIGHTS AND LIMITATIONS ON THE USE OF CONTRACT IN EXPLOITING PATENT RIGHTS

A third-party purchaser of a patented product enjoys certain rights with respect to the product. Under the principle of *patent exhaustion* (sometimes referred to as the first-sale doctrine) the patentee is stripped of his rights *in the product* that embodies the claimed invention once he (or his licensee acting within the scope of his license) sales the product.² *See Intel Corp. v.*

1. Specifically, § 282 states:

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

- (1) Noninfringement, absence of liability for infringement or unenforceability,
- (2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability [including §§ 101-103 and 112],
- (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,
- (4) Any other fact or act made a defense by this title.

2. The counterpart provision in copyright law is found in 17 U.S.C. § 109(a) (stating “the owner of a particular copy or phonorecord lawfully made under this title, or any person authorized by such owner, is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord”).

USLI System Technology, Inc., 955 F.2d 1566, 1568 (Fed. Cir. 1993) (stating “[t]he law is well settled that an authorized sale of a patented product places that product beyond the reach of the patent. The patent owner’s rights with respect to the product end with its sale, and a purchaser of such a product may use or resell the product free of the patent”). Importantly, the exhaustion principle only applies to the product sold, and does not affect (or exhaust) the patentee’s statutory right to exclude. The rationale for this principle is that the patentee presumably received consideration, which includes remuneration for the use and resale of the product, and therefore, should not be permitted to exercise control over the sold product. As the Supreme Court stated in *U.S. v. Univis Lens Co.*, 316 U.S. 241, 251 (1942), “[o]ur decisions have uniformly recognized that the purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward for the use of his invention by the sale of the article, and that once that purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold.” See also *Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997) (stating “[t]he theory behind [exhaustion] is that in such a transaction [*i.e.*, unconditional sale of a patented device], the patentee has bargained for, and received, an amount equal to the full value of the goods”).³

Once a product is sold, therefore, the product becomes the personal property (or tangible property) of its owner. In *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 549 (1852), the Supreme Court recognized that “when the machine passes to the hands of the purchaser, it is no longer within the limits of the monopoly. It passes outside of it, and is not longer under the protection of the act of Congress.” What exactly can the purchaser—absent an express contract—do with the product? It is clear that while the patent rights are naturally retained by the patentee, the purchaser can use and resell the product as purchased. But what if the product needs to be fixed or modified in some way? The answer to this question is the domain of the *repair-reconstruction doctrine*, which can be viewed as attempting to define the scope of patent exhaustion. The repair-reconstruction doctrine holds that a purchaser of a patented product may repair the product, but may not reconstruct it. Where to draw the line between permissible repair and impermissible reconstruction has perpetually vexed courts. The repair-reconstruction doctrine and the issues associated therewith are explored in the principal case of *Jazz Photo* in A.1, below.

In addition to the patentee’s statutory rights as constrained by the exhaustion doctrine, it is quite common for a patentee to turn to private law, namely contract, to exploit his patent rights in a manner consistent with the patent code and traditional contract principles. A patentee may contractually restrict a licensee’s or purchaser’s use of the product, and therefore render irrelevant the default rule embodied in the repair-reconstruction doctrine. The restriction may include limits on how many times the licensee or

3. Of course, exhaustion attaches only if the product sold is covered by the patent claims. See *Bandag v. Al Bolser’s Tire Stores, Inc.*, 750 F.2d 903, 924 (Fed. Cir. 1984) (finding no exhaustion because method claims did not cover product that was sold).

purchaser can use the product; define the particular purposes for which the product can be used; or condition access to the patented product on the purchase of an unpatented article—a practice commonly referred to as “tying.” But the patentee must be careful not to be overly restrictive, lest he be found to have “misused” his patent right. The misuse doctrine—which is different from antitrust—seeks to prevent a patentee from obtaining market benefit from leveraging his patent right beyond what the patent statute provides. To what extent a patentee can contractually limit a third-party’s use of the patented invention without engaging in patent misuse is an issue addressed by the four principal cases in § A.2, *Philips*, *Morton Salt*, *Mallinckrodt* and *Monsanto*.

The last subsection, A.3, discusses the ability of licensees to challenge the validity of the licensed patent. The principal cases of *Lear*, *MedImmune*, and *Sandisk* explore this issue. The remaining principal cases in this subsection analyze the legal appropriateness of license provisions that relate to how royalties should be paid. In *Brulotte*, the license required the licensee to pay royalties beyond the term of the patent; *Scheiber* provides a contemporary analysis of the *Brulotte* court’s reasoning.

1. The Scope of Patent Exhaustion and the Repair-Reconstruction Doctrine

The doctrine of repair-reconstruction can be thought of as providing contract default rules in the absence of a license or an express contract setting forth the particulars of how the purchased or licensed patented product can be used.⁴ In this regard, the repair-reconstruction rule, as explored in *Jazz Photo*, defines the scope of the patent exhaustion doctrine.

JAZZ PHOTO CORP. v. INTERNATIONAL TRADE COMMISSION

264 F.3d 1094 (Fed. Cir. 2001)

PAULINE NEWMAN, Circuit Judge.

In an action brought under section 337 of the Tariff Act of 1930 as amended, 19 U.S.C. § 337, Fuji Photo Film Co. charged twenty-seven respondents, including the appellants Jazz Photo Corporation, Dynatec International, Inc., and Opticolor, Inc., with infringement of fifteen patents owned by Fuji. The charge was based on the respondents’ importation of used “single-use” cameras called “lens-fitted film packages” (LFFP’s), which had been refurbished¹ for reuse in various overseas facilities. Section 337 makes unlawful “[t]he

4. See WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY 381-82 (2003) (stating the “repair-reconstruction distinction has nothing to do with patent policy”; rather, “[i]t is solely a matter of interpreting the license”).

1. We use “refurbish” as a convenient neutral term without legal significance, intended to connote neither “repair” nor “reconstruction” of the used cameras.

importation into the United States . . . of articles that . . . infringe a valid and enforceable United States patent . . . [or that] are made, produced, processed, . . . under, or by means of, a process covered by the claims of a valid and enforceable United States patent.” 19 U.S.C. § 1337(a)(1)(B).

The Commission determined that twenty-six respondents, including the appellants, had infringed all or most of the claims in suit of fourteen Fuji United States patents, and issued a General Exclusion Order and Order to Cease and Desist.

The Commission’s decision rests on its ruling that the refurbishment of the used cameras is prohibited “reconstruction,” as opposed to permissible “repair.” On review of the law and its application, we conclude that precedent does not support the Commission’s application of the law to the facts that were found. We conclude that for used cameras whose first sale was in the United States with the patentee’s authorization, and for which the respondents permitted verification of their representations that their activities were limited to the steps of (1) removing the cardboard cover, (2) cutting open the plastic casing, (3) inserting new film and a container to receive the film, (4) replacing the winding wheel for certain cameras, (5) replacing the battery for flash cameras, (6) resetting the counter, (7) resealing the outer case, and (8) adding a new cardboard cover, the totality of these procedures does not satisfy the standards required by precedent for prohibited reconstruction; precedent requires, as we shall discuss, that the described activities be deemed to be permissible repair.

For those cameras that meet the criteria outlined above, the Commission’s ruling of patent infringement is reversed and the Commission’s exclusion and cease and desist orders are vacated. For all other cameras, the Commission’s orders are affirmed.

DISCUSSION

* * *

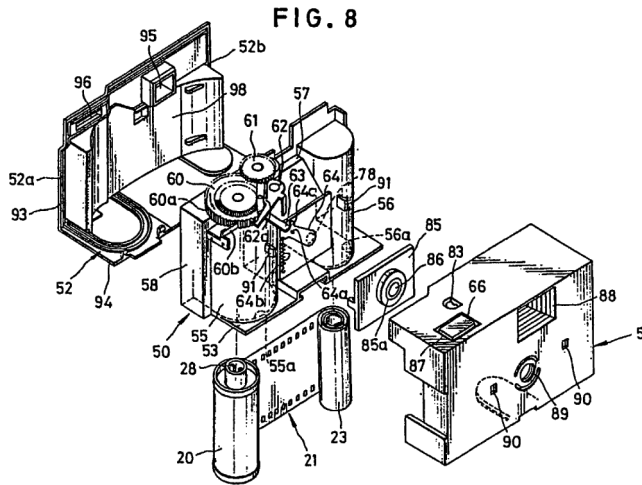
I

The Patented Inventions

The LFFP is a relatively simple camera, whose major elements are an outer plastic casing that holds a shutter, a shutter release button, a lens, a viewfinder, a film advance mechanism, a film counting display, and for some models a flash assembly and battery. The casing also contains a holder for a roll of film, and a container into which the exposed film is wound. At the factory a roll of film is loaded into the camera. The casing is then sealed by ultrasonic welding or light-tight latching, and a cardboard cover is applied to encase the camera.

LFFPs are intended by the patentee to be used only once. After the film is exposed the photo-processor removes the film container by breaking open a pre-weakened portion of the plastic casing which is accessed by removal of the cardboard cover. Discarded LFFPs, subsequently purchased and refurbished by the respondents, are the subject of this action.

The parts of an LFFP are illustrated in Figure 8 of the '087 patent:



Claim 1 of the '087 patent is representative of claims directed to the entire LFFP:

1. A lens-fitted photographic film package having an externally operable member for effecting an exposure, comprising:

a light-tight film casing which must be destroyed to open the same, having an opening through which said exposure is made when said externally operable member is operated;

an unexposed rolled film disposed on one side of said opening in said light-tight casing;

a removable light-tight film container having a film winding spool therein disposed on the opposite side of said opening in said light-tight casing from said rolled film, one end of said rolled film being attached to said film winding spool; means for winding said rolled film into said light-tight film container and around said film winding spool;

and winding control means responsive to operation of said externally operable member for allowing said film winding spool to rotate so as to enable said rolled film to be advanced by only one frame after every exposure;

said winding control means including: a sprocket wheel driven by movement of said rolled film;

and a frame counter driven by said sprocket wheel, said frame counter being provided with indications designating a series of frame numbers and means for disabling said winding control means responsive to said frame counter indicating there remains on said unexposed film no film frame capable of being exposed.

* * *

It is not disputed that the imported refurbished cameras contain all of the elements of all or most of the claims in suit.

The Accused Activities

The appellants import used LFFPs that have been refurbished by various overseas entities (called “remanufacturers” in the ITC proceeding). Some of the remanufacturers refused discovery entirely or in part, and some presented evidence that the ALJ found incomplete or not credible. The Commission explains: “Since so little was known about the accused infringing processes, the ALJ considered the common steps that each participating respondent admitted during the hearing were part of their processes.” The ALJ summarized these common steps as follows:

- removing the cardboard cover;
- opening the LFFP body (usually by cutting at least one weld);
- replacing the winding wheel or modifying the film cartridge to be inserted;
- resetting the film counter;
- replacing the battery in flash LFFPs;
- winding new film out of a canister onto a spool or into a roll;
- resealing the LFFP body using tape and/or glue;
- applying a new cardboard cover.

The Commission held that these activities constitute prohibited reconstruction. In view of this holding, it was not material to the Commission’s ruling that the full extent of various respondents’ activities was not made known, for in all events the importation would be infringing and unlawful.

The appellants argue that they are not building new LFFPs, but simply replacing the film in used cameras. They argue that the LFFPs have a useful life longer than the single use proposed by Fuji, that the patent right has been exhausted as to these articles, and that the patentee cannot restrict their right to refit the cameras with new film by the procedures necessary to insert the film and reset the mechanism. Unless these activities are deemed to be permissible, infringement of at least some of the patents in suit is conceded.

Burden and Standard of Proof

On this appeal there is much argument as to the burden and standard of proof. The administrative law judge ruled that the respondents must prove that their remanufactured cameras meet the criteria of permissible repair by clear and convincing evidence. The Commission held that this was not the correct standard, and that the respondents were required to prove the affirmative defense of permissible repair by no more than a preponderance of the evidence. However, the Commission found that this error did not change the correctness of the ALJ’s conclusion that the respondents’ actions were impermissible reconstruction of the patented articles.

While it is not disputed that repair is an affirmative defense, the parties disagree as to the order of coming forward with evidence, as well as the placement of the burden of proving that the accused activities are infringing reconstruction. The appellants state that the burden of proving infringement does not leave the patentee, and thus that the Commission incorrectly placed upon the appellants the burden of proving noninfringement. The appellants also argue that Fuji’s unrestricted first sale of the patented cameras satisfied *prima facie* the appellants’ burden on the affirmative defense of repair, for it established that the patent right had been exhausted; they state that this

shifted to the patentee the burden of proving that the accused activities were not repair. In support the appellants cite *General Electric Co. v. United States*, 572 F.2d 745, 783 n. 17 (1978), where the court noted that “Plaintiff, of course, has the burden of proof on issues relating to infringement (including ‘reconstruction’).”

The Commission ruled that “Once Fuji carried its burden of proof that its claims covered the remanufactured cameras, it was up to appellants to prove their affirmative defense that they were only repairing the cameras, not reconstructing them.” The Commission has correctly described this evidentiary sequence. The initial burden is upon the complainant to establish its cause of action, here patent infringement; the patentee must present evidence sufficient to establish that one or more patent claims are infringed. The respondents did not dispute that many or most of the claims in suit read literally on their refurbished cameras. Thus Fuji met its initial burden of showing infringement.

The burden of establishing an affirmative defense is on the party raising the defense. The Commission correctly held that the respondents had the burden of establishing this defense by a preponderance of the evidence, including the burden of coming forward with evidence to show that the activities performed in processing the used cameras constituted permissible repair.

The Law of Permissible Repair and Prohibited Reconstruction

The distinction between permitted and prohibited activities, with respect to patented items after they have been placed in commerce by the patentee, has been distilled into the terms “repair” and “reconstruction.” The purchaser of a patented article has the rights of any owner of personal property, including the right to use it, repair it, modify it, discard it, or resell it, subject only to overriding conditions of the sale. Thus patented articles when sold “become the private individual property of the purchasers, and are no longer specifically protected by the patent laws.” *Mitchell v. Hawley*, 83 U.S. (16 Wall.) 544, 548 (1872). The fact that an article is patented gives the purchaser neither more nor less rights of use and disposition. However, the rights of ownership do not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee.

While the ownership of a patented article does not include the right to make a substantially new article, it does include the right to preserve the useful life of the original article. It is readily apparent that there is a continuum between these concepts; precedent demonstrates that litigated cases rarely reside at the poles wherein “repair” is readily distinguished from “reconstruction.” Thus the law has developed in the body of precedent, illustrating the policy underlying the law as it has been applied in diverse factual contexts.

The principle of the distinction between permissible and prohibited activities was explained in *Wilson v. Simpson*, 50 U.S. (9 How.) 109 (1850), where the Court distinguished the right of a purchaser of a patented planing machine to replace the machine’s cutting-knives when they became dull or broken, from the patentee’s sole right to make or renew the entire machine. The Court observed that the knives had to be replaced every 60-90 days whereas the machines would last for several years, explaining, “what harm is done to the patentee in the use of his right of invention, when the repair and

replacement of a partial injury are confined to the machine which the purchaser has bought?" *Id.* at 123.

This principle underlies the application of the law. It was elaborated by the Court in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961), where the patented combination was a fabric convertible top and the associated metal support structure. The Court explained that replacement of the worn fabric top constituted permissible repair of the patented combination, and could not be controlled by the patentee. The Court restated the principles that govern the inquiry as applied to replacement of unpatented parts of a patented article:

The decisions of this Court require the conclusion that reconstruction of a patented entity, comprised of unpatented elements, is limited to such a true reconstruction of the entity as to "in fact make a new article," *United States v. Aluminum Co. of America*, [148 F.2d 416, 425 (2d Cir. 1945)], after the entity, viewed as a whole, has become spent. In order to call the monopoly, conferred by the patent grant, into play for a second time, it must, indeed, be a second creation of the patented entity, as, for example, in *American Cotton Tie Co. v. Simmons*, [106 U.S. 89 (1882)]. Mere replacement of individual unpatented parts, one at a time, whether of the same part repeatedly or different parts successively, is no more than the lawful right of the owner to repair his property.

365 U.S. at 346.

This right of repair, provided that the activity does not "in fact make a new article," accompanies the article to succeeding owners. In *Wilbur-Ellis Co. v. Kuther*, 377 U.S. 422 (1964), the Court dealt with the refurbishing of patented fish-canning machines by a purchaser of used machines. The Court held that the fairly extensive refurbishment by the new owner, including modification and resizing of six separate parts of the machine, although more than customary repair of spent or broken components, was more like repair than reconstruction, for it extended the useful life of the original machine. *See id.* at 425 ("Petitioners in adapting the old machines to a related use were doing more than repair in the customary sense; but what they did was kin to repair for it bore on the useful capacity of the old combination, on which the royalty had been paid.").

Precedent has classified as repair the disassembly and cleaning of patented articles accompanied by replacement of unpatented parts that had become worn or spent, in order to preserve the utility for which the article was originally intended. In *General Electric Co. v. United States*, 572 F.2d 745 (1978), the court held that the Navy's large scale "overhauling" of patented gun mounts, including disassembly into their component parts and replacement of parts that could not be repaired with parts from other gun mounts or new parts, was permissible repair of the original gun mounts. The court explained that the assembly-line method of reassembly, without regard to where each component had originated, was simply a matter of efficiency and economy, with the same effect as if each gun mount had been refurbished individually by disassembly and reassembly of its original components with replacement of a minor amount of worn elements. *Id.* at 780-86.

Similarly, in *Dana Corp. v. American Precision Co.*, 827 F.2d 755 (Fed. Cir. 1987), the court held that the "rebuilding" of worn truck clutches, although done on a commercial scale, was permissible repair. The defendants in *Dana*

Corp. acquired worn clutches that had been discarded by their original owners, disassembled them, cleaned and sorted the individual parts, replaced worn or defective parts with new or salvaged parts, and reassembled the clutches. Although the patentee stressed that some new parts were used and that the rebuilding was a large scale commercial operation, the activity was held to be repair. *Id.* at 759. The court also observed that in general the new parts were purchased from Dana, the original manufacturer of the patented clutches, and that repair of used clutches was contemplated by the patentee. The court rejected the argument that the complete disassembly and production-line reassembly of the clutches constituted a voluntary destruction followed by a “second creation of the patented entity,” invoking the phrase of *Aro Manufacturing*, 365 U.S. at 346.

“Reconstruction,” precedent shows, requires a more extensive rebuilding of the patented entity than is exemplified in *Aro Manufacturing*, *Wilbur-Ellis, General Electric*, and *Dana Corp.* In contrast, in *Sandvik Aktiebolag v. E.J. Co.*, 121 F.3d 669 (Fed. Cir. 1997), reconstruction was held to apply when a patented drill bit was “recreated” by construction of an entirely new cutting tip after the existing cutting tip could no longer be resharpened and reused. The court explained that it was not dispositive that the cutting tip was the “novel feature” of the invention, but that prohibited reconstruction occurred because a “new article” was made after the patented article, “viewed as a whole, has become spent.”

Underlying the repair/reconstruction dichotomy is the principle of exhaustion of the patent right. The unrestricted sale of a patented article, by or with the authority of the patentee, “exhausts” the patentee’s right to control further sale and use of that article by enforcing the patent under which it was first sold. In *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942), the Court explained that exhaustion of the patent right depends on “whether or not there has been such a disposition of the article that it may fairly be said that the patentee has received his reward for the use of the article.” See, e.g., *Intel Corp. v. USLI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (“The law is well settled that an authorized sale of a patented product places that product beyond the reach of the patent.”). Thus when a patented device has been lawfully sold in the United States, subsequent purchasers inherit the same immunity under the doctrine of patent exhaustion. However, the prohibition that the product may not be the vehicle for a “second creation of the patented entity” continues to apply, for such re-creation exceeds the rights that accompanied the initial sale.

Fuji states that some of the imported LFFP cameras originated and were sold only overseas, but are included in the refurbished importations by some of the respondents. The record supports this statement, which does not appear to be disputed. United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent. See *Boesch v. Graff*, 133 U.S. 697, 701-703 (1890) (a lawful foreign purchase does not obviate the need for license from the United States patentee before importation into and sale in the United States). Our decision applies only to LFFPs for which the United States patent right has been exhausted by first sale in the United States. Imported LFFPs of solely foreign provenance are not immunized from infringement of United States patents by the nature of their refurbishment.

Application of the Law

In the Commission's Initial Determination the administrative judge, applying the four factors discussed in *Sandvik Aktiebolag*, 121 F.3d at 673, held that the remanufacturers had made a new LFFP after the useful life of the original LFFP had been spent. Thus, the ALJ ruled that the remanufacturers were engaged in prohibited reconstruction. The Commission adopted the ALJ's findings and conclusions that the remanufacturers were not simply repairing an article for which either the producer or the purchaser expected a longer useful life, pointing out that the purchaser discarded the camera after use. The Commission ruled that the respondents were not simply repairing the LFFP in order to achieve its intended life span, but created a new single use camera that would again be discarded by its purchaser after use.

Although the Commission's conclusion is supported by its reasoning and reflects concern for the public interest, for there was evidence of imperfections and failures of some refurbished cameras, precedent requires that these cameras be viewed as repaired, not reconstructed. In *Dana Corp.*, for example, the truck clutches had lived their intended lives as originally produced, yet the court ruled that the "rebuilding" of the used clutches was more akin to repair than to reconstruction. The activities of disassembly and rebuilding of the gun mounts of *General Electric* were similarly extensive, yet were deemed to be repair. *Aro Manufacturing* and the other Supreme Court decisions which underlie precedent require that infringing reconstruction be a "second creation" of the patented article. Although the Commission deemed this requirement met by the "remanufactured" LFFPs, precedent places the acts of inserting new film and film container, resetting the film counter, and resealing the broken case—the principal steps performed by the remanufacturers—as more akin to repair.

The Court has cautioned against reliance on any specific set of "factors" in distinguishing permissible from prohibited activities, stating in *Aro Manufacturing* that "While there is language in some lower court opinions indicating that 'repair' or 'reconstruction' depends on a number of factors, it is significant that each of the three cases of this Court, cited for that proposition, holds that a license to use a patented combination includes the right 'to preserve its fitness for use. . .'" 365 U.S. at 345. Indeed, this criterion is the common thread in precedent, requiring consideration of the remaining useful capacity of the article, and the nature and role of the replaced parts in achieving that useful capacity. The appellants stress that all of the original components of the LFFP except the film and battery have a useful remaining life, and are reused. The appellants state that but for the exposed roll of film and its container, any portion of the case that was broken by the photo processor, and the winding wheel in certain cameras, the refurbished LFFP is substantially the original camera, for which the patent right has been exhausted.

The Commission placed weight on Fuji's intention that the LFFP not be reused. The '087 patent specification states that

forming an opening in the film package makes it impossible to reuse the film package. Therefore, it will be impossible to refill a new film into the used film package in order to reclaim a film package for reuse.

'087 patent, col. 6, lines 14-18. However, the patentee's unilateral intent, without more, does not bar reuse of the patented article, or convert repair into reconstruction. See *Hewlett-Packard*, 123 F.3d at 1453 ("a seller's intent, unless embodied in an enforceable contract, does not create a limitation on the right of a purchaser to use, sell, or modify a patented product so long as a reconstruction of the patented combination is avoided").

Claim 7 of the '087 patent is representative of those claims that specifically recite the film container and unexposed film roll, elements that are replaced by the remanufacturers:

7. A lens-fitted photographic film package comprising:
 - a light-tight film casing which must be destroyed to open the same, having an opening through which an exposure is made;
 - a light-tight film container having a film winding spool therein disposed on one side of said opening in said light-tight film casing;
 - a rotatable spool disposed on the opposite side of said opening in said light-tight film casing from said light-tight film container;
 - one end of said spool being exposed outside said light-tight film casing;
 - a film roll of unexposed film of which one end is attached to said film winding spool in said light-tight film container and which is rolled around said rotatable spool.

The appellants state that the film and its removable container are commercial items, and that their replacement in a camera cannot be deemed to be reconstruction. As discussed in *Aro Manufacturing*, the replacement of unpatented parts, having a shorter life than is available from the combination as a whole, is characteristic of repair, not reconstruction. On the totality of the circumstances, the changes made by the remanufacturers all relate to the replacement of the film, the LFFP otherwise remaining as originally sold.

* * *

License

Fuji alternatively contends that the right to repair the patented cameras is impliedly limited by the circumstances of sale, pointing to the instructions and warnings printed on the covers of the LFFPs, and arguing that these constituted a license limited to a single use. See *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 709 (Fed. Cir. 1992) (the conditions of sale of a "single-use" medical device may contractually restrict further use). The administrative law judge found that:

A Fuji flash QuickSnap single use camera is in a box and each of the box and the outer cardboard cover of the camera has statements instructing the purchaser to not remove the film and return the camera to the photoprocessor and further cautioning the purchaser about the risk of electrical shock if opened by the purchaser. . . . [The packaging also] instructs the purchaser that the single use camera will not be returned to the purchaser after processing. Similar notations are on [other cameras].

Initial Determination at 141.

A license is governed by the laws of contract. See *McCoy v. Mitsubishi Cutlery, Inc.*, 67 F.3d 917, 920 (Fed. Cir. 1995) ("Whether express or implied, a license

is a contract governed by ordinary principles of state contract law.”). It was undisputed that no express conditions of sale, license terms or restrictions attended the sale of these cameras. There was no express contractual undertaking by the purchaser. The administrative judge observed that any issue of implied contract or license was mooted by the finding of infringement based on reconstruction, *see* Initial Determination at 165, and made no findings on the issues of contract or license.

Determinations of express or implied license or contract are matters of law. As stated in *Hewlett-Packard*, “A seller’s intent, unless embodied in an enforceable contract, does not create a limitation on the right of a purchaser to use, sell, or modify a patented product as long as a reconstruction of the patented combination is avoided.” 123 F.3d at 1453. We do not discern an enforceable restriction on the reuse of these cameras based on the package statements. These statements are instructions and warnings of risk, not mutual promises or a condition placed upon the sale.

These package instructions are not in the form of a contractual agreement by the purchaser to limit reuse of the cameras. There was no showing of a “meeting of the minds” whereby the purchaser, and those obtaining the purchaser’s discarded camera, may be deemed to have breached a contract or violated a license limited to a single use of the camera. We conclude that no license limitation may be implied from the circumstances of sale.

* * *

Conclusion

The judgment of patent infringement is reversed with respect to LFFPs for which the patent right was exhausted by first sale in the United States, and that were permissibly repaired. Permissible repair is limited, as discussed herein, to the steps of removing the cardboard cover, cutting open the casing, inserting new film and film container, resetting the film counter, resealing the casing, and placing the device in a new cardboard cover. Included in permissible repair is replacement of the battery in flash cameras and the winding wheel in the cameras that so require. For these products the Commission’s orders are vacated.

LFFPs whose prior sale was not in the United States . . . remain subject to the Commission’s orders. For these products the Commission’s orders are affirmed.

Comments

1. ***Repair-Reconstruction and Patent Exhaustion.*** The principle of patent exhaustion applies when there is no express contractual restriction on the use of the patented product. In this scenario, the repair-reconstruction doctrine can be seen as providing default rules or filling in the interstices of the exhaustion principle. As the *Jazz Photo* court stated, “[u]nderlying the repair/reconstruction dichotomy is the principle of exhaustion of the patent right.” *See* Mark D. Janis, *A Tale of the Apocryphal Axe: Repair, Reconstruction, and the Implied License in Intellectual Property Law*, 58 MD. L.

REV. 423, 427 (1999) (referring to the exhaustion doctrine as the “organizing principle” for repair-reconstruction).

2. ***Distinguishing Between Repair and Reconstruction.*** In *Goodyear Shoe Machinery Co. v. Jackson*, 112 U.S. 146, 150 (1901), the Court asked the following questions: “What is legitimate repair, and what is reconstruction or reproduction as applied to a particular patented device or machine? When does repair destroy the identity of such device or machine and encroach upon invention? At what point does the legitimate repair of such device or machine end, and illegitimate reconstruction begin?” These questions are as relevant and perplexing today as they were when *Goodyear* was decided at the turn of the 20th century. Indeed, courts continue to struggle with defining the boundary between permissible repair and impermissible reconstruction. This difficulty arises, according to the Federal Circuit, because “[i]t is impracticable, as well as unwise, to attempt to lay down any rule on this subject, owing to the number and infinite variety of patented inventions.” *FMC Corp. v. Up-Right, Inc.*, 21 F.3d 1073, 1079 (Fed. Cir. 1994). (Of course, this is true for many areas on the common law of patents such as the doctrine of equivalents.)

But the situation is not hopeless. Indeed, it is helpful, as the court in *Jazz Photo* did, to discuss prior cases and provide context that can add resolution to this issue. For instance, the Federal Circuit, one year after *Jazz Photo*, identified “three primary repair and reconstruction situations.” In *Husky Injection Molding Systems Ltd. v. R & D Tool & Engineering Co.*, 291 F.3d 780, 786-87 (Fed. Cir. 2002), the court wrote:

First, there is the situation in which the entire patented item is spent, and the alleged infringer reconstructs it to make it useable again. Second, there is the situation in which a spent part is replaced. . . . [T]he Supreme Court set forth a definitive test in *Aro I*. Third, there is the situation in which a part is not spent but is replaced to enable the machine to perform a different function. This is a situation “kin to repair.”

Despite the number of cases concerning repair and reconstruction, difficult questions remain. One of these arises from the necessity of determining what constitutes replacement of a part of the device, which is repair or akin to repair, and what constitutes reconstruction of the entire device, which would not be repair or akin to repair. Some few situations suggest an obvious answer. For example, if a patent is obtained on an automobile, the replacement of the spark plugs would constitute permissible repair, but few would argue that the retention of the spark plugs and the replacement of the remainder of the car at a single stroke was permissible activity akin to repair. Thus, there may be some concept of proportionality inherent in the distinction between repair and reconstruction.

3. ***International Exhaustion.*** Can a patentee block the importation of his patented product that was manufactured and sold outside the U.S. by the patentee or someone with his authorization? The *Jazz Photo* court stated, “United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent.” 264 F.3d at 1105. *See also* *Fuji Photo Film Co., Ltd. v. Jazz Photo Corp.*, 394 F.3d 1368, 1376 (Fed. Cir. 2005) (stating first-sale doctrine is limited to sales occurring in the United States); *Boesch v. Graff*, 133 U.S. 697, 702 (1890)

(holding that a “dealer residing in the United States” cannot “purchase in another country articles patented there, from a person authorized to sell them, and import them to and sell them in the United States, without the license or consent of the owners of the United States patent”). *Cf. Curtiss Aeroplane & Motor Corp. v. United Aircraft Engineering Corp.*, 266 F. 71, 78 (2d Cir. 1920) (stating “[t]he purchaser of a patented article from a territorial licensee (one whose rights are limited to a restricted territory) may, unless there is a specific agreement to the contrary, use the article so purchased outside of the territory without interference from the patentee. The article is no longer within the monopoly of the patentee, and the purchaser can use it anywhere”).

The Europeans have adopted the principle of community-wide exhaustion. The European Court of Justice has held a lawful first sale of a patented product within the European Union exhausts patent rights within the EU. *See Centrafarm BV v. Sterling Drug Incorporated*, 2 C.M.L.R. 480 (1974); *Merck v. Stephar*, 3 C.M.L.R. 463 (1981). Exhaustion does not apply, however, for sales outside the EU.

4. **Implied License.** An implied license defense differs from patent exhaustion in that the former is concerned with the conduct of the patentee (or someone acting with his authorization), rather than on the actual sale of the patented product. Accordingly, “[a]ny language used by the *owner* of the patent, or any conduct on his part exhibited to another from which that other may *properly infer that the owner consents* to his use of the patent [*i.e.*, patented invention] . . . constitutes a license. . . .” (emphasis added). *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1559 (Fed. Cir. 1983). As this language indicates, the implied license defense is grounded in the doctrine of equitable estoppel, and “cannot arise out of the unilateral expectations or even reasonable hopes of one party. One must have been led to take action by the conduct of the other party.” *Id.* *See Bandag, Inc. v. Al Bolser’s Tire Stores, Inc.*, 750 F.2d 903 (Fed. Cir. 1984) (court refused to imply a license because alleged infringer’s behavior was not in response to patentee’s conduct). The implied license defense is rarely invoked successfully. But for a case where the defense was successfully asserted, *see Anton/Bauer, Inc. v. PAG, Ltd.*, 329 F.3d 1343 (Fed. Cir. 2003).

2. Contractual Limitations and the Misuse Doctrine

The use of contract in patent law is quite common, particularly in the form of patent licenses. A license that centers on the use of a patented product is negotiated between private parties, and therefore, as in other matters of commerce, the parties can choose the terms of the contract consistent with other areas of the law (*e.g.*, antitrust). For instance, a patentee and his licensee may agree on terms that restrict the use of the patented product, such as how many times the licensee can use the product and the manner and place in which the product can be used; condition access to the patented product on the purchase of an unpatented product; or agree to structure royalty payments based on various conditions and criteria. In addition, a patentee can restrict how a purchaser can use the patented product, thereby contractually constraining the purchaser’s rights under the exhaustion doctrine.

In these types of restrictive contracts, the issue is to what extent can a patentee restrict the use of the patented product or structure the terms of royalty payments without running afoul of patent law's misuse doctrine? (Antitrust implications and other forms of licensing are explored in Section B, below.) The misuse doctrine is designed to prevent a patentee from exploiting his patent rights beyond what the patent code provides. What this means and the relationship between restrictive contracting and the misuse doctrine are explored in the principal cases of *Philips*, *Morton Salt*, *Mallinckrodt*, and *Mon-santo*. The *Brulotte* and *Scheiber* cases discuss legal issues associated with how parties contractually structure royalty payments.

a. Package Licenses and Tying Arrangements

U.S. PHILIPS CORP. v. INTERNATIONAL TRADE COMMISSION

424 F.3d 1179 (Fed. Cir. 2005)

BRYSON, Circuit Judge.

U.S. Philips Corporation appeals from a final order of the United States International Trade Commission, in which the Commission held six of Philips's patents for the manufacture of compact discs to be unenforceable because of patent misuse. The Commission ruled that Philips had employed an impermissible tying arrangement because it required prospective licensees to license packages of patents rather than allowing them to choose which individual patents they wished to license and making the licensing fee correspond to the particular patents designated by the licensees. We reverse and remand.

I

Philips owns patents to technology for manufacturing recordable compact discs ("CD-Rs") and rewritable compact discs ("CD-RWs") in accordance with the technical standards set forth in a publication called the Recordable CD Standard (the "Orange Book"), jointly authored by Philips and Sony Corporation. Since the 1990s, Philips has been licensing those patents through package licenses. Philips specified that the same royalty was due for each disc manufactured by the licensee using patents included in the package, regardless of how many of the patents were used. Potential licensees who sought to license patents to the technology for manufacturing CD-Rs or CD-RWs were not allowed to license those patents individually and were not offered a lower royalty rate for licenses to fewer than all the patents in a package.

Initially, Philips offered four different pools of patents for licensing: (1) a joint CD-R patent pool that included patents owned by Philips and two other companies (Sony and Taiyo Yuden); (2) a joint CD-RW patent pool that included patents owned by Philips and two other companies (Sony and Ricoh); (3) a CD-R patent pool that included only patents owned by Philips; and (4) a CD-RW patent pool that included only patents owned by Philips. After 2001, Philips offered additional package options by grouping its patents into two categories, which Philips denominated "essential" and "nonessential" for producing compact discs compliant with the technical standards set forth in the Orange Book.

In the late 1990s, Philips entered into package licensing agreements with Princo Corporation and Princo America Corporation (collectively, "Princo");

GigaStorage Corporation Taiwan and GigaStorage Corporation USA (collectively, "GigaStorage"); and Linberg Enterprise Inc. ("Linberg"). Soon after entering into the agreements, however, Princo, GigaStorage, and Linberg stopped paying the licensing fees. Philips filed a complaint with the International Trade Commission that Princo, GigaStorage, and Linberg, among others, were violating section 337(a)(1)(B) of the Tariff Act of 1930, 19 U.S.C. § 1337(a)(1)(B), by importing into the United States certain CD-Rs and CD-RWs that infringed six of Philips's patents.

The Commission instituted an investigation and identified 19 respondents, including GigaStorage and Linberg. Additional respondents, including Princo, were added through intervention. In the course of the proceedings before an administrative law judge, the respondents raised patent misuse as an affirmative defense, alleging that Philips had improperly forced them, as a condition of licensing patents that were necessary to manufacture CD-Rs or CD-RWs, to take licenses to other patents that were not necessary to manufacture those products. In particular, the respondents argued that a number of the patents that Philips had included in the category of "essential" patents were actually not essential for manufacturing compact discs compliant with the Orange Book standards, because there were commercially viable alternative methods of manufacturing CD-Rs and CD-RWs that did not require the use of the technology covered by those patents. The allegedly nonessential patents included U.S. Patent Nos. 5,001,692 ("the Farla patent"), 5,740,149 ("the Iwasaki patent"), Re. 34,719 ("the Yamamoto patent"), and 5,060,219 ("the Lokhoff patent").

The administrative law judge ruled that the intervenors had infringed various claims of the six asserted Philips patents. The administrative law judge further ruled, however, that all six of the asserted patents were unenforceable by reason of patent misuse. Among the grounds invoked by the administrative law judge for finding patent misuse was his conclusion that the package licensing arrangements constituted tying arrangements that were illegal under analogous antitrust law principles and thus rendered the subject patents unenforceable.

Philips petitioned the Commission for review of the administrative law judge's decision. In an order that addressed only the findings concerning patent misuse, the Commission affirmed the administrative law judge's ruling that Philips's package licensing practice "constitutes patent misuse per se as a tying arrangement between (1) licenses to patents that are essential to manufacture CD-Rs or CD-RWs according to Orange Book standards and (2) licenses to other patents that are not essential to that activity." The Commission found that the Farla, Iwasaki, Yamamoto, and Lokhoff patents were not essential to manufacturing CD-Rs or CD-RWs. Specifically, the Commission found that the Farla and Lokhoff patents were nonessential with respect to the Philips-only CD-RW and CD-R licenses, and that the Farla, Iwasaki, Yamamoto, and Lokhoff patents were nonessential with respect to the joint CD-RW license. The Commission concluded that the four nonessential patents were impermissibly tied to patents that were essential to manufacturing CD-Rs and CD-RWs, because "none of the so-called essential patents could be licensed individually for the manufacture of CD-RWs and CD-Rs apart from the package" that Philips denominated as "essential." The Commission also found, based on the administrative law judge's findings and

analysis, that the joint license for CD-R and CD-RW technology unlawfully tied patents for CD-Rs and CD-RWs in accordance with the Orange Book standards to patents that were not essential to manufacture such discs.

The Commission explained why it concluded that each of the four patents was nonessential. According to the Commission, the Farla and Iwasaki patents were not essential because there was an economically viable alternative method of writing information to discs that did not require the producer to practice those patents; the Yamamoto patent was not essential because there was a potential alternative method of creating master discs that did not require the producer to practice that patent; and the Lokhoff patent was not essential because there were alternative possible methods of accomplishing copy protection that did not require the producer to practice that patent. Based on those findings, the Commission concluded that the four “nonessential” patents constituted separate products from the patents that were essential to the manufacture of the subject discs.

The Commission ruled that Philips’s patent package licensing arrangement constituted per se patent misuse because Philips did not give prospective licensees the option of licensing individual patents (presumably for a lower fee) rather than licensing one or more of the patent packages as a whole. The Commission took no position on the administrative law judge’s ruling that patent pooling arrangements between Philips and its co-licensors constituted patent misuse per se based on the theories of price fixing and price discrimination, and it took no position on the administrative law judge’s conclusion that the royalty structure of the patent pools was an unreasonable restraint of trade.

As an alternative ground, the Commission concluded that even if Philips’s patent package licensing practice was not per se patent misuse, it constituted patent misuse under the rule of reason. Adopting the administrative law judge’s findings, the Commission ruled that the anticompetitive effects of including nonessential patents in the packages of so-called essential patents outweighed the pro-competitive effects of that practice. In particular, the Commission held that including such nonessential patents in the licensing packages could foreclose alternative technologies and injure competitors seeking to license such alternative technologies to parties who needed to obtain licenses to Philips’s “essential” patents. The Commission took no position with respect to the portion of the administrative law judge’s rule of reason analysis in which the administrative law judge concluded that the royalty rate structure of the patent pooling arrangements constituted an unreasonable restraint on competition.

II

Patent misuse is an equitable defense to patent infringement. It “arose to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.” *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704 (Fed. Cir. 1992). The purpose of the patent misuse defense “was to prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right.” *Id.* As the Supreme Court has explained, the doctrine of patent misuse bars a patentee from using the “patent’s leverage” to “extend the monopoly of his patent to derive a benefit not at-

tributable to the use of the patent's teachings," such as requiring a licensee to pay a royalty on products that do not use the teaching of the patent. *Zenith Radio Corp. v. Hazeltine Res., Inc.*, 395 U.S. 100, 135-36 (1969). The "key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998).

This court summarized the principles of patent misuse as applied to "tying" arrangements in *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868-69 (Fed. Cir. 1997). The court there explained that because of the importance of anticompetitive effects in shaping the defense of patent misuse, the analysis of tying arrangements in the context of patent misuse is closely related to the analysis of tying arrangements in antitrust law. The court further explained that, depending on the circumstances, tying arrangements can be viewed as per se patent misuse or can be analyzed under the rule of reason. *Id.* The court noted that certain specific practices have been identified as constituting per se patent misuse, "including so-called 'tying' arrangements in which a patentee conditions a license under the patent on the purchase of a separable, staple good, and arrangements in which a patentee effectively extends the term of its patent by requiring post-expiration royalties." *Id.* at 869 (citations omitted). If the particular licensing arrangement in question is not one of those specific practices that has been held to constitute per se misuse, it will be analyzed under the rule of reason. *Id.* We have held that under the rule of reason, a practice is impermissible only if its effect is to restrain competition in a relevant market. *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004).

The Supreme Court's decisions analyzing tying arrangements under antitrust law principles are to the same effect. The Court has made clear that tying arrangements are deemed to be per se unlawful only if they constitute a "naked restrain[t] of trade with no purpose except stifling of competition" and "always or almost always tend to restrict competition and decrease output" in some substantial portion of a market. *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19-20 (1979). The Supreme Court has applied the per se rule only when "experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it." *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 344 (1982). *See also Jefferson Parish Hosp. Dist. v. Hyde*, 466 U.S. 2, 14 (1983) ("[T]he law draws a distinction between the exploitation of market power by merely enhancing the price of the tying product, on the one hand, and by attempting to impose restraints on competition in the market for a tied product, on the other."). Conduct is not considered per se anticompetitive if it has "redeeming competitive virtues and . . . the search for those values is not almost sure to be in vain." *Broad. Music*, 441 U.S. at 13.

While the doctrine of patent misuse closely tracks antitrust law principles in many respects, Congress has declared certain practices not to be patent misuse even though those practices might otherwise be subject to scrutiny under antitrust law principles. In 35 U.S.C. § 271(d), Congress designated several specific practices as not constituting patent misuse. The designated practices include "condition[ing] the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product," unless, in view of the circumstances,

the patent owner “has market power for the patent or patented product on which the license or sale is conditioned.” *Id.* § 271(d)(5). Because the statute is phrased in the negative, it does not require that patent misuse be found in the case of all such conditional licenses in which the patent owner has market power; instead, the statute simply excludes such conditional licenses in which the patent owner lacks market power from the category of arrangements that may be found to constitute patent misuse. To establish the defense of patent misuse, the accused infringer must show that the patentee has power in the market for the tying product. *See id.* at 1349 n.7.

Philips argues briefly that it lacks market power and that it is thus shielded from liability by section 271(d)(5). Based on detailed analysis by the administrative law judge, however, the Commission found that Philips has market power in the relevant market and that section 271(d)(5) is therefore inapplicable to this case. We sustain that ruling. Philips contends that at the time Philips and Sony first created their package license arrangements, CDs had significant competition among computer data storage devices and thus Philips lacked market power in the market for computer data storage discs. However, Philips first created the package licenses long before GigaStorage and Princo entered into their agreements. According to the administrative law judge, the patent package arrangements were instituted in the early 1990s. Yet Princo did not enter into its agreement until June of 1997, and GigaStorage did not enter into its licensing agreement until October of 1999. Thus, any lack of market power that Philips and its co-licensors may have had in the early 1990s is irrelevant to the situation in the late 1990s, when the parties entered into the agreements at issue in this case. At that time, according to the administrative law judge’s well-supported finding, compact discs had become “unique products [with] no close practice substitutes.” Philips’s argument about lack of market power is therefore unpersuasive, and for that reason section 271(d)(5) does not provide Philips a statutory safe haven from the judicially created defense of patent misuse.

Apart from its specific challenge to the Commission’s ruling on the market power issue, Philips launches a more broad-based attack on the Commission’s conclusion that Philips’s patent licensing policies constitute per se patent misuse. In so doing, Philips makes essentially two arguments: first, that the Commission was wrong as a legal matter in ruling that the package licensing arrangements at issue in this case are among those few practices that the courts have identified as so clearly anticompetitive as to warrant being condemned as per se illegal; and second, that the Commission erred as a factual matter in concluding that Philips’s package licensing arrangements reflect the use of market power in one market to foreclose competition in a separate market. We address the two arguments separately.

A

In its brief, the Commission argues that it is “hornbook law” that mandatory package licensing has been held to be patent misuse. Philips invites us to consider whether that broad proposition is sound. Upon consideration, we conclude that the proposition as applied to the circumstances of this case is not supported by precedent or reason.

In its opinion, the Commission acknowledged that the *Virginia Panel* case and many other patent tying cases “involve a tying patent and a tied product,

rather than a tying patent and a tied *patent*.” (emphasis in original). The Commission nonetheless concluded that “finding patent misuse based on a tying arrangement between patents in a mandatory package license is a reasonable application of Supreme Court precedent.” In so ruling, the Commission relied primarily on two Supreme Court cases: *United States v. Paramount Pictures, Inc.*, 334 U.S. 131, 156-59 (1948), and *United States v. Loew’s, Inc.*, 371 U.S. 38, 44-51 (1962). Those cases condemned the practice of “block-booking” movies to theaters (in the *Paramount* case) and to television stations (in the *Loew’s* case) as antitrust violations.

Block-booking is the practice in which a distributor licenses one feature or group of features to exhibitors on the condition that the exhibitors agree to license another (presumably inferior) feature or group of features released by the distributor during a given period. In *Paramount* and *Loew’s*, the Court held that block-booking, as practiced in those cases, was per se illegal. The Commission reasoned that the practice of block-booking that was the focus of the Court’s condemnation in *Paramount* and *Loew’s* is similar to the package licensing agreements at issue in this case and that under the analysis employed in *Paramount* and *Loew’s*, Philips’s package licensing agreements must be condemned as per se patent misuse.

We do not agree with the Commission that the decisions in *Paramount* and *Loew’s* govern this case. In *Paramount*, the district court held that the defendant movie distributor had engaged in unlawful conduct because it offered to permit exhibitors to show the films they wished to license only if they agreed to license and exhibit other films that they were not interested in licensing. The Supreme Court affirmed that ruling. The Court held that block-booking was illegal because it “prevents competitors from bidding for single features on their individual merits,” and because it “adds to the monopoly of a single copyrighted picture that of another copyrighted picture which must be taken and exhibited in order to secure the first.” 334 U.S. at 156-57. The result, the Court explained, “is to add to the monopoly of the copyright in violation of the principle of the patent cases involving tying clauses.” *Id.* at 158. Because the block-booking arrangement at issue in *Paramount* required the licensee to exhibit all of the films in the group for which a license was taken, the *Paramount* block-booking was more akin to a tying arrangement in which a patent license is tied to the purchase of a separate product, rather than to an arrangement in which a patent license is tied to another patent license. Indeed, all of the patent tying cases to which the Supreme Court referred in *Paramount* involved tying arrangements in which, as the Court described them, “the owner of a patent [conditioned] its use on the purchase or use of patented or unpatented materials.” 334 U.S. at 157. Because the arrangement in the *Paramount* case was equivalent in substance to a patent-to-product tying arrangement, *Paramount* does not stand for the proposition that a pure patent-to-patent tying arrangement, such as Philips’s package licensing agreement, is per se unlawful.

Philips gives its licensees the option of using any of the patents in the package, at the licensee’s option. Philips charges a uniform licensing fee to manufacture discs covered by its patented technology, regardless of which, or how many, of the patents in the package the licensee chooses to use in its manufacturing process. In particular, Philips’s package licenses do not require that licensees actually use the technology covered by any of the patents that

the Commission characterized as nonessential. In that respect, Philips's licensing agreements are different from the agreements at issue in *Paramount*, which imposed an obligation on the purchasers of package licenses to exhibit films they did not wish to license. That obligation not only extended the exclusive right in one product to products in which the distributor did not have exclusive rights, but it also precluded exhibitors, as a practical matter, from exhibiting other films that they may have preferred over the tied films they were required to exhibit. Because Philips's package licensing agreements do not compel the licensees to use any particular technology covered by any of the licensed patents, the *Paramount* case is not a sound basis from which to conclude that the package licensing arrangements at issue in this case constitute patent misuse per se.

In the case of patent-to-product tying, the patent owner uses the market power conferred by the patent to compel customers to purchase a product in a separate market that the customer might otherwise purchase from a competitor. The patent owner is thus able to use the market power conferred by the patent to foreclose competition in the market for the product. By contrast, a package licensing agreement that includes both essential and nonessential patents does not impose any requirement on the licensee. It does not bar the licensee from using any alternative technology that may be offered by a competitor of the licensor. Nor does it foreclose the competitor from licensing his alternative technology; it merely puts the competitor in the same position he would be in if he were competing with unpatented technology.

A package license is in effect a promise by the patentee not to sue his customer for infringing any patents on whatever technology the customer employs in making commercial use of the licensed patent. That surrender of rights might mean that the customer will choose not to license the alternative technology offered by the patentee's competition, but it does not compel the customer to use the patentee's technology. The package license is thus not anticompetitive in the way that a compelled purchase of a tied product would be.

Contrary to the Commission's characterization, the intervenors were not "forced" to "take" anything from Philips that they did not want, nor were they restricted from obtaining licenses from other sources to produce the relevant technology. Philips simply provided that for a fixed licensing fee, it would not sue any licensee for engaging in any conduct covered by the entire group of patents in the package. By analogy, if Philips had decided to surrender its "nonessential" patents or had simply announced that it did not intend to enforce them, there would have been no way for the manufacturers to decline or reject Philips's decision. Yet the economic effect of the package licensing arrangement for Philips's patents is not fundamentally different from the effect that such decisions would have had on third parties seeking to compete with the technology covered by those "nonessential" patents. Thus, we conclude that the Commission erred when it characterized the package license agreements as a way of forcing the intervenors to license technology that they did not want in order to obtain patent rights that they did.

The Commission stated that it would not have found the package licenses to constitute improper tying if Philips had offered to license its patents on an individual basis, as an alternative to licensing them in packages. The Commission's position, however, must necessarily be based on an assumption that,

if the patents were offered on an individual basis, individual patents would be offered for a lower price than the patent packages as a whole. If that assumption were not implicit in the Commission's conclusion, the Commission would be saying in effect that it would be unlawful for Philips to charge the same royalty for its essential patents that it charges for its patent packages and to offer the nonessential patents for free. Yet that sort of pricing policy plainly would not be unlawful.

[T]he Commission's assumption that a license to fewer than all the patents in a package would presumably carry a lower fee than the package itself ignores the reality that the value of any patent package is largely, if not entirely, based on the patents that are essential to the technology in question. A patent that is nonessential because it covers technology that can be fully replaced by alternative technology that is available for free is essentially valueless. A patent that is nonessential because it covers technology that can be fully replaced by alternative technology that is available through a license from another patent owner has value, but its value is limited by the price of the alternative technology. Short of imposing an obligation on the licensor to make some sort of allocation of fees across a group of licenses, there is no basis for the Commission to conclude that a smaller group of the licenses — the so-called "essential" licenses — would have been available for a lower fee if they had not been "tied to" the so-called nonessential patents.

It is entirely rational for a patentee who has a patent that is essential to particular technology, as well as other patents that are not essential, to charge what the market will bear for the essential patent and to offer the others for free. Because a license to the essential patent is, by definition, a prerequisite to practice the technology in question, the patentee can charge whatever maximum amount a willing licensee is able to pay to practice the technology in question. If the patentee allocates royalty fees between its essential and non-essential patents, it runs the risk that licensees will take a license to the essential patent but not to the nonessential patents. The effect of that choice will be that the patentee will not be able to obtain the full royalty value of the essential patent. For the patentee in this situation to offer its nonessential patents as part of a package with the essential patent at no additional charge is no more anticompetitive than if it had surrendered the nonessential patents or had simply announced a policy that it would not enforce them against persons who licensed the essential patent. In either case, those offering technology that competed with the nonessential patents would be unhappy, because they would be competing against free technology. But the patentee would not be using his essential patent to obtain power in the market for the technology covered by the nonessential patents. This package licensing arrangement cannot fairly be characterized as an exploitation of power in one market to obtain a competitive advantage in another.⁵

Aside from the absence of evidence that the package licensing arrangements in this case had the effect of impermissibly broadening the scope of the

5. The implication of the Commission's decision is that a party with both an essential patent and a nonessential patent is not allowed to package the two together and only offer the package for a single price. That would have the perverse effect of potentially putting a party owning both an essential patent and a nonessential but related patent in a worse position than a party owning only the essential patent. The party owning only the essential patent would be free to charge any

“essential” patents with anticompetitive effect, Philips argues that the Commission failed to acknowledge the unique pro-competitive benefits associated with package licensing. Philips points to the federal government’s guidelines for licensing intellectual property, which recognize that patent packages “may provide pro-competitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation. By promoting the dissemination of technology, cross-licensing and pooling arrangements are often pro-competitive.” U.S. Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* § 5.5 (1995).

Philips introduced evidence that package licensing reduces transaction costs by eliminating the need for multiple contracts and reducing licensors’ administrative and monitoring costs. See *Tex. Instruments, Inc. v. Hyundai Elecs.*, 49 F. Supp. 2d 893, 901 (E.D. Tex. 1999) (describing how “extremely expensive and time-consuming” it is for parties to license and manage the licensing of technology by using individual patents and how it is preferable to employ a patent portfolio). Package licensing can also obviate any potential patent disputes between a licensor and a licensee and thus reduce the likelihood that a licensee will find itself involved in costly litigation over unlicensed patents with potentially adverse consequences for both parties, such as a finding that the licensee infringed the unlicensed patents or that the unlicensed patents were invalid. Thus, package licensing provides the parties a way of ensuring that a single licensing fee will cover all the patents needed to practice a particular technology and protecting against the unpleasant surprise for a licensee who learns, after making a substantial investment, that he needed a license to more patents than he originally obtained. Finally, grouping licenses in a package allows the parties to price the package based on their estimate of what it is worth to practice a particular technology, which is typically much easier to calculate than determining the marginal benefit provided by a license to each individual patent. In short, package licensing has the pro-competitive effect of reducing the degree of uncertainty associated with investment decisions.

The package licenses in this case have some of the same advantages as the package licenses at issue in the *Broadcast Music* case. The Supreme Court determined in that case that the blanket copyright package licenses at issue had useful, pro-competitive purposes because they gave the licensees “unplanned, rapid, and indemnified access to any and all of the repertory of [musical] compositions, and [they gave the owners] a reliable method of collecting for the use of the their copyrights.” While “[i]ndividual sales transactions [would be] quite expensive, as would be individual monitoring and enforcement,” a package licensing agreement would ensure access and save costs. *Id.* Hence, the Supreme Court determined that such conduct should fall

licensing fee up to the maximum that a manufacturer would be willing to pay to practice the patented technology, while a party owning both the essential patent and a nonessential patent would be barred from extracting that maximum licensing fee for its essential patent and assuring the manufacturer that it would not be subject to suit on the nonessential patent.

under “a more discriminating examination under the rule of reason.” *Id.* at 24. In light of the efficiencies of package patent licensing and the important differences between product-to-patent tying arrangements and arrangements involving group licensing of patents, we reject the Commission’s conclusion that Philips’s conduct shows a “lack of any redeeming virtue” and should be “conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.” *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958). We therefore hold that the analysis that led the Commission to apply the rule of per se illegality to Philips’s package licensing agreements was legally flawed.

MORTON SALT CO. v. G. S. SUPPIGER CO.

314 U.S. 488 (1942)

Mr. Chief Justice STONE delivered the opinion of the Court.

Respondent brought this suit in the district court for an injunction and an accounting for infringement of its Patent No. 2,060,645, of November 10, 1936, on a machine for depositing salt tablets, a device said to be useful in the canning industry for adding predetermined amounts of salt in tablet form to the contents of the cans.

[T]he trial court, without passing on the issues of validity and infringement, granted summary judgment dismissing the complaint. It took the ground that respondent was making use of the patent to restrain the sale of salt tablets in competition with its own sale of unpatented tablets, by requiring licensees to use with the patented machines only tablets sold by respondent. The Court of Appeals for the Seventh Circuit reversed, as it did not appear that the use of its patent substantially lessened competition or tended to create a monopoly in salt tablets. We granted certiorari because of the public importance of the question presented.

The Clayton Act authorizes those injured by violations tending to monopoly to maintain suit for treble damages and for an injunction in appropriate cases. But the present suit is for infringement of a patent. The question we must decide is not necessarily whether respondent has violated the Clayton Act, but whether a court of equity will lend its aid to protect the patent monopoly when respondent is using it as the effective means of restraining competition with its sale of an unpatented article.

Both respondent’s wholly owned subsidiary and the petitioner manufacture and sell salt tablets used and useful in the canning trade. The tablets have a particular configuration rendering them capable of convenient use in respondent’s patented machines. Petitioner makes and leases to canners unpatented salt deposition machines, charged to infringe respondent’s patent. For reasons we indicate later, nothing turns on the fact that petitioner also competes with respondent in the sale of the tablets, and we may assume for purposes of this case that petitioner is doing no more than making and leasing the alleged infringing machines. The principal business of respondent’s subsidiary, from which its profits are derived, is the sale of salt tablets. In connection with this business, and as an adjunct to it, respondent leases its patented machines to commercial canners, some two hundred in all, under licenses to use the machines upon condition and with the agreement of the

licensees that only the subsidiary's salt tablets be used with the leased machines.

It thus appears that respondent is making use of its patent monopoly to restrain competition in the marketing of unpatented articles, salt tablets, for use with the patented machines, and is aiding in the creation of a limited monopoly in the tablets not within that granted by the patent. A patent operates to create and grant to the patentee an exclusive right to make, use and vend the particular device described and claimed in the patent. But a patent affords no immunity for a monopoly not within the grant, and the use of it to suppress competition in the sale of an unpatented article may deprive the patentee of the aid of a court of equity to restrain an alleged infringement by one who is a competitor. It is the established rule that a patentee who has granted a license on condition that the patented invention be used by the licensee only with unpatented materials furnished by the licensor, may not restrain as a contributory infringer one who sells to the licensee like materials for like use.

The grant to the inventor of the special privilege of a patent monopoly carries out a public policy adopted by the Constitution and laws of the United States, "to promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right. . . ." to their "new and useful" inventions. But the public policy which includes inventions within the granted monopoly excludes from it all that is not embraced in the invention. It equally forbids the use of the patent to secure an exclusive right or limited monopoly not granted by the Patent Office and which it is contrary to public policy to grant.

It is a principle of general application that courts, and especially courts of equity, may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest. Respondent argues that this doctrine is limited in its application to those cases where the patentee seeks to restrain contributory infringement by the sale to licensees of competing unpatented article, while here respondent seeks to restrain petitioner from a direct infringement, the manufacture and sale of the salt tablet depositor. It is said that the equitable maxim that a party seeking the aid of a court of equity must come into court with clean hands applies only to the plaintiff's wrongful conduct in the particular act or transaction which raises the equity, enforcement of which is sought; that where, as here, the patentee seeks to restrain the manufacture or use of the patented device, his conduct in using the patent to restrict competition in the sale of salt tablets does not foreclose him from seeking relief limited to an injunction against the manufacture and sale of the infringing machine alone.

Undoubtedly "equity does not demand that its suitors shall have led blameless lives," but additional considerations must be taken into account where maintenance of the suit concerns the public interest as well as the private interests of suitors. Where the patent is used as a means of restraining competition with the patentee's sale of an unpatented product, the successful prosecution of an infringement suit even against one who is not a competitor in such sale is a powerful aid to the maintenance of the attempted monopoly of the unpatented article, and is thus a contributing factor in thwarting the public policy underlying the grant of the patent. Maintenance and enlargement of the attempted monopoly of the unpatented article are dependent to

some extent upon persuading the public of the validity of the patent, which the infringement suit is intended to establish. Equity may rightly withhold its assistance from such a use of the patent by declining to entertain a suit for infringement, and should do so at least until it is made to appear that the improper practice has been abandoned and that the consequences of the misuse of the patent have been dissipated.

The reasons for barring the prosecution of such a suit against one who is not a competitor with the patentee in the sale of the unpatented product are fundamentally the same as those which preclude an infringement suit against a licensee who has violated a condition of the license by using with the licensed machine a competing unpatented article, *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, or against a vendee of a patented or copyrighted article for violation of a condition for the maintenance of resale prices. It is the adverse effect upon the public interest of a successful infringement suit in conjunction with the patentee's course of conduct which disqualifies him to maintain the suit, regardless of whether the particular defendant has suffered from the misuse of the patent. Similarly equity will deny relief for infringement of a trademark where the plaintiff is misrepresenting to the public the nature of his product either by the trademark itself or by his label. The patentee, like these other holders of an exclusive privilege granted in the furtherance of a public policy, may not claim protection of his grant by the courts where it is being used to subvert that policy.

It is unnecessary to decide whether respondent has violated the Clayton Act, for we conclude that in any event the maintenance of the present suit to restrain petitioner's manufacture or sale of the alleged infringing machines is contrary to public policy and that the district court rightly dismissed the complaint for want of equity.

Comments

1. **The Misuse Doctrine Defined.** Patent misuse is a common law, equitable doctrine that focuses on whether the patentee exploited his patent rights beyond its lawful statutory scope. See *Windsurfing Int'l Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986) (stating a finding of misuse "requires that the alleged infringer show that the patentee has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect"). What this means exactly is difficult to fully grasp, but misuse has typically applied (or is asserted) in the context of certain types of licensing arrangements, namely tying or post-expiration royalty provisions (*i.e.*, royalty payments made after the patent expires).
2. **The Misuse Doctrine: Diluted and Under Attack.** Over the past several years, the misuse doctrine has been greatly weakened both statutorily and judicially. Beginning in 1952, Congress enacted § 271(d) that stated a patent owner could not be found "guilty of misuse or illegal extension of the patent right" if he:

(1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent

would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement.

In *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176 (1980), the Supreme Court provided a lengthy historical analysis of events that led to the enactment of § 271(d). In *Dawson*, the Court held that the patentee's practice of conditioning the licensing of its process patent on the purchase of an unpatented product was not misuse because the product did not have a substantial non-infringing use—it had “no use except through practice of the patented method.” *Id.* at 199.

Two additional provisions were added to § 271(d) in 1988:

(4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

Subsection (4) reflects the long standing principle in the United States that—in contrast to countries such as Brazil and India—the patent owner has no duty to work, sell, or license his patented invention. See *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 429 (1908) (stating “exclusion may be said to have been of the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not use it, without question of motive”); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940) (patentee has right to refuse to license or sell its patented product). (This proposition will be reexamined in § B on antitrust in the context of a refusal to deal scenario.) Subsection (5) of § 271(d) is explored in greater detail in Comment 3.

There have also been judicial pronouncements that question the economic soundness of the misuse doctrine (and whether there is room for such a doctrine in the light of antitrust law). See *USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505 (7th Cir. 1982) (stating the traditional formulation of misuse is “too vague . . . to be useful” and “taken seriously it would put all patent rights at hazard”), or that place significant limits on the applicability of the doctrine. See *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), which is the next principal case. See also *Illinois Tool Works, Inc. v. Independent, Inc.*, 126 S. Ct. 1281, 1286 (2006) (stating “[o]ver the years, this Court’s strong disapproval of tying arrangements has substantially diminished”).

3. **Tying Arrangements.** One of the earliest and well-known cases dealing with misuse is *Morton Salt Co. v. G.S. Suppiger Co.*, the principal case above that involved a tying arrangement. The Supreme Court did not decide if Morton violated the antitrust laws, yet nonetheless asked “whether a court of equity will lend its aid to protect the patent monopoly when respondent is using it as the effective means of restraining competition with its sale of an unpatented article.” *Id.* at 490. The court viewed the patent grant as imbued with the public interest and held Morton was “making use of its patent monopoly to restrain competition in the marketing of unpatented articles, salt tablets, for use with the patented machines, and is aiding in the creation of a limited monopoly in the tablets not within that granted by the patent.”

Id. at 491. In other words, Morton was improperly attempting to extend his patent rights beyond what is statutorily permissible, and “courts, and especially courts of equity, may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest.” *Id.* at 492.

Section 271(d)(5) states a tying arrangement will not lead to misuse if the patentee lacks market power “for the patent or patented product on which the license or sale is conditioned.” (In this regard, § 271(d)(5) overruled *Morton Salt’s* per se prohibition of tying agreements.) Market power is an important condition because it is a rare case that a patent confers market power. (Section B.1 explores patents and market power in more detail.) Indeed, there are almost always viable substitutes to the patented product. See Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 VAND. L. REV. 1727, 1730 (2000) (explaining why “patents that confer monopoly market power are rare”). See also *Illinois Tool Works, Inc. v. Independent Ink, Inc.*, 126 S. Ct. 1281, 1284 (2006) (referring to the presumption of market power and patents, the court stated “when a seller conditions its sale of a patented product (the “tying” product) on the purchase of a second product (the “tied” product), [the presumption of market power] has its foundation in the judicially created patent misuse doctrine” and “[i]n 1988, Congress substantially undermined that foundation, amending the Patent Act to eliminate the market power presumption in patent misuse cases”).

In *Philips* the Federal Circuit affirmed the International Trade Commission’s finding that Philips had market power (a rare instance), and therefore, Philips was not statutorily protected by § 271(d)(5). But the court nonetheless reversed the Commission’s holding that Philips’s package license was an illegal tying arrangement. Judge Bryson, in an opinion consistent with recent economic thinking about tying arrangements, focused on the pro-competitive nature of package license as well as efficiency considerations. Both *Philips* and § 271(d)(5) seem to embrace the notion that it is difficult to leverage through tying or bundling arrangements market power from a patented product into a separate market, usually a market for the tied, unpatented good. In *Scheiber v. Dolby Laboratories, Inc.*, Judge Posner writes, “[t]he naive objection [to tying or bundling arrangements] is that they extend monopoly; the sophisticated objection is that they facilitate price discrimination.” He continues:

The traditional objection to tying is that by telling the buyer that he can’t buy the tying product unless he agrees to buy a separate product from the seller as well, the seller is trying to “lever” or “extend” his monopoly to the market for that separate product. Yet if the seller tries to charge a monopoly price for that separate product, the buyer will not be willing to pay as much for the tying product as he would if the separate product, which he has to buy also, were priced at a lower rate. Acquiring monopoly power in the tied-product market comes at the expense of losing it in the tying-product market. Thus, as these cases and a tidal wave of legal and economic scholarship point out, the idea that you can use tying to lever your way to a second monopoly is economic nonsense, imputing systematic irrationality to businessmen. Congress seems to have recognized this in the 1988 amendment.

293 F.3d 1014, 1020 (7th Cir. 2002). See also ROBERT H. BORK, *THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF* 372-81 (1978) (discussing why tying

arrangements do not injure competition). This approach should be contrasted with the more traditional notion that tying is a means of leveraging to restrain competition, and therefore should be deemed illegal per se. See Donald Turner, *The Validity of Tying Arrangements Under the Antitrust Laws*, 58 HARV. L. REV. 50, 62 (1958) (stating “it is a reasonable assumption that the purpose of the seller in using a tie-in is to restrain competition in the tied product”); *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 611 (1953) (stating tying arrangements allow a seller to leverage “his dominant position in one market to expand his empire into the next”).

4. ***The Differences Between Misuse and Antitrust.*** There are a few important differences between misuse and antitrust. Misuse has its origins in equity and arose from the doctrine of unclean hands. See *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998). It is an affirmative defense that has the effect of rendering the patent unenforceable, not invalid. Unenforceability, however, lasts only until the misuse is purged, meaning that the impermissible activity stops and the effects of misuse have dissipated. *Id.* Antitrust is employed as a counterclaim that can result in an award of damages. Thus, antitrust is more of a sword, whereas misuse assumes the role of a shield. Antitrust also has narrower applicability in that misuse may attach to a given scenario even though there is no antitrust violation. See *B. Braun Medical, Inc. v. Abbott Laboratories, Inc.*, 124 F.3d 1419, 1427 (Fed. Cir. 1997) (stating “[p]atent misuse arose, as an equitable defense available to the accused infringer, from the desire ‘to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.’ When used successfully, this defense results in rendering the patent unenforceable until the misuse is purged. It does not, however, result in an award of damages to the accused infringer”).

b. Field-of-Use Restrictions

MALLINCKRODT v. MEDIPART

976 F.2d 700 (Fed. Cir. 1992)

NEWMAN, Circuit Judge.

This action for patent infringement and inducement to infringe relates to the use of a patented medical device in violation of a “single use only” notice that accompanied the sale of the device. Mallinckrodt sold its patented device to hospitals, which after initial use of the devices sent them to Medipart for servicing that enabled the hospitals to use the device again. Mallinckrodt claimed that Medipart thus induced infringement by the hospitals and itself infringed the patent.

The district court held that violation of the “single use only” notice cannot be remedied by suit for patent infringement, and granted summary judgment of noninfringement.

* * *

[T]he district court held that no restriction whatsoever could be imposed under the patent law, whether or not the restriction was enforceable under

some other law, and whether or not this was a first sale to a purchaser with notice. This ruling is incorrect, for if Mallinckrodt's restriction was a valid condition of the sale, then in accordance with *General Talking Pictures Corp. v. Western Electric Co.*, it was not excluded from enforcement under the patent law.

We conclude that the district court misapplied precedent in holding that there can be no restriction on use imposed as a matter of law, even on the first purchaser. The restriction here at issue does not per se violate the doctrine of patent misuse or the antitrust law. Use in violation of a valid restriction may be remedied under the patent law, provided that no other law prevents enforcement of the patent. The district court's misapplication of precedent also led to an incorrect application of the law of repair/reconstruction, for if reuse is established to have been validly restricted, then even repair may constitute patent infringement.

BACKGROUND

The patented device is an apparatus for delivery of radioactive or therapeutic material in aerosol mist form to the lungs of a patient, for diagnosis and treatment of pulmonary disease. Radioactive material is delivered primarily for image scanning in diagnosis of lung conditions. Therapeutic agents may be administered to patients suffering various lung diseases.

The device is manufactured by Mallinckrodt, who sells it to hospitals as a unitary kit that consists of a "nebulizer" which generates a mist of the radioactive material or the prescribed drug, a "manifold" that directs the flow of oxygen or air and the active material, a filter, tubing, a mouthpiece, and a nose clip. In use, the radioactive material or drug is placed in the nebulizer, is atomized, and the patient inhales and exhales through the closed system. The device traps and retains any radioactive or other toxic material in the exhalate. The device fits into a lead-shielded container that is provided by Mallinckrodt to minimize exposure to radiation and for safe disposal after use.

The device is marked with the appropriate patent numbers, and bears the trademarks "Mallinckrodt" and "UltraVent" and the inscription "Single Use Only." The package insert provided with each unit states "For Single Patient Use Only" and instructs that the entire contaminated apparatus be disposed of in accordance with procedures for the disposal of biohazardous waste. The hospital is instructed to seal the used apparatus in the radiation-shielded container prior to proper disposal. The hospitals whose activities led to this action do not dispose of the UltraVent apparatus, or limit it to a single use.

Instead, the hospitals ship the used manifold/nebulizer assemblies to Medipart, Inc. Medipart in turn packages the assemblies and sends them to Radiation Sterilizers Inc., who exposes the packages to at least 2.5 megarads of gamma radiation, and returns them to Medipart. Medipart personnel then check each assembly for damage and leaks, and place the assembly in a plastic bag together with a new filter, tubing, mouthpiece, and nose clip. The "reconditioned" units, as Medipart calls them, are shipped back to the hospitals from whence they came. Neither Radiation Sterilizers nor Medipart tests the reconditioned units for any residual biological activity or for radioactivity. The assemblies still bear the inscription "Single Use Only" and the trademarks "Mallinckrodt" and "UltraVent."

Mallinckrodt filed suit against Medipart, asserting patent infringement and inducement to infringe. . . .

The district court granted Medipart's motion on the patent infringement counts, holding that the "Single Use Only" restriction could not be enforced by suit for patent infringement. The court also held that Medipart's activities were permissible repair, not impermissible reconstruction, of the patented apparatus. . . .

The district court also enjoined Mallinckrodt *recomp lite* from distributing a new notice to its hospital customers. The proposed new notice emphasized the "Single Use Only" restriction and stated that the purpose of this restriction is to protect the hospital and its patients from potential adverse consequences of reconditioning, such as infectious disease transmission, material instability, and/or decreased diagnostic performance; that the UltraVent device is covered by certain patents; that the hospital is licensed under these patents to use the device only once; and that reuse of the device would be deemed infringement of the patents.

Mallinckrodt appeals the grant of summary judgment on the infringement issue, and the grant of the preliminary injunction.

I

The Restriction on Reuse

Mallinckrodt describes the restriction on reuse as a label license for a specified field of use, wherein the field is single (*i.e.*, disposable) use. On this motion for summary judgment, there was no issue of whether this form of license gave notice of the restriction. Notice was not disputed. Nor was it disputed that sale to the hospitals was the first sale of the patented device. The issue that the district court decided on summary judgment was the enforceability of the restriction by suit for patent infringement. The court's premise was that even if the notice was sufficient to constitute a valid condition of sale, violation of that condition cannot be remedied under the patent law.

Mallinckrodt states that the restriction to single patient use is valid and enforceable under the patent law because the use is within the scope of the patent grant, and the restriction does not enlarge the patent grant. Mallinckrodt states that a license to less than all uses of a patented article is well recognized and a valid practice under patent law, and that such license does not violate the antitrust laws and is not patent misuse. Mallinckrodt also states that the restriction here imposed is reasonable because it is based on health, safety, efficacy, and liability considerations and violates no public policy. Thus Mallinckrodt argues that the restriction is valid and enforceable under the patent law. Mallinckrodt concludes that use in violation of the restriction is patent infringement, and that the district court erred in holding otherwise.

Medipart states that the restriction is unenforceable, for the reason that "the *Bauer* trilogy and *Motion Picture Patents* clearly established that *no* restriction is enforceable under patent law upon a purchaser of a sold article." (Medipart's emphasis). The district court so held. The district court also held that since the hospitals purchased the device from the patentee, not from a manufacturing licensee, no restraint on the use of the device could lawfully be imposed under the patent law.

The enforceability of restrictions on the use of patented goods derives from the patent grant, which is in classical terms of property: the right to exclude.

35 U.S.C. § 154. Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . .

This right to exclude may be waived in whole or in part. The conditions of such waiver are subject to patent, contract, antitrust, and any other applicable law, as well as equitable considerations such as are reflected in the law of patent misuse. As in other areas of commerce, private parties may contract as they choose, provided that no law is violated thereby:

[T]he rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the [patented] article, will be upheld by the courts.

E. Bement & Sons v. National Harrow Co., 186 U.S. 70, 91 (1902).

The district court's ruling that Mallinckrodt's restriction on reuse was unenforceable was an application of the doctrine of patent misuse, although the court declined to use that designation. The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy. The policy purpose was to prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right.

The district court's holding that Mallinckrodt's restriction to single patient use was unenforceable was, as we have remarked, based on "policy" considerations. The district court relied on a group of cases wherein resale price-fixing of patented goods was held illegal, viz. *Bauer & Cie. v. O'Donnell*; *Straus v. Victor Talking Machine Co.*; *Boston Store of Chicago v. American Graphophone Co.* ("the *Bauer* trilogy"), and that barred patent-enforced tie-ins, viz. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*

* * *

These cases established that price-fixing and tying restrictions accompanying the sale of patented goods were per se illegal. These cases did not hold, and it did not follow, that all restrictions accompanying the sale of patented goods were deemed illegal. In *General Talking Pictures* the Court, discussing restrictions on use, summarized the state of the law as follows:

That a restrictive license is legal seems clear. *Mitchell v. Hawley* [83 U.S.], 16 Wall. 544 (1873). As was said in *United States v. General Electric Co.*, 272 U.S. 476, 489 (1926), the patentee may grant a license "upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure." . . .

The practice of granting licenses for restricted use is an old one, see *Rubber Company v. Goodyear*. So far as it appears, its legality has never been questioned. 305 U.S. at 127.

In *General Talking Pictures* the patentee had authorized the licensee to make and sell amplifiers embodying the patented invention for a specified use (home radios). The defendant had purchased the patented amplifier from the

manufacturing licensee, with knowledge of the patentee's restriction on use. The Supreme Court stated the question as "whether the restriction in the license is to be given effect" against a purchaser who had notice of the restriction. The Court observed that a restrictive license to a particular use was permissible, and treated the purchaser's unauthorized use as infringement of the patent, deeming the goods to be unlicensed as purchased from the manufacturer.

The Court, in its opinion on rehearing, stated that it

[did not] consider what the rights of the parties would have been if the amplifier had been manufactured under the patent and had passed into the hands of a purchaser in the ordinary channels of trade.

305 U.S. at 127. The district court interpreted this reservation as requiring that since the hospitals purchased the UltraVent device from the patentee Mallinckrodt, not from a manufacturing licensee, no restraint on the purchasers' use of the device could be imposed under the patent law. However, in *General Talking Pictures* the Court did not hold that there must be an intervening manufacturing licensee before the patent can be enforced against a purchaser with notice of the restriction. The Court did not decide the situation where the patentee was the manufacturer and the device reached a purchaser in ordinary channels of trade.

The UltraVent device was manufactured by the patentee; but the sale to the hospitals was the first sale and was with notice of the restriction. Medipart offers neither law, public policy, nor logic, for the proposition that the enforceability of a restriction to a particular use is determined by whether the purchaser acquired the device from a manufacturing licensee or from a manufacturing patentee. We decline to make a distinction for which there appears to be no foundation. Indeed, Mallinckrodt has pointed out how easily such a criterion could be circumvented. That the viability of a restriction should depend on how the transaction is structured was denigrated as "formalistic line drawing" in *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 57-59 (1977), the Court explaining, in overruling *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365 (1967), that the legality of attempts by a manufacturer to regulate resale does not turn on whether the reseller had purchased the merchandise or was merely acting as an agent of the manufacturer. The Court having disapproved reliance on formalistic distinctions of no economic consequence in antitrust analysis, we discern no reason to preserve formalistic distinctions of no economic consequence, simply because the goods are patented.

The district court, holding Mallinckrodt's restriction unenforceable, described the holding of *General Talking Pictures* as in "some tension" with the earlier price-fixing and tie-in cases. The district court observed that the Supreme Court did not cite the *Bauer*, *Boston Store*, or *Motion Picture Patents* cases when it upheld the use restriction in *General Talking Pictures*. That observation is correct, but it should not be remarkable. By the time of *General Talking Pictures*, price-fixing and tie-ins were generally prohibited under the antitrust law as well as the misuse law, while other conditions were generally recognized as within the patent grant. The prohibitions against price-fixing and tying did not make all other restrictions per se invalid and unenforceable. [footnote omitted] Further, the Court could not have been unaware of the

Bauer trilogy in deciding *General Talking Pictures*, because Justice Black's dissent is built upon those cases.

Restrictions on use are judged in terms of their relation to the patentee's right to exclude from all or part of the patent grant, and where an anticompetitive effect is asserted, the rule of reason is the basis of determining the legality of the provision. In *Windsurfing International, Inc. v. AMF, Inc.*, this court stated:

To sustain a misuse defense involving a licensing arrangement not held to have been per se anticompetitive by the Supreme Court, a factual determination must reveal that the overall effect of the license tends to restrain competition unlawfully in an appropriately defined relevant market.

782 F.2d at 1001-1002. The district court, stating that it "refuse[s] to limit *Bauer* and *Motion Picture Patents* to tying and price-fixing not only because their language suggests broader application, but because there is a strong public interest in not stretching the patent laws to authorize restrictions on the use of purchased goods", *Mallinckrodt*, 15 U.S.P.Q.2d at 1119, has contravened this precedent.

* * *

Viewing the entire group of these early cases, it appears that the Court simply applied, to a variety of factual situations, the rule of contract law that sale may be conditioned. *Adams v. Burke* and its kindred cases do not stand for the proposition that no restriction or condition may be placed upon the sale of a patented article. It was error for the district court to derive that proposition from the precedent. Unless the condition violates some other law or policy (in the patent field, notably the misuse or antitrust law, e.g., *United States v. Univis Lens Co.*, private parties retain the freedom to contract concerning conditions of sale. As we have discussed, the district court cited the price-fixing and tying cases as reflecting what the court deemed to be the correct policy, viz., that no condition can be placed on the sale of patented goods, for any reason. However, this is not a price-fixing or tying case, and the per se antitrust and misuse violations found in the *Bauer* trilogy and *Motion Picture Patents* are not here present. The appropriate criterion is whether *Mallinckrodt's* restriction is reasonably within the patent grant, or whether the patentee has ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason.

Should the restriction be found to be reasonably within the patent grant, i.e., that it relates to subject matter within the scope of the patent claims, that ends the inquiry. However, should such inquiry lead to the conclusion that there are anticompetitive effects extending beyond the patentee's statutory right to exclude, these effects do not automatically impeach the restriction. Anticompetitive effects that are not per se violations of law are reviewed in accordance with the rule of reason. Patent owners should not be in a worse position, by virtue of the patent right to exclude, than owners of other property used in trade.

We conclude that the district court erred in holding that the restriction on reuse was, as a matter of law, unenforceable under the patent law. If the sale of the UltraVent was validly conditioned under the applicable law such as the law governing sales and licenses, and if the restriction on reuse was within the scope of the patent grant or otherwise justified, then violation of the restriction may be remedied by action for patent infringement. The grant of summary judgment is reversed, and the cause is remanded.

MONSANTO CO. v. McFARLING

363 F.3d 1336 (Fed. Cir. 2004)

CLEVENGER, Circuit Judge.

The United States District Court for the Eastern District of Missouri entered summary judgment against defendant Homan McFarling and in favor of the Monsanto Company (“Monsanto”) on some, but not all, of the claims being litigated. The district court held that, when McFarling replanted some of Monsanto’s patented ROUNDUP READY® soybeans that he had saved from his prior year’s crop, McFarling breached the Technology Agreement that he had signed as a condition of his purchase of the patented seeds.

I

Monsanto manufactures ROUNDUP® herbicide. ROUNDUP® contains glyphosate, a chemical that indiscriminately kills vegetation by inhibiting the metabolic activity of a particular enzyme, 5-enolpyruvyl-shikimate-3 phosphate synthase (“EPSPS”). EPSPS is necessary for the conversion of sugars into amino acids—and thus for growth—in many plants and weeds.

Monsanto also markets ROUNDUP READY® genetic-modification technology. In soybean seeds, the ROUNDUP READY® technology operates by inserting the gene sequence for a variant of EPSPS that is not affected by the presence of glyphosate but that still performs the sugar-conversion function required for cell growth. Thus, ROUNDUP READY® soybean seeds produce both a “natural” version of EPSPS that is rendered ineffective in the presence of the glyphosate in ROUNDUP® herbicide, and a genetically modified version of EPSPS that permits the soybean seeds to grow nonetheless. ROUNDUP®, or other glyphosate-based herbicides, can thus be sprayed over the top of an entire field, killing the weeds without harming the ROUNDUP READY® soybeans.

The Monsanto Technology Agreement in dispute in this case lists six patents related to the various seeds that are licensed by the agreement, but Monsanto has asserted infringement in this case only under two patents that read on aspects of the use of the ROUNDUP READY® technology in soybeans. United States Patent No. 5,633,435 (“the ’435 patent”) relates to the gene encoding the modified EPSPS enzyme. United States Patent No. 5,352,605 (“the ’605 patent”) relates to the use of a particular promoter in genetically modified plant cells. The ’605 patent claims DNA sequences and plant cells containing the promoter. A promoter sequence is a DNA sequence

located in proximity to the DNA sequence that encodes a protein and that, in part, tells the cellular machinery how much of the protein to make.

Monsanto licenses its proprietary ROUNDUP READY® technology through two interrelated licensing schemes. First, it licenses the patented gene to seed companies that manufacture the glyphosate-tolerant seeds that are sold to farmers. Under this license, seed companies gain the right to insert the genetic trait into the germplasm of their own seeds (which can differ from seed company to seed company), and Monsanto receives the right to a royalty or “technology fee” of \$6.50 for every 50-pound bag of seed containing the ROUNDUP READY® technology sold by the seed company. Monsanto also owns several subsidiary seed companies that comprise approximately 20 percent of the market for ROUNDUP READY® soybeans.

Second, Monsanto requires that seed companies execute licenses, rather than conduct unconditional sales, with their farmer customers. The 1998 version of this “Monsanto Technology Agreement” (the “Technology Agreement”) between Monsanto and the soybean farmers using ROUNDUP READY® soybeans places several conditions on the soybean farmers’ use of the licensed soybeans. In exchange for the “[o]ppportunity to purchase and plant seed containing” the ROUNDUP READY® technology, soybean farmers agree:

To use the seed containing Monsanto gene technologies for planting a commercial crop only in a single season.

To not supply any of this seed to any other person or entity for planting, and to not save any crop produced from this seed for replanting, or supply saved seed to anyone for replanting.

To not use this seed or provide it to anyone for crop breeding, research, generation of herbicide registration data or seed production.

II

Homan McFarling operates a 5000-acre farm in Pontotoc County, Mississippi. In 1998, McFarling executed the Technology Agreement in connection with the license of 1000 bags of ROUNDUP READY® soybean seed. McFarling concedes that he saved 1500 bushels of seed from his 1998 crop, enough to plant approximately 1500 acres, and that he replanted them in 1999. He subsequently saved 3075 bags of soybeans from his 1999 crop, replanting them in 2000.

Soybeans destined for replanting are apparently cleaned after harvest. When McFarling sent his seeds saved from the 1998 season to a third party for cleaning, Monsanto had some samples taken, had the genetic makeup of the seeds tested at Mississippi State University, and thus learned that McFarling was saving ROUNDUP READY® seeds.

III

In January 2000, Monsanto filed suit against McFarling, alleging infringement of the '435 and '605 patents and breach of the Technology Agreement, and seeking a preliminary injunction prohibiting McFarling from “planting, transferring or selling the infringing articles to a third party.” In his answer, McFarling raised affirmative defenses (styled alternatively as counterclaims

when possible) both to liability—including, *inter alia*, violations of the patent misuse doctrine, and the patent exhaustion and first sale doctrines.

Back in the district court, Monsanto moved for summary judgment on the infringement claim under the '605 patent, the breach of the Technology Agreement claim, and all of McFarling's affirmative defenses. The district court granted summary judgment in favor of Monsanto on all of McFarling's defenses as well as on liability with respect to Monsanto's '605 patent infringement claim and the Technology Agreement claim. . . .

IV

McFarling appealed the district court's final judgment to us, and we have jurisdiction to hear his appeal pursuant to 28 U.S.C. § 1295(a)(1). McFarling argues that the district court's grant of summary judgment on the breach-of-contract claim was erroneous [based] on his patent-misuse defense.

V

McFarling argues that Monsanto has committed patent misuse because Monsanto has impermissibly tied an unpatented product to a patented product. In McFarling's words, "[b]y prohibiting seed-saving, Monsanto has extended its patent on the gene technology to include an unpatented product—the germplasm—or God-made soybean seed which is not within the terms of the patent."

The policy of the patent misuse doctrine is "to prevent a patentee from using the patent to obtain market benefit beyond that which inures in the statutory patent right." *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704 (Fed. Cir. 1992). Therefore, in evaluating a patent-misuse defense, "[t]he key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998). In the cases in which the restriction is reasonably within the patent grant, the patent misuse defense can never succeed. *See Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127, (1938); *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426-27 (Fed. Cir. 1997); *Mallinckrodt*, 976 F.2d at 708. In cases in which a condition controlling the use of a patented invention extends beyond the patentee's statutory right to exclude, however, either a *per se* rule of patent misuse, or a rule of reason analysis, *Windsurfing Int'l v. AMF, Inc.*, 782 F.2d at 1001-02 ("To sustain a misuse defense involving a licensing arrangement not held to have been *per se* anticompetitive by the Supreme Court, a factual determination must reveal that the overall effect of the license tends to restrain competition unlawfully in an appropriately defined relevant market."), must be applied.

Tying can constitute patent misuse: A patent licensor who conditions the license on a patent licensee's purchase of an unpatented material for use in the invention may, under certain conditions, be impermissibly extending the scope of the subject matter encompassed by the patent grant.

We need not plumb the complexities of tying as misuse of a patent, however, to determine that the district court correctly granted summary judgment for Monsanto. McFarling does not raise a typical tying allegation, and the mere recitation of the word "tying" is not sufficient to state a patent misuse defense. McFarling does not argue that he cannot purchase soybean germplasm without

the genetic trait that brings the soybean within the ambit of Monsanto's patent. In fact, a market for such unmodified soybeans exists. Neither does McFarling argue that he sought (or is capable of performing under) the type of license granted to the seed companies to purchase, make or use the patented gene sequence prior to its insertion into the seed.

McFarling's "tying" argument instead centers on his desire to replant the entire seed, including the genetic modifications, and on Monsanto's refusal to grant him permission to do so. McFarling proposes that Monsanto could "untie" the seed and the trait by permitting the farmer to save and replant ROUNDUP READY® seed each year, provided the farmer still pays directly to Monsanto the required technology fee, rather than requiring a farmer to purchase both the seed and the genetic technology together at the beginning of each growing season. By suggesting that he should be allowed to pay the technology fee in conjunction with replanting of the second-generation soybeans, the closest McFarling comes to alleging a tying argument is a suggestion that Monsanto has tied together the legal right to exclude granted by a patent and the entire, physical patented product (or combination of germ-plasm and trait). At its simplest, McFarling effectively argues in different words that he should be granted a compulsory license to use the patent rights in conjunction with the second-generation ROUNDUP READY® soybeans in his possession after harvest. We decline to hold that Monsanto's raw exercise of its right to exclude from the patented invention by itself is a "tying" arrangement that exceeds the scope of the patent grant.

What perhaps truly irks McFarling is that the license controls what McFarling can do with second-generation seeds—the seeds that McFarling "made" using the seeds that he acquired under a strict license. McFarling argues that the prohibition in the Technology Agreement on "sav[ing] any crop produced from this seed for replanting" constitutes patent misuse; he does not suggest that the prohibitions on "supply[ing] any of this seed to any other person or entity for planting" and on "supply[ing] saved seed to anyone for replanting" should render the patent unenforceable. Nonetheless, Monsanto tries rather unconvincingly to paint its restrictions in the Technology Agreement as permissible field-of-use restrictions on the first-generation seeds. *Cf. B. Braun*, 124 F.3d at 1426 ("[F]ield of use restrictions . . . are generally upheld."). Monsanto argues that it "may license a grower to 'use' its patented ROUNDUP READY® biotechnology to grow a commercial crop, but decline to license a grower to 'make' patented seed for use or sale as a crop seed." Based on the record before us, McFarling plants and grows the first-generation seed in an identical fashion whether he intends to sell the second-generation seed as a commercial crop for consumption or whether he intends to replant it. Thus, the Technology Agreement does not impose a restriction on the use of the product purchased under license but rather imposes a restriction on the use of the goods made by the licensed product.

Our case law has not addressed in general terms the status of such restrictions placed on goods made by, yet not incorporating, the licensed good under the patent misuse doctrine. However, the Technology Agreement presents a unique set of facts in which licensing restrictions on the use of goods produced by the licensed product are not beyond the scope of the patent grant at issue: The licensed and patented product (the first-generation seeds) and the good made by the licensed product (the second-generation seeds) are nearly identical

copies. Thus, given that we must presume that Monsanto's '435 patent reads on the first-generation seeds, it also reads on the second-generation seeds. Because the '435 patent would read on all generations of soybeans produced, we hold that the restrictions in the Technology Agreement prohibiting the replanting of the second generation of ROUNDUP READY[®] soybeans do not extend Monsanto's rights under the patent statute.

Comments

- 1. *The Benefits of Patent Licensing.*** Patent licensing is a very common activity and typically leads to efficiency gains and pro-competitive effects. Patent owners are not always in the best position to exploit their patent rights or have the means to commercialize their inventions or otherwise capture the return on their investment. Licensing provides the patent owner with an opportunity to integrate various complementary factors related to production such as manufacturing and distribution, thus putting the patented invention to the most efficient and productive use. As a government report on antitrust and licensing of intellectual property stated, integration through licensing "can lead to more efficient exploitation of the intellectual property, benefiting consumers through the reduction of costs and the introduction of new products," and also "increase the value of intellectual property to consumers and to the developers of the technology." ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 2.3 (U.S. Department of Justice and Federal Trade Commission 1995). See also WILLIAM J. BAUMOL, *THE FREE-MARKET INNOVATION MACHINE: ANALYZING THE GROWTH MIRACLE OF CAPITALISM* 77-91 (2002) (discussing the economic incentives and benefits of licensing); ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (Department of Justice and Federal Trade Commission 2007).
- 2. *Conditional Licensing and the Exhaustion Doctrine.*** What is clear from the *Mallinckrodt* and *Monsanto* decisions is a licensee's or purchaser's use of patented goods can be contractually restricted. In *Mallinckrodt*, the restriction was "single use only" for the patented device, and the "Technology Agreement" in *Monsanto* limited McFarling's use of the seed to a "single season," and prohibited him from supplying the seed to third parties or saving "any crop produced" from the seed "for replanting." A field-of-use contract allows the patentee to exercise greater control over the use of his patented technology while also enhancing the financial return from the technology. But these restrictive licenses are not without costs for the licensor, namely potentially high transactions costs such as identifying, negotiating, and overseeing what are oftentimes several licenses. But, as one commentator noted, these extra costs are worth the effort, "when more than one company is needed to fully develop a technology's potential, when different licensees are needed to address different markets, or when field-of-use licensing has the potential to significantly increase the financial return from a technology." S.L. Shotwell, *Field-of-Use Licensing* in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 1113 (A. Krattiger, R.T. Mahoney, L. Nelsen et al., eds., 2007).

In this regard, *Mallinckrodt* and *Monsanto* held it was permissible (not misuse) for the patentees and the purchasers/users to contractually agree to render the patent exhaustion doctrine inapplicable. As the Federal Circuit stated in *Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997), the “exhaustion doctrine does not apply to an expressly conditional sale or license” because “[i]n such a transaction, it is more reasonable to infer that the parties negotiated a price that reflects only the value of the ‘use’ rights conferred by the patentee. As a result, express conditions accompanying the sale or license of a patented product are generally upheld.” See also *USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505, 510-11 (7th Cir. 1982) (stating “[t]he patentee who insists on limiting the freedom of his purchaser or licensee—whether to price, to use complementary inputs of the purchaser’s choice, or to make competing items—will have to compensate the purchaser for the restriction by charging a lower price for the use of the patent”). Moreover, recall the repair/reconstruction doctrine comes into play when there is an unconditional sale. As such, the doctrine is inapplicable in the face of a conditional license. See *Mallinckrodt*, 976 F.2d at 709 (stating in the light of the single-use restriction, there is “no need to choose between repair and reconstruction” because “even repair of an unlicensed device constitutes infringement”).

The Federal Circuit’s approach to the role of contract in *Mallinckrodt* and *Monsanto* is perhaps better appreciated in the light of the proposition that a patentee has no duty to sell, license, or use his patented product. As the Supreme Court stated in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 429 (1908), “exclusion may be said to have been of the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not use it, without question of motive.” See also *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940) (patentee has right to refuse to license or sell its patented product). (This proposition will be reexamined in Section B on antitrust in the context of the refusal to deal cases.)

The rationale of *Mallinckrodt* was applied in *Arizona Cartridge Remanufacturers Ass’n, Inc. v. Lexmark Intern., Inc.*, 421 F.3d 981 (9th Cir. 2005). Lexmark made and sold laser printers and toner (printer) cartridges, and also remanufactured its cartridges. As part of its “Prebate” program, Lexmark gave consumers an upfront discount on its patented printer cartridges. The Prebate cartridges cost consumers on average 30 dollars (or 20 percent) less than a regular cartridge. In return, Lexmark required the consumer to return the depleted cartridge to Lexmark or its agent. The Prebate cartridge package set forth the following terms on the outside of the package:

RETURN EMPTY CARTRIDGE TO L’MARK FOR REMANUFACTURING AND RECYCLING

Please read before opening. Opening of this package or using the patented cartridge inside confirms your acceptance of the following license agreement. The patented cartridge is sold at a special price subject to a restriction that it may be used only once. Following this initial use, you agree to return the empty cartridge only to L’Mark for remanufacturing and recycling. If you don’t accept these terms, return the unopened package to your point of purchase. A regular price cartridge without these terms is available.

Consumers can opt to buy L'Mark cartridges without the Prebate post-sale restriction, but at the higher price. According to Lexmark, its post-sale restriction on reusing the Prebate cartridges does not require consumers to return the cartridge at all; it only precludes giving the cartridge to another remanufacturer. ACRA, which represents wholesalers that remanufacture emptied Lexmark printer cartridges for reuse, alleged that Lexmark engaged in anti-competitive behavior. The Ninth Circuit disagreed and held that the terms on the package created a valid contract, and that under *Mallinckrodt* Lexmark could restrict the use of its patented product.

3. ***The Power of the Contract-Patent Combination.*** The *Mallinckrodt* case highlights the power of using contract and property rights in combination. Recall in *Mallinckrodt* the single-use notice applied to the entire patented device, and therefore (assuming the license is valid) the hospitals reuse of the inhaler would be direct infringement, and Medipart would be liable for indirect infringement. Contrast this scenario with *Kendall Co. v. Progressive Medical Technology, Inc.*, 85 F.3d 1570 (Fed. Cir. 1996). In *Kendall*, the patent related to a medical device—known as the SCD System—for applying compressive pressure to a patient's limbs in order to increase blood flow. The patent claiming the SCD System comprised several limitations, one of which was “elongated pressure sleeves.” The sleeves were not covered by a separate patent. Kendall sold its SCD System to medical care facilities, with the understanding that customers would replace the pressure sleeves to reduce the risk of contamination. Indeed, Kendall marked “FOR SINGLE PATIENT USE ONLY. DO NOT REUSE” on the packaging of the replacement sleeves that it sold to its customers. Some patients purchased replacement sleeves from Kendall, but others purchased sleeves from the defendant, Progressive, which supplied the medical care facilities with the replacement sleeves. Kendall sued Progressive for indirect infringement. Relying on *Mallinckrodt*, Kendall asserted it placed a valid single-use restriction on the use of the sleeves.

The Federal Circuit held *Mallinckrodt* was not helpful to Kendall's position. According to the court:

In . . . *Mallinckrodt*, the patentee, sold patented inhalers to hospitals subject to a notice that they were for “single use only.” The “single use only” notice referred to reuse of the entire patented device. The hospitals *disregarded* that notice and permitted the defendant, Medipart, to collect used inhalers from the hospitals, recondition them, and sell them back to the hospitals for reuse. . . . Here, unlike the facts in *Mallinckrodt*, Kendall's customers *followed* rather than disregarded the single-use notice. They replaced the pressure sleeves after each use. Also, Kendall's customers did not agree to purchase replacement sleeves *from Kendall*. Kendall argued in the district court that such an obligation existed in view of the statement in its product literature that, “To ensure product safety and efficiency, the Kendall SCD Compression System must only be used with SCD Sleeves and Tubing Assemblies.” The district court correctly recognized that this language did not have contractual significance; by its terms, it was only the manufacturer's recommendation for purposes of “safety and efficiency,” not a customer obligation.

Id. at 1575-76 (emphasis in original). Thus, in retrospect, Kendall should have done a few things differently. First, if possible, it should have patented the “elongated pressure sleeves,” thus rendering Progressive a

direct infringer. Second, Kendall could have crafted its contractual language in a more binding manner, perhaps requiring its customers to purchase the entire patented product, or purchase replacement sleeves from Kendall.

4. *The Supreme Court Weighs In.* In September 2007, the Supreme Court granted certiorari on a case directly related to the Federal Circuit's approach to conditional licensing and its affect on the exhaustion principle. In *Quanta Computer, Inc. v. LG Electronics, Inc.*, 2007 WL 2768020, the Court will answer "[w]hether the Federal Circuit erred by holding, in conflict with decisions of this Court and other courts of appeals, that respondent's patent rights were not exhausted by its license agreement with Intel Corporation, and Intel's subsequent sale of products under the license to petitioners." According to Quanta and some amici, the *Mallinckrodt* decision is inconsistent with Supreme Court precedent, namely *Univis Lens*, 316 U.S. 241 (1942), which, argue the petitioners, "held that the authorized sale of an article manufactured 'under the patent' exhausts all patent claims in the article regardless of any purported limitation on the subsequent use and enjoyment of the article." The case will most likely be decided in 2008.

c. Contractual Provisions Relating to Royalty Payments

BRULOTTE v. THYS CO.

379 U.S. 29 (1964)

Justice DOUGLAS delivered the opinion of the Court.

Respondent, owner of various patents for hop-picking, sold a machine to each of the petitioners for a flat sum and issued a license for its use. Under that license there is payable a minimum royalty of \$500 for each hop picking season or \$3.33 1/3 per 200 pounds of dried hops harvested by the machine, whichever is greater. The licenses by their terms may not be assigned nor may the machines be removed from Yakima County. The licenses issued to petitioners listed 12 patents relating to hop-picking machines; but only seven were incorporated into the machines sold to and licensed for use by petitioners. Of those seven all expired on or before 1957. But the licenses issued by respondent to them continued for terms beyond that date.

Petitioners refused to make royalty payments accruing both before and after the expiration of the patents. This suit followed. One defense was misuse of the patents through extension of the license agreements beyond the expiration date of the patents. The trial court rendered judgment for respondent and the Supreme Court of Washington affirmed. The case is here on a writ of certiorari.

We conclude that the judgment below must be reversed insofar as it allows royalties to be collected which accrued after the last of the patents incorporated into the machines had expired.

The Constitution by Art. I, § 8 authorizes Congress to secure "for limited times" to inventors "the exclusive right" to their discoveries. Congress exercised that power by 35 U.S.C. § 154 which provides in part as follows:

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, of the right to

exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof. . . .

The right to make, the right to sell, and the right to use “may be granted or conferred separately by the patentee.” *Adams v. Burke*, 17 Wall. 453, 456. But these rights become public property once the 17-year period expires. As stated by Chief Justice Stone, speaking for the Court in *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 256:

. . . any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws.

The Supreme Court of Washington held that in the present case the period during which royalties were required was only “a reasonable amount of time over which to spread the payments for the use of the patent.” 382 P.2d, at 275. But there is intrinsic evidence that the agreements were not designed with that limited view. As we have seen, [footnote omitted] the purchase price in each case was a flat sum, the annual payments not being part of the purchase price but royalties for use of the machine during that year. The royalty payments due for the post-expiration period are by their terms for use during that period, and are not deferred payments for use during the pre-expiration period. Nor is the case like the hypothetical ones put to us where non patented articles are marketed at prices based on use. The machines in issue here were patented articles and the royalties exacted were the same for the post-expiration period as they were for the period of the patent. That is peculiarly significant in this case in view of other provisions of the license agreements. The license agreements prevent assignment of the machines or their removal from Yakima County after, as well as before, the expiration of the patents.

Those restrictions are apt and pertinent to protection of the patent monopoly; and their applicability to the post-expiration period is a telltale sign that the licensor was using the licenses to project its monopoly beyond the patent period. They forcefully negate the suggestion that we have here a bare arrangement for a sale or a lease at an undetermined price based on use. The sale or lease of unpatented machines on long-term payments based on a deferred purchase price or on use would present wholly different considerations. Those arrangements seldom rise to the level of a federal question. But patents are in the federal domain; and “whatever the legal device employed” (*Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S., at 256) a projection of the patent monopoly after the patent expires is not enforceable. The present licenses draw no line between the term of the patent and the post-expiration period. The same provisions as respects both use and royalties are applicable to each. The contracts are, therefore, on their face a bald attempt to exact the same terms and conditions for the period after the patents have expired as they do for the monopoly period. We are, therefore, unable to conjecture what the bargaining position of the parties might have been and what resultant arrangement might have emerged had the provision for post-expiration royalties been divorced from the patent and nowise subject to its leverage.

In light of those considerations, we conclude that a patentee’s use of a royalty agreement that projects beyond the expiration date of the patent is unlawful per se. If that device were available to patentees, the free market

visualized for the post-expiration period would be subject to monopoly influences that have no proper place there.

Automatic Radio Co. v. Hazeltine, 339 U.S. 827, is not in point. While some of the patents under that license apparently had expired, the royalties claimed were not for a period when all of them had expired. That license covered several hundred patents and the royalty was based on the licensee's sales, even when no patents were used. The Court held that the computation of royalty payments by that formula was a convenient and reasonable device. We decline the invitation to extend it so as to project the patent monopoly beyond the 17-year period.

A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly. But to use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly of the patent by tying the sale or use of the patented article to the purchase or use of unpatented ones. See *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436; *Mercoird Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 664-665, and cases cited. The exaction of royalties for use of a machine after the patent has expired is an assertion of monopoly power in the post-expiration period when, as we have seen, the patent has entered the public domain. We share the views of the Court of Appeals in *Ar-Tik Systems, Inc. v. Dairy Queen, Inc.*, 3 Cir., 302 F.2d 496, 510, that after expiration of the last of the patents incorporated in the machines "the grant of patent monopoly was spent" and that an attempt to project it into another term by continuation of the licensing agreement is unenforceable.

Justice HARLAN, dissenting.

The Court holds that the Thys Company unlawfully misused its patent monopoly by contracting with purchasers of its patented machines for royalty payments based on use beyond the patent term. I think that more discriminating analysis than the Court has seen fit to give this case produces a different result.

The patent laws prohibit post-expiration restrictions on the use of patented ideas; they have no bearing on use restrictions upon nonpatented, tangible machines. We have before us a mixed case involving the sale of a tangible machine which incorporates an intangible, patented idea. My effort in what follows is to separate out these two notions, to show that there is no substantial restriction on the use of the Thys idea, and to demonstrate that what slight restriction there may be is less objectionable than other post-expiration use restrictions which are clearly acceptable.

I.

It surely cannot be questioned that Thys could have lawfully set a fixed price for its machine and extended credit terms beyond the patent period. It is equally unquestionable, I take it, that if Thys had had no patent or if its patent had expired, it could have sold its machines at a flexible, undetermined price based on use; for example, a phonograph record manufacturer could sell a recording of a song in the public domain to a juke-box owner for an undetermined consideration based on the number of times the record was played.

Conversely it should be equally clear that if Thys licensed another manufacturer to produce hop-picking machines incorporating any of the Thys patents, royalties could not be exacted beyond the patent term. Such royalties

would restrict the manufacturer's exploitation of the idea after it falls into the public domain, and no such restriction should be valid. To give another example unconnected with a tangible machine, a song writer could charge a royalty every time his song—his idea—was sung for profit during the period of copyright. But once the song falls into the public domain each and every member of the public should be free to sing it.

In fact Thys sells both a machine and the use of an idea. The company should be free to restrict the use of its machine, as in the first two examples given above. It may not restrict the use of its patented idea once it has fallen into the public domain. Whether it has done so must be the point of inquiry.

Consider the situation as of the day the patent monopoly ends. Any manufacturer is completely free to produce Thys-type hop-pickers. The farmer who has previously purchased a Thys machine is free to buy and use any other kind of machine whether or not it incorporates the Thys idea, or make one himself if he is able. Of course, he is not entitled as against Thys to the free use of any Thys machine. The Court's opinion must therefore ultimately rest on the proposition that the purchasing farmer is restricted in using his particular machine, embodying as it does an application of the patented idea, by the fact that royalties are tied directly to use.

To test this proposition I again put a hypothetical. Assume that a Thys contract called for neither an initial flat-sum payment nor any annual minimum royalties; Thys' sole recompense for giving up ownership of its machine was a royalty payment extending beyond the patent term based on use, without any requirement either to use the machine or not to use a competitor's. A moment's thought reveals that, despite the clear restriction on use both before and after the expiration of the patent term, the arrangement would involve no misuse of patent leverage. Unless the Court's opinion rests on technicalities of contract draftsmanship and not on the economic substance of the transaction, the distinction between the hypothetical and the actual case lies only in the cumulative investment consisting of the initial and minimum payments independent of use, which the purchaser obligated himself to make to Thys. I fail to see why this distinguishing feature should be critical. If anything the investment will encourage the purchaser to use his machine in order to amortize the machine's fixed cost over as large a production base as possible. Yet the gravamen of the majority opinion is restriction, not encouragement, of use.

II.

The essence of the majority opinion may lie in some notion that "patent leverage" being used by Thys to exact use payments extending beyond the patent term somehow allows Thys to extract more onerous payments from the farmers than would otherwise be obtainable. If this be the case, the Court must in some way distinguish long-term use payments from long-term installment payments of a flat-sum purchase price. For the danger which it seems to fear would appear to inhere equally in both, and as I read the Court's opinion, the latter type of arrangement is lawful despite the fact that failure to pay an installment under a conditional sales contract would permit the seller to recapture the machine, thus terminating—not merely restricting—the farmer's use of it. Furthermore, since the judgments against petitioners were based almost entirely on defaults in paying the \$500 minimums and not on failures

to pay for above minimum use, any such distinction of extended use payments and extended installments, even if accepted, would not justify eradicating all petitioners' obligations beyond the patent term, but only those based on use above the stated minimums; for the minimums by themselves, being payable whether or not a machine has been used, are precisely identical in substantive economic effect to flat installments.

In fact a distinction should not be accepted based on the assumption that Thys, which exploits its patents by selling its patented machines rather than licensing others to manufacture them, can use its patent leverage to exact more onerous payments from farmers by gearing price to use instead of charging a flat sum. Four possible situations must be considered. The purchasing farmer could overestimate, exactly estimate, underestimate, or have no firm estimate of his use requirements for a Thys machine. If he overestimates or exactly estimates, the farmer will be fully aware of what the machine will cost him in the long run, and it is unrealistic to suppose that in such circumstances he would be willing to pay more to have the machine on use than on straight terms. If the farmer underestimates, the thought may be that Thys will take advantage of him; but surely the farmer is in a better position than Thys or anyone else to estimate his own requirements and is hardly in need of the Court's protection in this respect. If the farmer has no fixed estimate of his use requirements he may have good business reasons entirely unconnected with 'patent leverage' for wanting payments tied to use, and may indeed be willing to pay more in the long run to obtain such an arrangement. One final example should illustrate my point:

At the time when the Thys patent term still has a few years to run, a farmer who has been picking his hops by hand comes into the Thys retail outlet to inquire about the mechanical pickers. The salesman concludes his description of the advantages of the Thys machine with the price tag—\$20,000. Value to the farmer depends completely on the use he will derive from the machine; he is willing to obligate himself on long credit terms to pay \$10,000, but unless the machine can substantially outpick his old hand-picking methods, it is worth no more to him. He therefore offers to pay \$2,000 down, \$400 annually for 20 years, and an additional payment during the contract term for any production he can derive from the machine over and above the minimum amount he could pick by hand. Thys accepts, and by doing so, according to the majority, commits a *per se* misuse of its patent. I cannot believe that this is good law.

Furthermore, it should not be overlooked that we are dealing here with a patent, not an antitrust, case, there being no basis in the record for concluding that Thys' arrangements with its licensees were such as to run afoul of the antitrust laws.

III.

The possibility remains that the Court is basing its decision on the technical framing of the contract and would have treated the case differently if title had been declared to pass at the termination instead of the outset of the contract term, or if the use payments had been verbally disassociated from the patent licenses and described as a convenient means of spreading out payments for the machine. If indeed the impact of the opinion is that Thys must redraft its contracts to achieve the same economic results, the decision is not only wrong, but conspicuously ineffectual.

Comments

1. **Criticism of *Brulotte*.** The *Brulotte* decision has not been immune from criticism. (As you will see after reading Judge Posner's *Scheiber* opinion, below.) Building on Justice Harlan's dissent, William Landes and Richard Posner write:

After the patent expires, anyone can make the patented process or product without being guilty of patent infringement. As the patent can no longer be used to exclude anybody from such production, expiration has accomplished what it was supposed to accomplish. If the licensee agrees to continue paying royalties after the patent expires, the royalty rate will be lower during the period before expiration. The duration of the patent fixes the limit of the patentee's power to extract royalties; it is a detail whether he extracts them at a higher rate over a shorter period of time or at a lower rate over a longer period of time.

WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 380 (2003). See also Rochelle Cooper Dreyfuss, *Dethroning Lear: Licensee Estoppel and the Incentive to Innovate*, 72 VA. L. REV. 677, 709 (1986) (noting that the *Brulotte* decision is "vulnerable on several grounds").

2. **Many Ways to Slice a License.** One of the primary criticisms of *Brulotte* is that it ignores the preferences of the contracting parties. A license—which is nothing more than a contract—can provide for a variety of payment methods. A licensee can agree to pay all royalties at the end or the beginning of the term; or prefer to make installment payments that go beyond the patent's statutory term simply because he was financially unable to make the necessary payments during the life of the patent.

SCHEIBER v. DOLBY LABORATORIES, INC.

293 F.3d 1014 (7th Cir. 2002)

POSNER, Circuit Judge.

The plaintiff in a suit to enforce a patent licensing agreement appeals to us from the grant of summary judgment to the defendants, Dolby for short. Scheiber, the plaintiff, a musician turned inventor who held U.S. and Canadian patents on the audio system known as "surround sound," sued Dolby in 1983 for infringement of his patents. The parties settled the suit by agreeing that Scheiber would license his patents to Dolby in exchange for royalties. The last U.S. patent covered by the agreement was scheduled to expire in May 1993, while the last Canadian patent was not scheduled to expire until September 1995. During the settlement negotiations Dolby suggested to Scheiber that in exchange for a lower royalty rate the license agreement provide that royalties on all the patents would continue until the Canadian patent expired, including, therefore, patents that had already expired. That way Dolby could, it hoped, pass on the entire royalty expense to its sublicensees without their balking at the rate. Scheiber acceded to the suggestion and the agreement was drafted accordingly, but Dolby later refused to pay royalties on any patent after it expired, precipitating this suit. Federal jurisdiction over the suit is

based on diversity of citizenship, because a suit to enforce a patent licensing agreement does not arise under federal patent law.

Dolby argues that the duty to pay royalties on any patent covered by the agreement expired by the terms of the agreement itself as soon as the patent expired, because the royalties were to be based on Dolby's sales of equipment within the scope of the patents and once a patent expires, Dolby argues, there is no equipment within its scope. The argument would make meaningless the provision that Dolby itself proposed for continuing the payment of royalties until the last patent expired. Anyway the reference to equipment within the scope of the patent was clearly meant to *identify* the equipment on which royalties would be based (Dolby makes equipment that does not utilize Scheiber's patents as well as equipment that does) rather than to limit the duration of the obligation to pay royalties.

Dolby's principal argument is that the Supreme Court held in a decision that has never been overruled that a patent owner may not enforce a contract for the payment of patent royalties beyond the expiration date of the patent. The decision was *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), dutifully followed by lower courts. *Brulotte* involved an agreement licensing patents that expired at different dates, just like this case; the two cases are indistinguishable. The decision has, it is true, been severely, and as it seems to us, with all due respect, justly, criticized, beginning with Justice Harlan's dissent, 379 U.S. at 34, and continuing with our opinion in *USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505, 510-11 (7th Cir. 1982). The Supreme Court's majority opinion reasoned that by extracting a promise to continue paying royalties after expiration of the patent, the patentee extends the patent beyond the term fixed in the patent statute and therefore in violation of the law. That is not true. After the patent expires, anyone can make the patented process or product without being guilty of patent infringement. The patent can no longer be used to exclude anybody from such production. Expiration thus accomplishes what it is supposed to accomplish. For a licensee in accordance with a provision in the license agreement to go on paying royalties after the patent expires does not extend the duration of the patent either technically or practically, because, as this case demonstrates, if the licensee agrees to continue paying royalties after the patent expires the royalty rate will be lower. The duration of the patent fixes the limit of the patentee's power to extract royalties; it is a detail whether he extracts them at a higher rate over a shorter period of time or a lower rate over a longer period of time.

This insight is not original with us. "The *Brulotte* rule incorrectly assumes that a patent license has significance after the patent terminates. When the patent term ends, the exclusive right to make, use or sell the licensed invention also ends. Because the invention is available to the world, the license in fact ceases to have value. Presumably, licensees know this when they enter into a licensing agreement. If the licensing agreement calls for royalty payments beyond the patent term, the parties base those payments on the licensees' assessment of the value of the license during the patent period. These payments, therefore, do not represent an extension in time of the patent monopoly. . . . Courts do not remove the obligation of the consignee to pay because payment after receipt is an extension of market power—it is

simply a division of the payment-for-delivery transaction. Royalties beyond the patent term are no different. If royalties are calculated on post-patent term sales, the calculation is simply a risk-shifting credit arrangement between patentee and licensee. The arrangement can be no more than that, because the patentee at that time has nothing else to sell.” Harold See & Frank M. Caprio, *The Trouble with Brulotte: The Patent Royalty Term and Patent Monopoly Extension*, 1990 UTAH L. REV. 813, 814, 851.

These criticisms might be wide of the mark if *Brulotte* had been based on a interpretation of the patent clause of the Constitution, or of the patent statute or any other statute; but it seems rather to have been a free-floating product of a misplaced fear of monopoly (“a patentee’s use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*. If that device were available to patentees, the free market visualized for the post-expiration period would be subject to monopoly influences that have no proper place there,” 379 U.S. at 32-33) that was not even tied to one of the antitrust statutes. The doctrinal basis of the decision was the doctrine of patent misuse, of which more later.

A patent confers a monopoly, and the longer the term of the patent the greater the monopoly. The limitation of the term of a patent, besides being commanded by the Constitution, and necessary to avoid impossible tracing problems (imagine if some caveman had gotten a perpetual patent on the wheel), serves to limit the monopoly power conferred on the patentee. But as we have pointed out, charging royalties beyond the term of the patent does not lengthen the patentee’s monopoly; it merely alters the timing of royalty payments. This would be obvious if the license agreement between Scheiber and Dolby had become effective a month before the last patent expired. The parties could have agreed that Dolby would pay royalties for the next 100 years, but obviously the royalty rate would be minuscule because of the imminence of the patent’s expiration.

However, we have no authority to overrule a Supreme Court decision no matter how dubious its reasoning strikes us, or even how out of touch with the Supreme Court’s current thinking the decision seems. In *Agostini v. Felton*, 521 U.S. 203, 237 (1997), the Supreme Court “reaffirm[ed] that ‘[i]f a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions,’” quoting *Rodriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989). In *Khan*, the lower court (namely us), pointing out that the Supreme Court decision that we refused to declare defunct was clearly out of touch with the Court’s current antitrust thinking, invited the Court to reverse, see *Khan v. State Oil Co.*, 93 F.3d 1358, 1363 (7th Cir. 1996), vacated and remanded, and it did, but pointedly noted that we had been right to leave the execution and interment of the Court’s discredited precedent to the Court.

Now it is true that in *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257 (1979), a case decided some years after *Brulotte*, the Supreme Court upheld an agreement superficially similar to the one invalidated in *Brulotte* and at issue in the present case: a patent applicant granted a license for the invention it hoped to

patent to a firm that agreed, if a patent were not granted, to pay the inventor-applicant royalties for as long as the firm sold products embodying the invention. The Court was careful to distinguish *Brulotte*, and not a single Justice suggested that any cloud had been cast over the earlier decision. Since no patent was granted, the doctrine of patent misuse could not be brought into play, and there was no other federal ground for invalidating the license. The Court emphasized that *Brulotte* had been based on the “leverage” that the patent had granted the patentee to extract royalties beyond the date of expiration, 440 U.S. at 265, and that leverage was of course missing in *Aronson*.

If *Aronson* and *Brulotte* were inconsistent with each other and the Court had not reaffirmed *Brulotte* in *Aronson*, then we would have to follow *Aronson*, the later opinion, since to follow *Brulotte* in those circumstances would be to overrule *Aronson*. But the reaffirmation of *Brulotte* in *Aronson* tells us that the Court did not deem the cases inconsistent, and so, whether we agree or not, we have no warrant for declaring *Brulotte* overruled.

Scheiber argues further, however, that *Brulotte* has been superseded by a 1988 amendment to the patent statute which provides, so far as bears on this case, that “no patent owner otherwise entitled to relief for infringement . . . shall be . . . deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product” unless the patentee has market power in the market for the conditioning product (which is not argued here). 35 U.S.C. § 271(d)(5). The statute is doubly inapplicable to this case. It merely limits defenses to infringement suits, and Scheiber isn’t suing for infringement; he’s suing to enforce a license agreement. He can’t sue for infringement; his patents have expired. Scheiber argues that since the agreement was in settlement of his infringement suit, the only effect of limiting the statute to such suits would be to dissuade patentees from settling them. Not so. Had Scheiber pressed his 1983 infringement suit against Dolby to judgment, he would not have obtained royalties beyond the expiration date of his patents, because Dolby had not as yet agreed to pay any royalties; there was no license agreement before the case was settled. The significance of the statute is that if some subsequent infringer should point to the license agreement with Dolby as a misuse of Scheiber’s patent by reason of the tying together of different patents, Scheiber could plead the statute as a bar to the infringer’s defense of patent misuse.

In any event, the new statutory defense is explicitly limited to tying, *Lasercomb America, Inc. v. Reynolds*, 911 F.2d 970, 976 and n.15 (4th Cir. 1990); normally of a nonpatented product to a patented product, as in a number of famous patent misuse cases, such as *Henry v. A.B. Dick Co.*, 224 U.S. 1 (1912), and antitrust tying cases, such as *International Business Machines Corp. v. United States*, 298 U.S. 131 (1936). The 1988 amendment limited the tying doctrine, in cases in which the tying product is a patent, to situations in which the patentee has real market power, not merely the technical monopoly (right to exclude) that every patent confers. *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d at 869. There are multiple products here, and they are tied together in the sense of having been licensed as a package. The more exact term is bundling, because a single price is charged for the tied goods, rather than separate prices

as in the canonical tying cases. *United States v. Microsoft Corp.*, 253 F.3d 34, 87, 96 (D.C. Cir. 2001) (en banc). We may assume that the statute encompasses bundling. We can't find a case on the point, but certainly the statutory language encompasses it and the objections to tying and bundling, such as they are, are the same. (The naive objection is that they extend monopoly; the sophisticated objection is that they facilitate price discrimination.) But it is not the bundling of the U.S. and Canadian patents on which Dolby pitches its refusal to pay royalties; it is the duration of the royalty obligation. The objection would be the same if there were a single patent and the agreement required the licensee to continue paying royalties after the patent expired.

.... There just is no evidence that Congress in the 1988 amendment wanted to go or did go beyond tying. Had it wanted to, it would have chosen different words. We are not literalists, but there must be *some* semantic handle on which to hang a proposed statutory interpretation, and there is none here, though we have found a district court case that did hold that the 1988 amendment had overruled *Brulotte*.

Comment

1. *A Scenario Waiting for the Supreme Court.* With *Scheiber* in mind, *Brulotte* seems to be one of those cases waiting to be revisited by the Supreme Court. Of course, circuit courts have their hands tied when applying Supreme Court precedent even though they and a significant majority of commentators disagree with the precedent. This was the scenario in *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F.3d 1342 (Fed. Cir. 2005), which addressed the issue of patents and market power. In arguing that a patent should not give rise to a presumption of market power, the defendants cited dissents and concurrences from Supreme Court cases and a great deal of academic commentary. But the Federal Circuit clearly understood its institutional limitations:

The fundamental error in all of defendants' arguments is that they ignore the fact that it is the duty of a court of appeals to follow the precedents of the Supreme Court until the Court itself chooses to expressly overrule them. This message has been conveyed repeatedly by the Court. The Court's "decisions remain binding precedent until [it] see[s] fit to reconsider them, regardless of whether subsequent cases have raised doubts about their continuing vitality." *Hohn v. United States*, 524 U.S. 236, 252-53 (1998). "If a precedent of th[e] Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to th[e] Court the prerogative of overruling its own decisions." *Rodriguez de Quijas v. Shearson/American Exp., Inc.*, 490 U.S. 477, 484 (1989). Even where a Supreme Court precedent contains many "infirmities" and rests upon "wobbly, moth-eaten foundations," it remains the "Court's prerogative alone to overrule one of its precedents." *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997). None of the authorities that defendants present . . . constituted an express overruling of [Supreme Court precedent]. . . . The time may have come to abandon the doctrine, but it is up to the Congress or the Supreme Court to make this judgment.

Id. at 1351. The Federal Circuit “teed” the issue up for the Supreme Court, knowing if the Court decided to hear the case, it would most likely reverse the Federal Circuit. The Supreme Court did grant certiorari in *Independent Ink*, and, as expected, reversed the Federal Circuit. *Independent Ink* is a principal case in Section B, below.

3. Contractual and Jurisdictional Restrictions Relating to Challenging Patent Validity

The principal cases of *Lear* and *MedImmune* explore, respectively, whether licensees should be able to challenge the validity of the licensed patent, and, if so, under what conditions can a licensee invoke the declaratory judgment jurisdiction of a district court. The *Sandisk* case involves not a license, but an alleged infringer’s ability to invoke declaratory judgment jurisdiction after receiving a communication from a patentee, a common scenario in patent litigation. The nature of the communication and the signals it sends are important considerations, particularly in the light of the *MedImmune* case.

a. Licensee’s Ability to Challenge Patent Validity

LEAR, INC. v. ADKINS

395 U.S. 653 (1969)

Justice HARLAN delivered the opinion of the Court.

In January of 1952, John Adkins, an inventor and mechanical engineer, was hired by Lear, Incorporated, for the purpose of solving a vexing problem the company had encountered in its efforts to develop a gyroscope which would meet the increasingly demanding requirements of the aviation industry. The gyroscope is an essential component of the navigational system in all aircraft, enabling the pilot to learn the direction and altitude of his airplane. With the development of the faster airplanes of the 1950’s, more accurate gyroscopes were needed, and the gyro industry consequently was casting about for new techniques which would satisfy this need in an economical fashion. Shortly after Adkins was hired, he developed a method of construction at the company’s California facilities which improved gyroscope accuracy at a low cost. Lear almost immediately incorporated Adkins’ improvements into its production process to its substantial advantage.

The question that remains unsettled in this case, after eight years of litigation in the California courts, is whether Adkins will receive compensation for Lear’s use of those improvements which the inventor has subsequently patented. At every stage of this lawsuit, Lear has sought to prove that, despite the grant of a patent by the Patent Office, none of Adkins’ improvements were sufficiently novel to warrant the award of a monopoly under the standards delineated in the governing federal statutes. Moreover, the company has sought to prove that Adkins obtained his patent by means of a fraud on the Patent Office. In response, the inventor has argued that since Lear had entered into a licensing agreement with Adkins, it was obliged to pay the agreed royalties regardless of the validity of the underlying patent.

The Supreme Court of California unanimously vindicated the inventor's position. While the court recognized that generally a manufacturer is free to challenge the validity of an inventor's patent, it held that "one of the oldest doctrines in the field of patent law establishes that so long as a licensee is operating under a license agreement he is estopped to deny the validity of his licensor's patent in a suit for royalties under the agreement. The theory underlying this doctrine is that a licensee should not be permitted to enjoy the benefit afforded by the agreement while simultaneously urging that the patent which forms the basis of the agreement is void."

Almost 20 years ago, in its last consideration of the doctrine, this Court also invoked an estoppel to deny a licensee the right to prove that his licensor was demanding royalties for the use of an idea which was in reality a part of the public domain. *Automatic Radio Manufacturing Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 836 (1950). We granted certiorari in the present case to reconsider the validity of the *Hazeltine* rule in the light of our recent decisions emphasizing the strong federal policy favoring free competition in ideas which do not merit patent protection. *Sears, Roebuck v. Stiffel Co.*, 376 U.S. 225 (1964); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964).

I.

At the very beginning of the parties' relationship, Lear and Adkins entered into a rudimentary one-page agreement which provided that although "[a]ll new ideas, discoveries, inventions, etc., related to . . . vertical gyros become the property of Mr. John S. Adkins," the inventor promised to grant Lear a license as to all ideas he might develop "on a mutually satisfactory royalty basis." As soon as Adkins' labors yielded tangible results, it quickly became apparent to the inventor that further steps should be taken to place his rights to his ideas on a firmer basis. On February 4, 1954, Adkins filed an application with the Patent Office in an effort to gain federal protection for his improvements. At about the same time, he entered into a lengthy period of negotiations with Lear in an effort to conclude a licensing agreement which would clearly establish the amount of royalties that would be paid.

These negotiations finally bore fruit on September 15, 1955, when the parties approved a complex 17-page contract which carefully delineated the conditions upon which Lear promised to pay royalties for Adkins' improvements. The parties agreed that if "the U.S. Patent Office refuses to issue a patent on the substantial claims (contained in Adkins' original patent application) or if such a patent so issued is subsequently held invalid, then in any of such events Lear at its option shall have the right forthwith to terminate the specific license so affected or to terminate this entire Agreement. . . ."

. . . . The [Patent Office] regulations do not require the Office to make a final judgment on an invention's patentability on the basis of the inventor's original application. While it sometimes happens that a patent is granted at this early stage, it is far more common for the Office to find that although certain of the applicant's claims may be patentable, certain others have been fully anticipated by the earlier developments in the art. In such a situation, the Patent Office does not attempt to separate the wheat from the chaff on its own initiative. Instead, it rejects the application, giving the inventor the right to make an amendment which narrows his claim to cover only those aspects of the invention which are truly novel. . . .

The progress of Adkins' effort to obtain a patent followed the typical pattern. In his initial application, the inventor made the ambitious claim that his entire method of constructing gyroscopes was sufficiently novel to merit protection. The Patent Office, however, rejected this initial claim, as well as two subsequent amendments, which progressively narrowed the scope of the invention sought to be protected. Finally, Adkins narrowed his claim drastically to assert only that the design of the apparatus used to achieve gyroscope accuracy was novel. In response, the Office issued its 1960 patent, granting a 17-year monopoly on this more modest claim.

During the long period in which Adkins was attempting to convince the Patent Office of the novelty of his ideas, however, Lear had become convinced that Adkins would never receive a patent on his invention and that it should not continue to pay substantial royalties on ideas which had not contributed substantially to the development of the art of gyroscopy. In 1957, after Adkins' patent application had been rejected twice, Lear announced that it had searched the Patent Office's files and had found a patent which it believed had fully anticipated Adkins' discovery. As a result, the company stated that it would no longer pay royalties on the large number of gyroscopes it was producing at its plant in Grand Rapids, Michigan (the Michigan gyros). Payments were continued on the smaller number of gyros produced at the company's California plant (the California gyros) for two more years until they too were terminated on April 8, 1959.

[The California Supreme Court] rejected the District Court of Appeal's conclusion that the 1955 license gave Lear the right to terminate its royalty obligations in 1959. Since the 1955 agreement was still in effect, the court concluded, relying on the language we have already quoted, that the doctrine of estoppel barred Lear from questioning the propriety of the Patent Office's grant. The court's adherence to estoppel, however, was not without qualification. After noting Lear's claim that it had developed its Michigan gyros independently, the court tested this contention by considering "whether what is being built by Lear (in Michigan) springs entirely" (emphasis supplied) from the prior art. Applying this test, it found that Lear had in fact "utilized the apparatus patented by Adkins throughout the period in question," and reinstated the jury's \$888,000 verdict on this branch of the case.

II.

* * *

A.

While the roots of the doctrine have often been celebrated in tradition, we have found only one 19th century case in this Court that invoked estoppel in a considered manner. And that case was decided before the Sherman Act made it clear that the grant of monopoly power to a patent owner constituted a limited exception to the general federal policy favoring free competition. . . .

In the very next year, this Court found the doctrine of patent estoppel so inequitable that it refused to grant an injunction to enforce a licensee's promise never to contest the validity of the underlying patent. "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected

in his monopoly. . . .” *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892).

Although this Court invoked an estoppel in 1905 without citing or considering Pope’s powerful argument, the doctrine was not to be applied again in this Court until it was revived in *Automatic Radio Manufacturing Co. v. Hazeltine Research, Inc.*, *supra*, which declared, without prolonged analysis, that licensee estoppel was “the general rule.” 339 U.S., at 836. In so holding, the majority ignored the teachings of a series of decisions this Court had rendered during the 45 years since *Harvey* had been decided. During this period, each time a patentee sought to rely upon his estoppel privilege before this Court, the majority created a new exception to permit judicial scrutiny into the validity of the Patent Office’s grant. Long before *Hazeltine* was decided, the estoppel doctrine had been so eroded that it could no longer be considered the “general rule,” but was only to be invoked in an ever narrowing set of circumstances.

* * *

III.

The uncertain status of licensee estoppel in the case law is a product of judicial efforts to accommodate the competing demands of the common law of contracts and the federal law of patents. On the one hand, the law of contracts forbids a purchaser to repudiate his promises simply because he later becomes dissatisfied with the bargain he has made. On the other hand, federal law requires, that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent. *Sears, Roebuck v. Stiffel Co.*, *supra*; *Compco Corp. v. Day-Brite Lighting, Inc.*, *supra*. When faced with this basic conflict in policy, both this Court and courts throughout the land have naturally sought to develop an intermediate position which somehow would remain responsive to the radically different concerns of the two different worlds of contract and patent. The result has been a failure. Rather than creative compromise, there has been a chaos of conflicting case law, proceeding on inconsistent premises. Before renewing the search for an acceptable middle ground, we must reconsider on their own merits the arguments which may properly be advanced on both sides of the estoppel question.

A.

It will simplify matters greatly if we first consider the most typical situation in which patent licenses are negotiated. In contrast to the present case, most manufacturers obtain a license after a patent has issued. Since the Patent Office makes an inventor’s ideas public when it issues its grant of a limited monopoly, a potential licensee has access to the inventor’s ideas even if he does not enter into an agreement with the patent owner. Consequently, a manufacturer gains only two benefits if he chooses to enter a licensing agreement after the patent has issued. First, by accepting a license and paying royalties for a time, the licensee may have avoided the necessity of defending an expensive infringement action during the period when he may be least able to afford one. Second, the existence of an unchallenged patent may deter others from attempting to compete with the licensee.

Under ordinary contract principles the mere fact that some benefit is received is enough to require the enforcement of the contract, regardless of the validity of the underlying patent. Nevertheless, if one tests this result by the standard of good-faith commercial dealing, it seems far from satisfactory. For the simple contract approach entirely ignores the position of the licensor who is seeking to invoke the court's assistance on his behalf. Consider, for example, the equities of the licensor who has obtained his patent through a fraud on the Patent Office. It is difficult to perceive why good faith requires that courts should permit him to recover royalties despite his licensee's attempts to show that the patent is invalid.

Even in the more typical cases, not involving conscious wrongdoing, the licensor's equities are far from compelling. A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity. Consequently, it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue, especially since the licensor's case is buttressed by the presumption of validity which attaches to his patent. Thus, although licensee estoppel may be consistent with the letter of contractual doctrine, we cannot say that it is compelled by the spirit of contract law, which seeks to balance the claims of promisor and estoppel in accord with the requirements of good faith.

Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification. We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest in the typical situation involving the negotiation of a license after a patent has issued.

We are satisfied that *Automatic Radio Manufacturing Co. v. Hazeltine Research, Inc.*, *supra*, itself the product of a clouded history, should no longer be regarded as sound law with respect to its "estoppel" holding, and that holding is now overruled.

B.

The case before us, however, presents a far more complicated estoppel problem than the one which arises in the most common licensing context. The problem arises out of the fact that Lear obtained its license in 1955, more than four years before Adkins received his 1960 patent. Indeed, from the very outset of the relationship, Lear obtained special access to Adkins' ideas in return for its promise to pay satisfactory compensation.

Thus, during the lengthy period in which Adkins was attempting to obtain a patent, Lear gained an important benefit not generally obtained by the typical licensee. For until a patent issues, a potential licensee may not learn his licensor's ideas simply by requesting the information from the Patent Office.

During the time the inventor is seeking patent protection, the governing federal statute requires the Patent Office to hold an inventor's patent application in confidence. If a potential licensee hopes to use the ideas contained in a secret patent application, he must deal with the inventor himself, unless the inventor chooses to publicize his ideas to the world at large. By promising to pay Adkins royalties from the very outset of their relationship, Lear gained immediate access to ideas which it may well not have learned until the Patent Office published the details of Adkins' invention in 1960. At the core of this case, then, is the difficult question whether federal patent policy bars a State from enforcing a contract regulating access to an unpatented secret idea.

Adkins takes an extreme position on this question. The inventor does not merely argue that since Lear obtained privileged access to his ideas before 1960, the company should be required to pay royalties accruing before 1960 regardless of the validity of the patent which ultimately issued. He also argues that since Lear obtained special benefits before 1960, it should also pay royalties during the entire patent period (1960-1977), without regard to the validity of the Patent Office's grant. We cannot accept so broad an argument.

Adkins' position would permit inventors to negotiate all important licenses during the lengthy period while their applications were still pending at the Patent Office, thereby disabling entirely all those who have the strongest incentive to show that a patent is worthless. While the equities supporting Adkins' position are somewhat more appealing than those supporting the typical licensor, we cannot say that there is enough of a difference to justify such a substantial impairment of overriding federal policy.

Nor can we accept a second argument which may be advanced to support Adkins' claim to at least a portion of his post-patent royalties, regardless of the validity of the Patent Office grant. The terms of the 1955 agreement provide that royalties are to be paid until such time as the "patent . . . is held invalid," § 6, and the fact remains that the question of patent validity has not been finally determined in this case. Thus, it may be suggested that although Lear must be allowed to raise the question of patent validity in the present lawsuit, it must also be required to comply with its contract and continue to pay royalties until its claim is finally vindicated in the courts.

The parties' contract, however, is no more controlling on this issue than is the State's doctrine of estoppel, which is also rooted in contract principles. The decisive question is whether overriding federal policies would be significantly frustrated if licensees could be required to continue to pay royalties during the time they are challenging patent validity in the courts.

It seems to us that such a requirement would be inconsistent with the aims of federal patent policy. Enforcing this contractual provision would give the licensor an additional economic incentive to devise every conceivable dilatory tactic in an effort to postpone the day of final judicial reckoning. We can perceive no reason to encourage dilatory court tactics in this way. Moreover, the cost of prosecuting slow-moving trial proceedings and defending an inevitable appeal might well deter many licensees from attempting to prove patent invalidity in the courts. The deterrent effect would be particularly severe in the many scientific fields in which invention is proceeding at a rapid rate. In these areas, a patent may well become obsolete long before its 17-year term has expired. If a licensee has reason to believe that he will replace a patented idea with a new one in the near future, he will have little incentive to

initiate lengthy court proceedings, unless he is freed from liability at least from the time he refuses to pay the contractual royalties. Lastly, enforcing this contractual provision would undermine the strong federal policy favoring the full and free use of ideas in the public domain. For all these reasons, we hold that Lear must be permitted to avoid the payment of all royalties accruing after Adkins' 1960 patent issued if Lear can prove patent invalidity.

C.

Adkins' claim to contractual royalties accruing before the 1960 patent issued is, however, a much more difficult one, since it squarely raises the question whether, and to what extent, the States may protect the owners of unpatented inventions who are willing to disclose their ideas to manufacturers only upon payment of royalties. The California Supreme Court did not address itself to this issue with precision, for it believed that the venerable doctrine of estoppel provided a sufficient answer to all of Lear's claims based upon federal patent law. Thus, we do not know whether the Supreme Court would have awarded Adkins recovery even on his pre-patent royalties if it had recognized that previously established estoppel doctrine could no longer be properly invoked with regard to royalties accruing during the 17-year patent period. Our decision today will, of course, require the state courts to reconsider the theoretical basis of their decisions enforcing the contractual rights of inventors and it is impossible to predict the extent to which this reevaluation may revolutionize the law of any particular State in this regard. Given the difficulty and importance of this task, it should be undertaken only after the state courts have, after fully focused inquiry, determined the extent to which they will respect the contractual rights of such inventors in the future. Indeed, on remand, the California courts may well reconcile the competing demands of patent and contract law in a way which would not warrant further review in this Court.

MEDIMMUNE, INC. v. GENENTECH, INC.

127 S. Ct. 764 (2007)

Justice SCALIA delivered the opinion of the Court.

We must decide whether Article III's limitation of federal courts' jurisdiction to "Cases" and "Controversies," reflected in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires a patent licensee to terminate or be in breach of its license agreement before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed.

I

Because the declaratory-judgment claims in this case were disposed of at the motion-to-dismiss stage, we take the following facts from the allegations in petitioner's amended complaint and the unopposed declarations that petitioner submitted in response to the motion to dismiss. Petitioner MedImmune, Inc., manufactures Synagis, a drug used to prevent respiratory tract disease in

infants and young children. In 1997, petitioner entered into a patent license agreement with respondent Genentech, Inc. (which acted on behalf of itself as patent assignee and on behalf of the coassignee, respondent City of Hope). The license covered an existing patent relating to the production of “chimeric antibodies” and a then-pending patent application relating to “the coexpression of immunoglobulin chains in recombinant host cells.” Petitioner agreed to pay royalties on sales of “Licensed Products,” and respondents granted petitioner the right to make, use, and sell them. The agreement defined “Licensed Products” as a specified antibody, “the manufacture, use or sale of which . . . would, if not licensed under th[e] Agreement, infringe one or more claims of either or both of [the covered patents,] which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken.” App. 399. The license agreement gave petitioner the right to terminate upon six months’ written notice.

In December 2001, the “coexpression” application covered by the 1997 license agreement matured into the “Cabilly II” patent. Soon thereafter, respondent Genentech delivered petitioner a letter expressing its belief that Synagis was covered by the Cabilly II patent and its expectation that petitioner would pay royalties beginning March 1, 2002. Petitioner did not think royalties were owing, believing that the Cabilly II patent was invalid and unenforceable, and that its claims were in any event not infringed by Synagis. Nevertheless, petitioner considered the letter to be a clear threat to enforce the Cabilly II patent, terminate the 1997 license agreement, and sue for patent infringement if petitioner did not make royalty payments as demanded. If respondents were to prevail in a patent infringement action, petitioner could be ordered to pay treble damages and attorney’s fees, and could be enjoined from selling Synagis, a product that has accounted for more than 80 percent of its revenue from sales since 1999. Unwilling to risk such serious consequences, petitioner paid the demanded royalties “under protest and with reservation of all of [its] rights.” *Id.*, at 426. This declaratory-judgment action followed.

Petitioner sought the declaratory relief discussed in detail in Part II below. Petitioner also requested damages and an injunction with respect to other federal and state claims not relevant here. The District Court granted respondents’ motion to dismiss the declaratory-judgment claims for lack of subject-matter jurisdiction, relying on the decision of the United States Court of Appeals for the Federal Circuit in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (2004). *Gen-Probe* had held that a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of the patent because the license agreement “obliterate[s] any reasonable apprehension” that the licensee will be sued for infringement. *Id.*, at 1381. The Federal Circuit affirmed the District Court, also relying on *Gen-Probe*. 427 F.3d 958 (2005). We granted certiorari.

* * *

III

The Declaratory Judgment Act provides that, “[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such

declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a). There was a time when this Court harbored doubts about the compatibility of declaratory-judgment actions with Article III’s case-or-controversy requirement. We dispelled those doubts, however, in *Nashville, C. & St. L. R. Co. v. Wallace*, 288 U.S. 249 (1933), holding (in a case involving a declaratory judgment rendered in state court) that an appropriate action for declaratory relief *can* be a case or controversy under Article III. The federal Declaratory Judgment Act was signed into law the following year, and we upheld its constitutionality in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937). Our opinion explained that the phrase “case of actual controversy” in the Act refers to the type of “Cases” and “Controversies” that are justiciable under Article III. *Id.*, at 240.

Aetna and the cases following it do not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not. Our decisions have required that the dispute be “definite and concrete, touching the legal relations of parties having adverse legal interests”; and that it be “real and substantial” and “admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *Id.*, at 240-241. In *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), we summarized as follows: “Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”

There is no dispute that these standards would have been satisfied if petitioner had taken the final step of refusing to make royalty payments under the 1997 license agreement. Respondents claim a right to royalties under the licensing agreement. Petitioner asserts that no royalties are owing because the Cabilly II patent is invalid and not infringed; and alleges (without contradiction) a threat by respondents to enjoin sales if royalties are not forthcoming. The factual and legal dimensions of the dispute are well defined and, but for petitioner’s continuing to make royalty payments, nothing about the dispute would render it unfit for judicial resolution. Assuming (without deciding) that respondents here could not claim an anticipatory breach and repudiate the license, the continuation of royalty payments makes what would otherwise be an imminent threat at least remote, if not nonexistent. As long as those payments are made, there is no risk that respondents will seek to enjoin petitioner’s sales. Petitioner’s own acts, in other words, eliminate the imminent threat of harm. The question before us is whether this causes the dispute no longer to be a case or controversy within the meaning of Article III.

Our analysis must begin with the recognition that, where threatened action by *government* is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat—for example, the constitutionality of a law threatened to be enforced. The plaintiff’s own action (or inaction) in failing to violate the law eliminates the imminent threat of prosecution, but nonetheless does not eliminate Article III jurisdiction. For example, in *Terrace v. Thompson*, 263 U.S. 197 (1923), the State threatened the plaintiff with forfeiture of his farm, fines, and penalties if he

entered into a lease with an alien in violation of the State's anti-alien land law. Given this genuine threat of enforcement, we did not require, as a prerequisite to testing the validity of the law in a suit for injunction, that the plaintiff bet the farm, so to speak, by taking the violative action. *Id.*, at 216. Likewise, in *Steffel v. Thompson*, 415 U.S. 452 (1974), we did not require the plaintiff to proceed to distribute handbills and risk actual prosecution before he could seek a declaratory judgment regarding the constitutionality of a state statute prohibiting such distribution. *Id.*, at 458-460. As then-Justice Rehnquist put it in his concurrence, "the declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity." *Id.*, at 480. In each of these cases, the plaintiff had eliminated the imminent threat of harm by simply not doing what he claimed the right to do (enter into a lease, or distribute handbills at the shopping center). That did not preclude subject-matter jurisdiction because the threat-eliminating behavior was effectively coerced. See *Terrace, supra*, at 215-216; *Steffel, supra*, at 459. The dilemma posed by that coercion—putting the challenger to the choice between abandoning his rights or risking prosecution—is "a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 152 (1967).

Supreme Court jurisprudence is more rare regarding application of the Declaratory Judgment Act to situations in which the plaintiff's self-avoidance of imminent injury is coerced by threatened enforcement action of a *private party* rather than the government. Lower federal courts, however (and state courts interpreting declaratory judgment Acts requiring "actual controversy"), have long accepted jurisdiction in such cases.

The only Supreme Court decision in point is, fortuitously, close on its facts to the case before us. *Altwater v. Freeman*, 319 U.S. 359 (1943), held that a licensee's failure to cease its payment of royalties did not render nonjusticiable a dispute over the validity of the patent. In that litigation, several patentees had sued their licensees to enforce territorial restrictions in the license. The licensees filed a counterclaim for declaratory judgment that the underlying patents were invalid, in the meantime paying "under protest" royalties required by an injunction the patentees had obtained in an earlier case. The patentees argued that "so long as [licensees] continue to pay royalties, there is only an academic, not a real controversy, between the parties." *Id.*, at 364. We rejected that argument and held that the declaratory-judgment claim presented a justiciable case or controversy: "The fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'" *Ibid.* (quoting *Aetna*, 300 U.S., at 240). The royalties "were being paid under protest and under the compulsion of an injunction decree," and "[u]nless the injunction decree were modified, the only other course [of action] was to defy it, and to risk not only actual but treble damages in infringement suits." 319 U.S., at 365. We concluded that "the requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim." *Ibid.*

The Federal Circuit's *Gen-Probe* decision distinguished *Altwater* on the ground that it involved the compulsion of an injunction. But *Altwater* cannot be so readily dismissed. Never mind that the injunction had been privately

obtained and was ultimately within the control of the patentees, who could permit its modification. More fundamentally, and contrary to the Federal Circuit's conclusion, *Altwater* did not say that the coercion dispositive of the case was governmental, but suggested just the opposite. The opinion acknowledged that the licensees had the option of stopping payments in defiance of the injunction, but explained that the *consequence* of doing so would be to risk "actual [and] treble damages in infringement suits" by the patentees. 319 U.S., at 365. It significantly did not mention the threat of prosecution for contempt, or any other sort of governmental sanction. Moreover, it cited approvingly a treatise which said that an "actual or threatened serious injury to business or employment" by a private party can be as coercive as other forms of coercion supporting restitution actions at common law; and that "[t]o imperil a man's livelihood, his business enterprises, or his solvency, [was] ordinarily quite as coercive" as, for example, "detaining his property." F. Woodward, *The Law of Quasi Contracts* § 218 (1913), cited in *Altwater*, *supra*, at 365.¹¹

Jurisdiction over the present case is not contradicted by *Willing v. Chicago Auditorium Association*, 277 U.S. 274. There a ground lessee wanted to demolish an antiquated auditorium and replace it with a modern commercial building. The lessee believed it had the right to do this without the lessors' consent, but was unwilling to drop the wrecking ball first and test its belief later. Because there was no declaratory judgment act at the time under federal or applicable state law, the lessee filed an action to remove a "cloud" on its lease. This Court held that an Article III case or controversy had not arisen because "[n]o defendant ha[d] wronged the plaintiff or ha[d] threatened to do so." *Id.*, at 288, 290. It was true that one of the colessors had disagreed with the lessee's interpretation of the lease, but that happened in an "informal, friendly, private conversation," *id.*, at 286, a year before the lawsuit was filed; and the lessee never even bothered to approach the other co-lessors. The Court went on to remark that "[w]hat the plaintiff seeks is simply a declaratory judgment," and "[t]o grant that relief is beyond the power conferred upon the federal judiciary." *Id.*, at 289. Had *Willing* been decided after the enactment (and our upholding) of the Declaratory Judgment Act, and had the legal disagreement between the parties been as lively as this one, we are confident a different result would have obtained. The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.

11. Even if *Altwater* could be distinguished as an "injunction" case, it would still contradict the Federal Circuit's "reasonable apprehension of suit" test (or, in its evolved form, the "reasonable apprehension of imminent suit" test, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit. It is also in tension with *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98 (1993), which held that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.

Respondents assert that the parties in effect settled this dispute when they entered into the 1997 license agreement. When a licensee enters such an agreement, they contend, it essentially purchases an insurance policy, immunizing it from suits for infringement so long as it continues to pay royalties and does not challenge the covered patents. Permitting it to challenge the validity of the patent without terminating or breaking the agreement alters the deal, allowing the licensee to continue enjoying its immunity while bringing a suit, the elimination of which was part of the patentee's *quid pro quo*. Of course even if it were valid, this argument would have no force with regard to petitioner's claim that the agreement does not call for royalties because their product does not infringe the patent. But even as to the patent invalidity claim, the point seems to us mistaken. To begin with, it is not clear where the prohibition against challenging the validity of the patents is to be found. It can hardly be implied from the mere promise to pay royalties on patents "which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken," App. 399. Promising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity.

Respondents appeal to the common-law rule that a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits, citing *Commodity Credit Corp. v. Rosenberg Bros. & Co.*, 243 F.2d 504, 512 (C.A.9 1957), and *Kingman & Co. v. Stoddard*, 85 F. 740, 745 (C.A.7 1898). *Lear*, they contend, did not suspend that rule for patent licensing agreements, since the plaintiff in that case had already repudiated the contract. Even if *Lear's* repudiation of the doctrine of licensee estoppel was so limited (a point on which, as we have said earlier, we do not opine), it is hard to see how the common-law rule has any application here. Petitioner is not repudiating or impugning the contract while continuing to reap its benefits. Rather, it is asserting that the contract, properly interpreted, does not prevent it from challenging the patents, and does not require the payment of royalties because the patents do not cover its products and are invalid. Of course even if respondents were correct that the licensing agreement or the common-law rule precludes this suit, the consequence would be that respondents win this case *on the merits*—*not* that the very genuine contract dispute disappears, so that Article III jurisdiction is somehow defeated. In short, Article III jurisdiction has nothing to do with this "insurance-policy" contention.

* * *

We hold that petitioner was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed. The Court of Appeals erred in affirming the dismissal of this action for lack of subject-matter jurisdiction.

Comments

1. **Licensee Estoppel.** The doctrine of licensee estoppel was rejected by the *Lear* Court, which held that a licensee may challenge the validity of a patent—he is not estopped. The Court cited that the public interest is served

by having the licensee weed out bad patents. But what about the interest of the patentee and the validity of the contract the licensee signed agreeing to pay royalties? What incentives are created by allowing licensees to challenge patent validity? Will there be fewer licenses? More express license terms prohibiting licensees from challenging validity? Indeed, *Lear* is not without criticism, particularly relating to its interference with private ordering and contractual allocation of risk. See, e.g., Rochelle Cooper Dreyfuss, *Dethroning Lear: Licensee Estoppel and the Incentive to Innovate*, 72 VA. L. REV. 677, 680-81 (1986) (stating *Lear* failed to appreciate the “economic function” of licensee estoppel and eliminating estoppels has increased “inventors’ exposure to litigation and prevent[ed] them from allocating to others the risk that their patents will be invalidated”).

2. **MedImmune and the Court’s Broadening Declaratory Power.** *MedImmune* was concerned with declaratory-judgment plaintiffs having to expose themselves to liability before bringing suit, and held that a licensee does not have to breach an agreement before seeking a declaratory judgment of invalidity or non-infringement. Is *MedImmune* consistent with the rationale of *Lear*—that is, the policy of weeding out “bad” patents trumps contractual obligations? In *Lear* the licensee repudiated the contract. In contrast, *MedImmune* did not breach the license agreement; thus, was *MedImmune* simply asking the Court to determine what its liability (if any) would be if it decided to breach?

The results of *MedImmune* may be that fewer licenses are negotiated and consummated because of patentee-licensor fears of looking over his shoulder during the entire term of the license. Fewer licenses—or license/settlements—may lead to more litigation and greater inefficiencies in the use and exploitation of patent rights. Of course, licensors may make greater use of up-front payment provisions (reduced over time depending on sales), or include language in the contract prohibiting licensees from challenging the validity of the patent (this was done after *Lear*). As *MedImmune* stated, referring to the license agreement: “it is not clear where the prohibition against challenging the validity of the patents is to be found. It can hardly be implied from the mere promise to pay royalties. . . . Promising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity.” (Emphasis in original). But whether licensees would agree to such terms is questionable.

3. **Assignor Estoppel.** The related doctrine of assignor estoppels precludes an assignor from challenging the validity of the patent. In *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224 (Fed. Cir. 1988), the court distinguished licensee estoppel and *Lear* in upholding the doctrine of assignor estoppel. The court focused on preventing the assignor from “benefitting from his own wrong” and to “prevent unfairness and injustice.”

b. Declaratory Judgment Jurisdiction

The *MedImmune* ruling has implications beyond the licensor/licensee scenario. In footnote 11, the Court seemingly overruled the Federal Circuit’s “reasonable apprehension” test and, as a result, expanded opportunities of alleged infringers to invoke declaratory judgment jurisdiction. In fact, in patent liti-

gation, a declaratory judgment action—or “DJ”—is most commonly employed by alleged infringers or parties whom the patentee believes are infringing. The DJ allows the alleged infringer to take the initiative and assume greater control over the litigation, particularly with respect to choice of venue. But to invoke the DJ jurisdiction, the alleged infringer/DJ plaintiff must show there is an “actual controversy” under the Declaratory Judgment Act, which provides, in relevant part, that

[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). The *Sandisk* case explores the circumstances under which a party thought to be infringing can bring suit—alleging an “actual controversy”—after receiving a communication from a patentee. The nature of the communication (*e.g.*, threatening litigation or asking for a license) is an important consideration.

SANDISK CORP. v. STMICROELECTRONICS, INC.

480 F.3d 1372 (Fed. Cir. 2007)

LINN, Circuit Judge

SanDisk Corporation (“SanDisk”) appeals from a decision of the U.S. District Court for the Northern District of California granting STMicroelectronics’ (“ST’s”) motion to dismiss SanDisk’s second through twenty-ninth claims relating to declaratory judgment of noninfringement and invalidity for failure to present an actual controversy. Because the district court erred in dismissing the declaratory judgment claims for lack of subject matter jurisdiction, we vacate the judgment and remand the case to the district court.

I. BACKGROUND

SanDisk is in the flash memory storage market and owns several patents related to flash memory storage products. ST, traditionally in the market of semiconductor integrated circuits, more recently entered the flash memory market and has a sizeable portfolio of patents related to flash memory storage products. On April 16, 2004, ST’s vice president of intellectual property and licensing, Lisa Jorgenson (“Jorgenson”), sent a letter to SanDisk’s chief executive officer requesting a meeting to discuss a cross-license agreement. The letter listed eight patents owned by ST that Jorgenson believed “may be of interest” to SanDisk. On April 28, 2004, SanDisk responded that it would need time to review the listed patents and would be in touch in several weeks to discuss the possibility of meeting in June.

On July 12, 2004, having heard nothing further from SanDisk, Jorgenson sent a letter to SanDisk reiterating her request to meet in July to discuss a cross-license agreement and listing four additional ST patents that “may also be of interest” to SanDisk. On July 21, 2004, SanDisk’s chief intellectual property counsel and senior director, E. Earle Thompson (“Thompson”), responded to ST’s letter by informing Jorgenson of his “understanding that both sides wish to

continue . . . friendly discussions” such as those between the business representatives in May and June. The discussions of May and June that Thompson referred to were discussions among managers and vice presidents of SanDisk and ST at business meetings held on May 18, 2004, and June 9, 2004, to explore the possibility of ST’s selling flash memory products to SanDisk. The business meetings were unrelated to any patents. Thompson also requested that Jorgenson join the next business meeting on August 5, 2005. On July 27, 2004, Jorgenson replied, again urging a meeting with Thompson, noting that it was “best to separate the business discussions from the patent license discussions.”

On August 5, 2004, when the business representatives next met, SanDisk presented an analysis of three of its patents and orally offered ST a license. ST declined to present an analysis of any of its patents, stating instead that any patent and licensing issues should be discussed in a separate meeting with Jorgenson. Later that same day, Thompson wrote a letter to Jorgenson objecting to separating business and intellectual property issues and stating that “[i]t has been SanDisk’s hope and desire to enter into a mutually beneficial discussion without the rattling of sabers.” On August 11, 2004, Jorgenson replied, stating that it was her understanding that the parties were going to have a licensing/intellectual property meeting later that month “to discuss the possibility for a patent cross-license.” Letter from Jorgenson to Thompson (Aug. 11, 2004). She said that SanDisk should come to that meeting prepared to present an analysis of the three SanDisk patents it identified during the August 5th business meeting, as well as “any infringement analyses of an ST device or need for ST to have a license to these patents.” *Id.* She also said that ST would be prepared at that meeting to discuss the twelve patents identified in her prior letters. In closing, Jorgenson said that ST was “look[ing] forward to open and frank discussions with SanDisk concerning fair and reasonable terms for a broad cross-license agreement.” *Id.*

On August 27, 2004, the licensing meeting was held. Jorgenson, two ST licensing attorneys, and three technical experts retained by ST to perform the infringement analyses of SanDisk’s products, attended on behalf of ST. Thompson and an engineer attended on behalf of SanDisk. At the meeting, Jorgenson requested that the parties’ discussions be treated as “settlement discussions” under Federal Rule of Evidence 408.¹ ST then presented a slide show which compared statistics regarding SanDisk’s and ST’s patent portfolios, revenue, and research and development expenses, and listed SanDisk’s various “unlicensed activities.” This slide show was followed by a four- to five-hour presentation by ST’s technical experts, during which they identified and discussed the specific claims of each patent and alleged that they were in-

1. To avoid the risk of a declaratory judgment action, ST could have sought SanDisk’s agreement to the terms of a suitable confidentiality agreement. The record before us reflects that the parties did not enter into such an agreement. Rather, ST sought to condition its open licensing discussions and the infringement study on adherence to Federal Rule of Evidence 408. That rule expressly relates to evidence of efforts toward compromising or attempting to compromise a claim in litigation and does not prevent SanDisk from relying on the licensing discussions and infringement study to support its claims. *See* Fed. R. Evid. 408. Furthermore, ST’s presentation was made outside the context of litigation, and there is nothing on the record to indicate that it could be properly considered an “offer” to settle a claim which was then in dispute.

fringed by SanDisk. According to Thompson, the presentation by ST's technical experts included "mapp[ing] the elements of each of the allegedly infringed claims to the aspects of the accused SanDisk products alleged to practice the elements." Thompson declares that "the experts liberally referred to SanDisk's (alleged) infringement of [ST's] products." SanDisk's engineer then made a presentation, describing several of SanDisk's patents and analyzing how a semiconductor chip product sold by ST infringes.

At the end of the meeting, Jorgenson handed Thompson a packet of materials containing, for each of ST's fourteen patents under discussion, a copy of the patent, reverse engineering reports for certain of SanDisk's products, and diagrams showing how elements of ST's patent claims cover SanDisk's products. According to SanDisk, Jorgenson indicated (in words to this effect):

I know that this is material that would allow SanDisk to DJ [ST] on. We have had some internal discussions on whether I should be giving you a copy of these materials in light of that fact. But I have decided that I will go ahead and give you these materials.

Jorgenson further told Thompson that "ST has absolutely no plan whatsoever to sue SanDisk." Thompson responded to Jorgenson that "SanDisk is not going to sue you on Monday" and that another meeting might be appropriate.

On September 1, 2004, Jorgenson wrote to Thompson, enclosing copies of ST's general slide presentation from the August meeting and also enclosing a hard copy booklet containing each of the engineering reports "for each claim on all products where ST demonstrated coverage by the 14 ST patents to-date [sic]." Jorgenson requested that SanDisk provide ST with a copy of SanDisk's presentation and information about the three SanDisk patents presented. On September 8, 2004, Thompson replied by e-mail, confirming receipt of the package from ST, attaching a copy of SanDisk's presentation, indicating it was his "personal feeling . . . that we have got to trust one another during these negotiations," and seeking a non-disclosure agreement. Thompson also wrote "I still owe you the rates quoted."

On September 15, 2004, Thompson again corresponded with Jorgenson, this time by letter, enclosing a confidential version of SanDisk's cross licensing offer, which noted that the offer would expire on September 27, 2004. Jorgenson destroyed this confidential offer and did not retain a copy, and, on September 16, 2004, sent Thompson an e-mail requesting that a non-confidential version be sent for ST's consideration. SanDisk refused to send a non-confidential version. Instead, on September 27, 2004, Thompson offered to send another confidential version, or to communicate the offer orally. Thompson also indicated that SanDisk did not need additional information regarding ST's patents because SanDisk was "quite comfortable with its position" and that it was "time to let our business people talk and see if a peaceful resolution is possible." On September 28, 2004, Jorgenson repeated her request for a written non-confidential version of SanDisk's licensing offer. The following day, Thompson e-mailed Jorgenson another confidential version of SanDisk's offer.

On October 15, 2004, after several further e-mails and phone calls between the business representatives trying to establish another meeting, SanDisk filed

the instant lawsuit. SanDisk alleged infringement of one of its patents and sought a declaratory judgment of noninfringement and invalidity of the fourteen ST patents that had been discussed during the cross licensing negotiations. On December 3, 2004, ST filed a motion to dismiss SanDisk's declaratory judgment claims for lack of subject matter jurisdiction, maintaining that there was no actual controversy at the time SanDisk filed its complaint.

The district court granted ST's motion to dismiss, holding that no actual controversy existed for purposes of the Declaratory Judgment Act because SanDisk did not have an objectively reasonable apprehension of suit, even though it may have subjectively believed that ST would bring an infringement suit. The district court reasoned that "SanDisk has presented no evidence that ST threatened it with litigation at any time during the parties' negotiations, nor has SanDisk shown other conduct by ST rising to a level sufficient to indicate an intent on the part of ST to initiate an infringement action." The district court found that the studied and determined infringement analyses that ST presented to SanDisk did not constitute the requisite "express charges [of infringement] carrying with them the threat of enforcement." The district court also found that the totality of the circumstances did not evince an actual controversy because ST told SanDisk that it did not intend to sue SanDisk for infringement.

II. DISCUSSION

* * *

B. Analysis

SanDisk argues that the district court erred as a matter of law by requiring an express accusation of patent infringement coupled with an explicit threat of judicial enforcement to support declaratory judgment jurisdiction, and that, under the correct legal standard articulated by this court in *Arrowhead*, 846 F.2d at 736, the facts of this case illustrate that SanDisk's apprehension of an infringement suit was objectively reasonable. SanDisk asserts that the infringement analysis presented by ST and its experts at the August 27, 2004 licensing meeting constituted an allegation of infringement and that the totality of the circumstances shows that ST's conduct gave rise to an actual case or controversy. SanDisk further points out that negotiations regarding licensing had ceased by the time SanDisk filed its claims for declaratory judgment.

ST counters that the district court applied the correct legal standard and argues that SanDisk ignores the line of cases that have followed and interpreted *Arrowhead*. ST asserts that the cases following *Arrowhead* reveal that the bare mention of infringement, particularly during license negotiations, is not sufficient to meet the standard set forth in *Arrowhead*. ST asserts that its conduct at the August 27, 2004 licensing meeting was to strengthen its position during licensing negotiations and that, under the totality of the circumstances, SanDisk has not shown that ST's conduct gave rise to declaratory judgment jurisdiction. Moreover, ST argues that the district court did not abuse its discretion when it concluded, as an alternative basis for its ruling, that it would exercise discretion to decline to decide SanDisk's claims.

1. Case or Controversy

The first question we address is whether the facts alleged in this case show that there is a case or controversy within the meaning of the Declaratory Judgment Act, 28 U.S.C. § 2201(a).

The Declaratory Judgment Act provides, in relevant part, that

[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). The “actual controversy” requirement of the Declaratory Judgment Act is rooted in Article III of the Constitution, which provides for federal jurisdiction over only “cases and controversies.” Thus, our jurisdiction extends only to matters that are Article III cases or controversies.

The Supreme Court, in the context of a patent license dispute, recently examined Article III’s case or controversy requirement as it relates to the Declaratory Judgment Act. See *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007). In *MedImmune*, the Supreme Court considered “whether Article III’s limitation of federal courts’ jurisdiction to ‘Cases’ and ‘Controversies,’ reflected in the ‘actual controversy’ requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires a patent licensee to terminate or be in breach of its license agreement before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed.” *Id.* at 767.

The Supreme Court began its analysis

with the recognition that, where threatened action by government is concerned, [the Court] do[es] not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat—for example, the constitutionality of a law threatened to be enforced. The plaintiff’s own action (or inaction) in failing to violate the law eliminates the imminent threat of prosecution, but nonetheless does not eliminate Article III jurisdiction.

Id. at 772. The Supreme Court quoted its earlier decision in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), where the Court stated that “the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune*, 127 S. Ct. at 771. The Supreme Court emphasized that Article III requires that the dispute at issue be “‘definite and concrete, touching the legal relations of parties having adverse legal interests’; and that it be ‘real and substantial’ and ‘admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.’” *Id.* (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937)). The Supreme Court stated that, when faced with a genuine threat of enforcement that the government will penalize a certain private action, Article III “d[oes] not require, as a prerequisite to testing the validity of the law in a suit for injunction, that the plaintiff bet the farm, so to speak, by taking the violative action.” *Id.* at 772. As the Supreme Court noted, “the declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity.” *Id.* The Supreme Court clarified that, although a declaratory judgment plaintiff may

eliminate an “imminent threat of harm by simply not doing what he claimed the right to do[,] . . . [t]hat did not preclude subject-matter jurisdiction [where] the threat-eliminating behavior was effectively coerced.” *Id.* “The dilemma posed by that coercion—putting the challenger to the choice between abandoning his rights or risking prosecution—is a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.” *Id.* at 773.

The Supreme Court then applied these principles to the facts of the case and remarked that “the requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim.” *Id.* The Supreme Court held that “[t]he rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.” *Id.* at 775.

With regard to patent disputes, prior to *MedImmune*, this court articulated a two-part test that first considers whether conduct by the patentee creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and second examines whether conduct by the declaratory judgment plaintiff amounts to infringing activity or demonstrates concrete steps taken with the intent to conduct such activity. See *Arrowhead*, 846 F.2d at 736. The Supreme Court, in *MedImmune*, addressed the “reasonable apprehension of suit” aspect of this court’s two-part test and concluded that it conflicts with *Aetna Life Insurance* and *Maryland Casualty*, and is in tension with *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 98 (1993).

In *Aetna Life Insurance*, an insurer sought a declaratory judgment that the insured was not relieved of his duty to continue to pay insurance premiums and that, since the insured had stopped making the payments, the insurance policy had lapsed. In that case, the Supreme Court first upheld the constitutionality of the federal Declaratory Judgment Act. 300 U.S. at 240-41. The Supreme Court then held that, although the insured party gave no indication that he would file suit, *id.* at 239, the case nevertheless presented a controversy under Article III because the parties had taken adverse positions with regard to their obligations, each side presenting a concrete claim of a specific right—the insured claiming that he had become disabled and therefore was relieved of making insurance premium payments and the insurer claiming that the insured was not disabled and that the failure to make payments caused the policy to lapse, *id.* at 244. Similarly, in *Maryland Casualty*, the declaratory judgment plaintiff, an insurance company which had agreed to indemnify and defend the insured against actions brought by third parties against the insured, sought a declaration that it had no duty to defend or to indemnify the insured. 312 U.S. at 272. In that case, the insured could not have sued the declaratory judgment plaintiff without first obtaining a judgment against the third party and the underlying action against the third party “[a]pparently . . . ha[d] not proceeded to judgment.” *Id.* at 271. Nevertheless, the Supreme Court held that “[i]t is clear that there is an actual controversy between petitioner and the insured” since the insured was in the process of seeking a judgment and had a statutory right to proceed against the declaratory judgment plaintiff if such judgment were obtained and not satisfied. *Id.*

at 274. Finally, in *Cardinal Chemical*, the Supreme Court held that this court's affirmance of a judgment of noninfringement does not necessarily moot a declaratory judgment counterclaim of patent invalidity. 508 U.S. at 98. The Supreme Court's rationale for holding that the declaratory judgment action can proceed consistent with Article III was that a contrary result would create the potential for relitigation or uncertainty with regard to the validity of patents and would be contrary to *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971).

The Supreme Court's opinion in *MedImmune* represents a rejection of our reasonable apprehension of suit test.² The Court first noted that "the continuation of royalty payments makes what would otherwise be an imminent threat at least remote, if not nonexistent. . . . Petitioner's own acts, in other words, eliminate the imminent threat of harm." *MedImmune*, 127 S. Ct. at 772. The Court nonetheless concluded that declaratory judgment jurisdiction existed relying in particular on its earlier decision in *Altwater v. Freeman*, 319 U.S. 359 (1943). There, the patentee brought suit to enjoin patent infringement, and the accused infringer filed declaratory judgment counterclaims of invalidity. The district court found that there was no infringement and that the patent was invalid. *Id.* at 362. The appellate court affirmed the finding of noninfringement but vacated the finding of invalidity as moot. *Id.* The Supreme Court held that the declaratory judgment counterclaims were not mooted by the finding of noninfringement. *Id.* at 365-66. In finding declaratory judgment jurisdiction in *MedImmune*, the Court specifically addressed and rejected our reasonable apprehension test:

[e]ven if *Altwater* could be distinguished as an "injunction" case, it would still contradict the Federal Circuit's "reasonable apprehension of suit" test (or, in its evolved form, the "reasonable apprehension of imminent suit" test, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit. It is also in tension with *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98 (1993), which held that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.

MedImmune, 127 S. Ct. at 774 n.11.

The Supreme Court in *MedImmune* addressed declaratory judgment jurisdiction in the context of a signed license. In the context of conduct prior to the existence of a license, declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned

2. In this case, we address only the first prong of this court's two-part test. There is no dispute that the second prong is met. We therefore leave to another day the effect of *MedImmune*, if any, on the second prong.

by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. We need not define the outer boundaries of declaratory judgment jurisdiction, which will depend on the application of the principles of declaratory judgment jurisdiction to the facts and circumstances of each case. We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights. *See id. Contra Cygnus Therapeutics Sys. v. ALZA Corp.*, 92 F.3d 1153 (Fed. Cir. 1996) (holding that declaratory judgment jurisdiction was not supported where the “patentee does nothing more than exercise its lawful commercial prerogatives and, in so doing, puts a competitor in the position of having to choose between abandoning a particular business venture or bringing matters to a head by engaging in arguably infringing activity”).

* * *

Under the facts alleged in this case, SanDisk has established an Article III case or controversy that gives rise to declaratory judgment jurisdiction. ST sought a right to a royalty under its patents based on specific, identified activity by SanDisk. For example, at the August 27, 2004 licensing meeting, ST presented, as part of the “license negotiations,” a thorough infringement analysis presented by seasoned litigation experts, detailing that one or more claims of its patents read on one or more of SanDisk’s identified products. At that meeting, ST presented SanDisk with a detailed presentation which identified, on an element-by-element basis, the manner in which ST believed each of SanDisk’s products infringed the specific claims of each of ST’s patents. During discussions, the experts liberally referred to SanDisk’s present, ongoing infringement of ST’s patents and the need for SanDisk to license those patents. ST also gave SanDisk a packet of materials, over 300 pages in length, containing, for each of ST’s fourteen patents under discussion, a copy of the patent, reverse engineering reports for certain of SanDisk’s products, and diagrams showing a detailed infringement analysis of SanDisk’s products. ST communicated to SanDisk that it had made a studied and determined infringement determination and asserted the right to a royalty based on this determination. SanDisk, on the other hand, maintained that it could proceed in its conduct without the payment of royalties to ST. These facts evince that the conditions of creating “a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment” were fulfilled. SanDisk need not “bet the farm,” so to speak, and risk a suit for infringement by cutting off licensing discussions³ and continuing in the identified activity before seeking a decla-

3. Although the district court found that licensing negotiations had not been terminated, we note that SanDisk in fact declined to participate in further negotiations, effectively bringing them to an end. Regardless, however, a party to licensing negotiations is of course within its rights to terminate negotiations when it appears that they will be unproductive.

ration of its legal rights. See *MedImmune*, 127 S. Ct. at 774 n.11. *Contra Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051 (Fed. Cir. 1995) (“When there are proposed or ongoing license negotiations, a litigation controversy normally does not arise until the negotiations have broken down.”).

2. Promise Not to Sue

We next address whether Jorgenson’s direct and unequivocal statement that “ST has absolutely no plan whatsoever to sue SanDisk” eliminates any actual controversy and renders SanDisk’s declaratory judgment claims moot.

We decline to hold that Jorgenson’s statement that ST would not sue SanDisk eliminates the justiciable controversy created by ST’s actions, because ST has engaged in a course of conduct that shows a preparedness and willingness to enforce its patent rights despite Jorgenson’s statement. Having approached SanDisk, having made a studied and considered determination of infringement by SanDisk, having communicated that determination to SanDisk, and then saying that it does not intend to sue, ST is engaging in the kinds of “extra-judicial patent enforcement with scare-the-customer-and-run tactics” that the Declaratory Judgment Act was intended to obviate. *Arrowhead*, 846 F.2d at 735. ST’s statement that it does not intend to sue does not moot the actual controversy created by its acts.

* * *

BRYSON, Circuit Judge, concurring in the result.

Under our law, as things stood before the Supreme Court’s decision in *MedImmune*, the district court’s order in this case was correct. ST, the patentee, had offered a license to SanDisk, but had not threatened suit and had sought to continue licensing negotiations. Although ST had made a detailed showing as to why it believed SanDisk’s products were within the scope of its patent rights, there is nothing exceptional in that. In the typical case, we would expect competent patent counsel who offers a license to another party to be prepared to demonstrate why such a license is required. By the time the suit was brought, ST had done nothing to give SanDisk cause to be in reasonable apprehension of suit, and in fact ST had expressly stated that it did not intend to sue SanDisk. In short, ST was simply availing itself of the safe haven our cases had created for patentees to offer licenses without opening themselves up to expensive litigation.

The decision in *MedImmune* dealt with a narrow issue: whether a declaratory judgment action can be brought by a patent licensee without terminating the licensing agreement. Footnote 11 of the *MedImmune* opinion, however, went further and criticized this court’s “reasonable apprehension of suit” test for declaratory judgment jurisdiction. I agree with the court that the footnote calls our case law into question and would appear to make declaratory judgments more readily available to parties who are approached by patentees seeking to license their patents. In particular, the reasoning of the *MedImmune* footnote seems to require us to hold that the district court in this case had jurisdiction to entertain SanDisk’s declaratory judgment action. For that reason I concur in the judgment of the court in this case reversing the jurisdictional dismissal of the complaint.

I think it is important, however, to point out the implications of the footnote in *MedImmune* as applied here, because the implications are broader than one might suppose from reading the court's opinion in this case. While noting that it is not necessary to define the outer boundaries of declaratory judgment jurisdiction, the court holds that "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license," the party may bring a declaratory judgment action. Applying that principle, the court concludes that in this case, where "ST sought a right to a royalty under its patents based on specific, identified activity by SanDisk," an Article III case or controversy has arisen.

In practical application, the new test will not be confined to cases with facts similar to this one. If a patentee offers a license for a fee, the offer typically will be accompanied by a suggestion that the other party's conduct is within the scope of the patentee's patent rights, or it will be apparent that the patentee believes that to be the case. Offers to license a patent are not requests for gratuitous contributions to the patentee; the rationale underlying a license offer is the patentee's express or implied suggestion that the other party's current or planned conduct falls within the scope of the patent. Therefore, it would appear that under the court's standard virtually any invitation to take a paid license relating to the prospective licensee's activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent. Indeed, as the court makes clear, even a representation by the patentee that it does not propose to file suit against the prospective licensee will not suffice to avoid the risk that the patentee will face a declaratory judgment action. And if there is any uncertainty on that score, all the prospective licensee has to do in order to dispel any doubt is to inquire of the patentee whether the patentee believes its activities are within the scope of the patent. If the patentee says "no," it will have made a damaging admission that will make it very hard ever to litigate the issue, and thus will effectively end its licensing efforts. If it says "yes" or equivocates, it will have satisfied the court's test and will have set itself up for a declaratory judgment lawsuit.

For these reasons, I see nothing about the particular facts surrounding this licensing negotiation in this case that triggers SanDisk's right to bring a declaratory judgment action under the new standard. The court emphasizes that ST made a "detailed presentation [to SanDisk] which identified, on an element-by-element basis, the manner in which ST believed each of SanDisk's products infringed the specific claims of each of ST's patents." The court summarizes ST's presentation by stating that "ST communicated to SanDisk that it had made a studied and determined infringement determination and asserted a right to a royalty based on this determination" and that SanDisk "maintained that it could proceed in its conduct without the payment of royalties to ST." Those facts, the court concludes, evinced a sufficient controversy to entitle SanDisk to institute its declaratory judgment suit.

But what is the significance of those facts? The court's legal test does not suggest that the case would come out differently if ST had been less forthcoming about why it believed SanDisk should take a license, or even if ST had simply contacted SanDisk, provided copies of its patents, and suggested that SanDisk consider taking a license. I doubt the court would hold that there was

no controversy in that setting, as long as SanDisk was prepared to assert that it believed its products were not within the scope of ST's valid patent rights. If SanDisk's lawyers had any question about whether this court would permit them to seek a declaratory judgment under those circumstances, they could readily resolve that question by sending a "put up or shut up" response to ST's licensing offer—asking ST to state expressly whether it regarded SanDisk's products to be within the scope of ST's patents and to identify with particularity how SanDisk's products read on particular claims of those patents. Any response by ST would either end its licensing efforts or expose it to a declaratory judgment action.¹

In sum, the rule adopted by the court in this case will effect a sweeping change in our law regarding declaratory judgment jurisdiction. Despite the references in the court's opinion to the particular facts of this case, I see no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a patent license elects to dispute the need for a license and then to sue the patentee. Although I have reservations about the wisdom of embarking on such a course, I agree with the court that a fair reading of footnote 11 of the Supreme Court's opinion in *MedImmune* compels that result, and I therefore concur in the judgment reversing the district court's dismissal order in this case.

Comments

1. **Opening DJ's Doors.** The Federal Circuit has interpreted *MedImmune's* footnote 11 as a rejection of the court's "reasonable apprehension" test. In its place, the question is "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." As *Sandisk* shows, it is much easier to obtain declaratory judgment jurisdiction after the *MedImmune* case. In a pre-licensing context, "declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." Nonetheless, "Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." Several district courts have also questioned the continuing viability of the reasonable apprehension test. See, e.g., *Rite-Hite Corp. v. Delta T Corp.*, Slip Copy, 2007 WL 725327 *8 (E.D. Wis. 2007) ("The bottom line is that the Supreme Court has called into serious question the continued viability of the Federal Circuit's 'reasonable

1. The court suggests that ST could have avoided the risk of a declaratory judgment action by obtaining a suitable confidentiality agreement. The problem with that suggestion is that it would normally work only when it was not needed—only a party that was not interested in bringing a declaratory judgment action would enter into such an agreement. A party that contemplates bringing a declaratory judgment action or at least keeping that option open would have no incentive to enter into such an agreement.

apprehension of suit’ test in patent declaratory judgment actions. In light of such fact, this court is reluctant to employ that test in ruling on the defendants’ motions to dismiss.); *Highway Equipment Co., Inc. v. Cives Corp.*, 476 F. Supp. 2d 1079, 1087 (N.D. Iowa 2007) (stating *MedImmune* “abrogated the Federal Circuit Court of Appeals’ reasonable-apprehension test”). For a discussion of *MedImmune* in the pharma/generic intersection, see *Teva v. Novartis* (Fed. Cir. 2007) (citing footnote 11 in *MedImmune*, the court stated Supreme Court “disagreed with our ‘reasonable apprehension of imminent suit’ test and re-affirmed that the ‘actual controversy’ requirement in the Declaratory Judgment Act is the same as the ‘Cases’ and ‘Controversies’ requirement in Article III”).

2. ***Bryson’s Concurrence and MedImmune’s Broad Implications.*** Judge Bryson expressed concerns that patentees may have about the ease with which DJ jurisdiction can be obtained. Accordingly,

it would appear that under the court’s standard virtually any invitation to take a paid license relating to the prospective licensee’s activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent.

480 F.3d at 1384. A patentee will not be able to recover damages until the alleged infringer has actual or constructive notice, and then damages will be available only for subsequent infringing activity. See 35 U.S.C. § 287(a). See also *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996). In the light of *SanDisk* and *MedImmune*, therefore, can a patentee satisfy the actual notice requirement without opening the door to a claim of invalidity or non-infringement? This may be one of the broad implications that Judge Bryson was referring to regarding the majority’s reading of *MedImmune*’s footnote 11.

B. ANTITRUST

Antitrust law and patent law have a long and contentious history. Traditionally, it was thought that these two areas of law had inconsistent goals. On the one hand, patent law was seen as creating monopolies, whereas antitrust law was focused on dismantling them. But economic thinking on the subject—beginning in the late 1970s and 1980s—portrays a more complementary relationship with each body of law viewed as vehicles to promote innovation and competition, albeit by different means.* Despite this greater harmony, however, certain forms of patentee behavior can have antitrust implications.

*See e.g., *Antitrust Guidelines for the Licensing of Intellectual Property* § 1.0 (Department of Justice and Federal Trade Commission 1995) (stating “intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare”); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) (stating “[t]he patent and antitrust laws are complementary, the patent system serving to encourage invention and the bringing of new products to market by adjusting investment-based risk, and the antitrust laws serving to foster industrial competition”).

This section explores the relationship between patent law and antitrust law. The first issue addressed, in *Illinois Tool Works*, relates to patents and market power, a notion that is at the core of antitrust doctrine. Thereafter, various forms of patentee behavior are examined through the lens of antitrust law, including—in *Nobelpharma*—enforcement of a fraudulently obtained patent; a patentee’s refusal to license his patent in *Independent Service Organizations Antitrust Litigation*; and, lastly, settlement agreements, particularly between a name-brand pharmaceutical company and a generic concern, in *Tamoxifen Citrate Antitrust Litigation*.

1. Patents and Market Power

Market power can be defined as the ability of a firm to price a product above its marginal cost without losing substantial sales, or as the “ability profitably to maintain prices above, or output below, competitive levels for a significant period of time.”* In a perfectly competitive market, no firm has market power or what can be called an *economic* monopoly. Patent rights give rise to a *legal* monopoly because the patentee can exclude others from making, using, or selling goods that fall within its claim scope. Importantly, however, patent rights seldom give rise to an *economic* monopoly or market power because there are almost always viable substitutes. The *Illinois Tool* case explores the issue of patents and market power.

ILLINOIS TOOL WORKS INC. v. INDEPENDENT INK, INC.

547 U.S. 28 (2006)

Justice STEVENS delivered the opinion of the Court.

The question presented to us today is whether the presumption of market power in a patented product should survive as a matter of antitrust law despite its demise in patent law. We conclude that the mere fact that a tying product is patented does not support such a presumption.

I

Petitioners, Trident, Inc., and its parent, Illinois Tool Works Inc., manufacture and market printing systems that include three relevant components: (1) a patented piezoelectric impulse ink jet printhead; (2) a patented ink container, consisting of a bottle and valved cap, which attaches to the printhead; and (3) specially designed, but unpatented, ink. Petitioners sell their systems to original equipment manufacturers (OEMs) who are licensed to incorporate the printheads and containers into printers that are in turn sold to companies for use in printing barcodes on cartons and packaging materials. The OEMs agree that they will purchase their ink exclusively from petitioners, and that neither they nor their customers will refill the patented containers with ink of any kind.

**Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (Department of Justice and Federal Trade Commission 1995).

Respondent, Independent Ink, Inc. has developed an ink with the same chemical composition as the ink sold by petitioners. After an infringement action brought by Trident against Independent was dismissed for lack of personal jurisdiction, Independent filed suit against Trident seeking a judgment of noninfringement and invalidity of Trident's patents. In an amended complaint, it alleged that petitioners are engaged in illegal tying and monopolization in violation of §§ 1 and 2 of the Sherman Act. 15 U.S.C. §§ 1, 2.

After a careful review of the "long history of Supreme Court consideration of the legality of tying arrangements," 396 F.3d 1342, 1346 (2005), the Court of Appeals for the Federal Circuit reversed the District Court's decision as to respondent's § 1 claim, *id.*, at 1354. Placing special reliance on our decisions in *International Salt Co. v. United States*, and *Loew's*, as well as our *Jefferson Parish* dictum, and after taking note of the academic criticism of those cases, it concluded that the "fundamental error" in petitioners' submission was its disregard of "the duty of a court of appeals to follow the precedents of the Supreme Court until the Court itself chooses to expressly overrule them." 396 F.3d, at 1351. We granted certiorari to undertake a fresh examination of the history of both the judicial and legislative appraisals of tying arrangements. Our review is informed by extensive scholarly comment and a change in position by the administrative agencies charged with enforcement of the antitrust laws.

II

Over the years this Court's strong disapproval of tying arrangements has substantially diminished. Rather than relying on assumptions, in its more recent opinions the Court has required a showing of market power in the tying product.

In rejecting the application of a *per se* rule that all tying arrangements constitute antitrust violations, we explained:

[W]e have condemned tying arrangements when the seller has some special ability—usually called 'market power'—to force a purchaser to do something that he would not do in a competitive market. . . .

Per se condemnation—condemnation without inquiry into actual market conditions—is only appropriate if the existence of forcing is probable. Thus, application of the *per se* rule focuses on the probability of anticompetitive consequences. . . .

For example, if the Government has granted the seller a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power. *United States v. Loew's Inc.*, 371 U.S., at 45-47. Any effort to enlarge the scope of the patent monopoly by using the market power it confers to restrain competition in the market for a second product will undermine competition on the merits in that second market. Thus, the sale or lease of a patented item on condition that the buyer make all his purchases of a separate tied product from the patentee is unlawful.

Jefferson, 466 U.S. at 13-16.

Notably, nothing in our opinion suggested a rebuttable presumption of market power applicable to tying arrangements involving a patent on the tying good. Instead, it described the rule that a contract to sell a patented

product on condition that the purchaser buy unpatented goods exclusively from the patentee is a *per se* violation of § 1 of the Sherman Act.

Justice O'Connor wrote separately in *Jefferson Parish*, concurring in the judgment on the ground that the case did not involve a true tying arrangement because, in her view, surgical services and anesthesia were not separate products. In her opinion, she questioned not only the propriety of treating any tying arrangement as a *per se* violation of the Sherman Act, but also the validity of the presumption that a patent always gives the patentee significant market power, observing that the presumption was actually a product of our patent misuse cases rather than our antitrust jurisprudence. It is that presumption, a vestige of the Court's historical distrust of tying arrangements, that we address squarely today.

III

Justice O'Connor was, of course, correct in her assertion that the presumption that a patent confers market power arose outside the antitrust context as part of the patent misuse doctrine. That doctrine had its origins in *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917), which found no support in the patent laws for the proposition that a patentee may "prescribe by notice attached to a patented machine the conditions of its use and the supplies which must be used in the operation of it, under pain of infringement of the patent," *id.*, at 509. Although *Motion Picture Patents Co.* simply narrowed the scope of possible patent infringement claims, it formed the basis for the Court's subsequent decisions creating a patent misuse defense to infringement claims when a patentee uses its patent "as the effective means of restraining competition with its sale of an unpatented article." *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 490 (1942).

Without any analysis of actual market conditions, these patent misuse decisions assumed that, by tying the purchase of unpatented goods to the sale of the patented good, the patentee was "restraining competition," *Morton Salt*, 314 U.S., at 490, or "secur[ing] a limited monopoly of an unpatented material," *Mercoide*, 320 U.S., at 664. In other words, these decisions presumed "[t]he requisite economic power" over the tying product such that the patentee could "extend [its] economic control to unpatented products." *Loew's*, 371 U.S., at 45-46.

The presumption that a patent confers market power migrated from patent law to antitrust law in *International Salt Co. v. United States*, 332 U.S. 392 (1947). In that case, we affirmed a District Court decision holding that leases of patented machines requiring the lessees to use the defendant's unpatented salt products violated § 1 of the Sherman Act and § 3 of the Clayton Act as a matter of law. *Id.*, at 396. Although the Court's opinion does not discuss market power or the patent misuse doctrine, it assumes that "[t]he volume of business affected by these contracts cannot be said to be insignificant or insubstantial and the tendency of the arrangement to accomplishment of monopoly seems obvious." *Ibid.*

IV

Although the patent misuse doctrine and our antitrust jurisprudence became intertwined in *International Salt*, subsequent events initiated their untwining. This process has ultimately led to today's reexamination of the

presumption of *per se* illegality of a tying arrangement involving a patented product, the first case since 1947 in which we have granted review to consider the presumption's continuing validity.

Three years before we decided *International Salt*, this Court had expanded the scope of the patent misuse doctrine to include not only supplies or materials used by a patented device, but also tying arrangements involving a combination patent and "unpatented material or [a] device [that] is itself an integral part of the structure embodying the patent." *Mercoïd*, 320 U.S., at 665. In reaching this conclusion, the Court explained that it could see "no difference in principle" between cases involving elements essential to the inventive character of the patent and elements peripheral to it; both, in the Court's view, were attempts to "expan[d] the patent beyond the legitimate scope of its monopoly." *Mercoïd*, 320 U.S., at 665.

Shortly thereafter, Congress codified the patent laws for the first time. At least partly in response to our *Mercoïd* decision, Congress included a provision in its codification that excluded some conduct, such as a tying arrangement involving the sale of a patented product tied to an "essential" or "nonstaple" product that has no use except as part of the patented product or method, from the scope of the patent misuse doctrine. § 271(d). Thus, at the same time that our antitrust jurisprudence continued to rely on the assumption that "tying arrangements generally serve no legitimate business purpose," *Fortner I*, 394 U.S., at 503, Congress began chipping away at the assumption in the patent misuse context from whence it came.

It is Congress' most recent narrowing of the patent misuse defense, however, that is directly relevant to this case. Four years after our decision in *Jefferson Parish* repeated the patent-equals-market-power presumption, 466 U.S., at 16, Congress amended the Patent Code to eliminate that presumption in the patent misuse context. The relevant provision reads:

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: . . . (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, *unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.*

35 U.S.C. § 271(d)(5) (emphasis added).

The italicized clause makes it clear that Congress did not intend the mere existence of a patent to constitute the requisite "market power." Indeed, fairly read, it provides that without proof that Trident had market power in the relevant market, its conduct at issue in this case was neither "misuse" nor an "illegal extension of the patent right."

While the 1988 amendment does not expressly refer to the antitrust laws, it certainly invites a reappraisal of the *per se* rule announced in *International Salt*. A rule denying a patentee the right to enjoin an infringer is significantly less severe than a rule that makes the conduct at issue a federal crime punishable by up to 10 years in prison. It would be absurd to assume that Congress intended to provide that the use of a patent that merited punishment as a felony would not constitute "misuse." Moreover, given the fact that the patent

misuse doctrine provided the basis for the market power presumption, it would be anomalous to preserve the presumption in antitrust after Congress has eliminated its foundation.

After considering the congressional judgment reflected in the 1988 amendment, we conclude that tying arrangements involving patented products should be evaluated under the standards applied in cases like *Fortner II* and *Jefferson Parish* rather than under the *per se* rule applied in *Morton Salt* and *Loew's*. While some such arrangements are still unlawful, such as those that are the product of a true monopoly or a marketwide conspiracy, that conclusion must be supported by proof of power in the relevant market rather than by a mere presumption thereof.⁴

V

Rather than arguing that we should retain the rule of *per se* illegality, respondent contends that we should endorse a rebuttable presumption that patentees possess market power when they condition the purchase of the patented product on an agreement to buy unpatented goods exclusively from the patentee. Respondent recognizes that a large number of valid patents have little, if any, commercial significance, but submits that those that are used to impose tying arrangements on unwilling purchasers likely do exert significant market power. Hence, in respondent's view, the presumption would have no impact on patents of only slight value and would be justified, subject to being rebutted by evidence offered by the patentee, in cases in which the patent has sufficient value to enable the patentee to insist on acceptance of the tie.

Respondent also offers a narrower alternative, suggesting that we differentiate between tying arrangements involving the simultaneous purchase of two products that are arguably two components of a single product—such as the provision of surgical services and anesthesiology in the same operation, *Jefferson Parish*, 466 U.S., at 43, or the licensing of one copyrighted film on condition that the licensee take a package of several films in the same transaction, and a tying arrangement involving the purchase of unpatented goods over a period of time, a so-called “requirements tie.” According to respondent, we should recognize a presumption of market power when faced with the latter type of arrangements because they provide a means for charging large volume purchasers a higher royalty for use of the patent than small purchasers must pay, a form of discrimination that “is strong evidence of market power.”

The opinion that imported the “patent equals market power” presumption into our antitrust jurisprudence, however, provides no support for respondent's proposed alternative. In *International Salt*, it was the existence of the patent on the tying product, rather than the use of a requirements tie, that led the Court to presume market power. Moreover, the requirements tie in that case did not involve any price discrimination between large volume and small volume purchasers or evidence of noncompetitive pricing. Instead, the leases at issue provided that if any competitor offered salt, the tied product, at a

4. Our imposition of this requirement accords with the vast majority of academic literature on the subject.

lower price, “the lessee should be free to buy in the open market, unless appellant would furnish the salt at an equal price.” *Id.*, at 396.

As we have already noted, the vast majority of academic literature recognizes that a patent does not necessarily confer market power. Similarly, while price discrimination may provide evidence of market power, particularly if buttressed by evidence that the patentee has charged an above-market price for the tied package, it is generally recognized that it also occurs in fully competitive markets. We are not persuaded that the combination of these two factors should give rise to a presumption of market power when neither is sufficient to do so standing alone. Rather, the lesson to be learned from *International Salt* and the academic commentary is the same: Many tying arrangements, even those involving patents and requirements ties, are fully consistent with a free, competitive market. For this reason, we reject both respondent’s proposed rebuttable presumption and their narrower alternative.

It is no doubt the virtual consensus among economists that has persuaded the enforcement agencies to reject the position that the Government took when it supported the *per se* rule that the Court adopted in the 1940’s. In antitrust guidelines issued jointly by the Department of Justice and the Federal Trade Commission in 1995, the enforcement agencies stated that in the exercise of their prosecutorial discretion they “will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner.” U.S. Dept. of Justice and FTC, Antitrust Guidelines for the Licensing of Intellectual Property § 2.2 (Apr. 6, 1995). While that choice is not binding on the Court, it would be unusual for the Judiciary to replace the normal rule of lenity that is applied in criminal cases with a rule of severity for a special category of antitrust cases.

Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion, and therefore hold that, in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product.

VI

In this case, respondent reasonably relied on our prior opinions in moving for summary judgment without offering evidence defining the relevant market or proving that petitioners possess power within it. When the case returns to the District Court, respondent should therefore be given a fair opportunity to develop and introduce evidence on that issue, as well as any other issues that are relevant to its remaining § 1 claims. Accordingly, the judgment of the Court of Appeals is vacated, and the case is remanded for further proceedings consistent with this opinion.

Comments

1. **Market Power and Patents.** Market power is the ability of a firm to price a product above its marginal cost without losing substantial sales. See Benjamin Klein, *Market Power in Antitrust: Economic Analysis After Kodak*, 3 SUP. CT. ECON. REV. 43, 72 (1993) (“Most economists . . . would label the

situation where a firm can increase the price of its product without losing significant sales, and thereby can engage in price discrimination, as one where the firm possesses some market power”); Marcel Kahan & Ehud Kamar, *Price Discrimination in the Market for Corporate Law*, 86 CORNELL L. REV. 1205, 1210-11 (2001) (stating “market power . . . is defined as the ability to charge more for a product than its marginal cost. Since charging more for a product than its marginal cost is a condition for earning a profit, the ability to earn a profit over an extended period of time is evidence that a producer has market power”).

There is an important distinction between, on the one hand, having market power or an *economic* monopoly, and, on the other hand, having a *legal* monopoly. A patent and its right to exclude confer a legal monopoly. But this right rarely gives rise to an economic monopoly because the claimed invention is usually accompanied by the availability of viable substitutes. *Illinois Tool Works* recognized this distinction, as have several scholars. See, e.g., *Panel Discussion: The Value of Patents and Other Legally Protected Commercial Rights*, 53 ANTITRUST L.J. 535, 547 (1985) (F.M. Scherer speaking) (“A patented product may well be unique. It may, however, face a lot of substitutes, perhaps equally unique; and, as a result of this extensive availability of substitutes, confer very little, if any, monopoly power. Statistical studies suggest that the vast majority of all patents confer very little monopoly power—at least, they are not very profitable.”); 1 HERBERT HOVENKAMP, MARK D. JANIS & MARK A. LEMLEY, *IP AND ANTITRUST* § 4.2a (2005) (noting a patent grant “is not even a guarantee of market success,” let alone giving rise to an economic monopoly); WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 374-75 (2003) (stating “[t]he *average* patent . . . confers too little market power on the patentee in a meaningful economic sense to interest a rational antitrust enforcer, and sometimes it confers no monopoly power at all”) (emphasis in original); Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 791 (2002) (stating “patents typically do not demonstrate market power, and the set of technological substitutes that cannot be practiced because of the patent grant often has little overlap with the set of products that consumers view as economic substitutes”).

But the lack of market power does not necessarily mean an absence of economic rents. Indeed, the ability of a patentee to price its patented good above marginal cost is a principal benefit of having a patent. See Kenneth Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 250 (1994) (asserting a “patent that reduces the cost of making a product will permit the patentee to enjoy economic rent. To be sure, this statement assumes that other producers are not able to use the innovation to reduce cost, but that is precisely the purpose of the power to exclude from ‘manufacture, use, and sale’ granted by a patent”). This point is particularly germane to the pricing of pharmaceuticals, as discussed in Comment 3, below.

2. ***Distinguishing Between Anticompetitive and Legitimate Conduct.*** While discerning whether a patent confers market power is obviously important, a finding of market power does not necessarily lead to antitrust liability. The patentee must also engage in anticompetitive conduct, which has been

defined as “conduct that serves no legitimate purpose, or is itself unprofitable, and is undertaken in order to exclude or weaken competitors in anticipation of increased market power and resulting supracompetitive recoupment.” A. Douglas Melamed & Ali M. Stoeppelwerth, *The CSU Case: Facts, Formalism and the Intersection of Antitrust and Intellectual Property Law*, 10 GEO. MASON L. REV. 407, 419 (2002). But market power and supracompetitive profits that result from “a superior product, business acumen, or historic accident” do not violate the antitrust laws.” *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (Department of Justice and Federal Trade Commission 1995). See also *U.S. v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966) (distinguishing between “willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident”); *U.S. v. Aluminum Co. of America*, 148 F.2d 416, 430 (2nd Cir. 1945) (Hand, J.) (stating “[t]he successful competitor, having been urged to compete, must not be turned upon when he wins”).

3. **Pharmaceuticals and Market Power.** To the extent there is an exception to the principle that patents rarely confer market power, it is likely to reside with drugs. See Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L. REV. 1789, 1814 n.94 (2003) (stating “pharmaceutical patents . . . sometimes do confer market power”); Douglas Gary Lichtman, *Pricing Prozac: Why the Government Should Subsidize the Purchase of Patented Pharmaceuticals*, 11 HARV. J.L. & TECH. 123, 123 n.2 (1997) (stating [a]lthough patents always confer some degree of market power, pharmaceutical patents are likely an extreme case. There are, after all, few substitutes for a patented drug like Prozac. Moreover, consumers in the pharmaceutical market (unlike consumers more generally) have no realistic option to defer consumption and thereby hold out for lower prices.” Cf. M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 676 (2003) (“[Antitrust] [p]laintiffs in pharmaceutical cases cannot simply assume the existence of market power from the existence of patents, from pricing above short-run marginal cost, from generic entry at prices below the price of a branded drug, or from reduced output of the branded drug upon generic entry. A plaintiff’s proposed narrow market definition that does not include therapeutic substitutes should be rejected unless the plaintiff presents a ‘formal test’ showing the various drugs’ impact on the price and quantity of sales.”).

The market power of drugs is likely to be stronger when pharmaceutical companies astutely employ—as they often do—patent and trademark protections. The signaling effect of a trademark can have a profound influence on consumers and physicians. See *In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 787 (7th Cir. 1999) (“Brand name prescription drugs ordinarily are patented, and, though the patent may have expired, the physicians who prescribe the drug may continue to prescribe the branded version rather than the generic substitute, whether out of inertia, or because they think the branded version may be produced under better quality control (the rationale for trademarks), or because the patient may feel greater confidence in a familiar brand. The same thing is

true if the original brand, whether or not still protected by a patent, now has a therapeutically close substitute sold under a brand name that is less familiar to physicians or patients than the original brand. It would not be surprising, therefore, if *every* manufacturer of brand name prescription drugs had some market power.”). *See also* Gideon Parchomovsky & Peter Seigleman, *Toward an Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455, 1460-61 (2002) (discussing how “both patents and trademarks allow firms to appropriate the benefits of investment in Research and Development (“R&D”) and product quality”).

2. *Walker Process* and “Sham” Litigation

Antitrust liability may arise if a patentee fraudulently obtains a patent right and employs that right in an anticompetitive manner, namely enforcing or threatening to enforce the patent. This type of antitrust violation is known as a *Walker Process* claim. In addition, an antitrust action can be sustained against a patentee who enforces his patent rights merely to interfere with a competitor’s business relationships; in other words, the patentee enforces his patent even though he knows his patent is either invalid (although not fraudulently obtained) or not infringed. This type of antitrust violation is called a *Handgards* claim. Both *Walker Process* and *Handgards*’ claims are explored in *Nobelpharma*.

NOBELPHARMA AB v. IMPLANT INNOVATIONS, INC.

141 F.3d 1059 (Fed. Cir. 1998)

LOURIE, Circuit Judge.

Nobelpharma AB and Nobelpharma USA, Inc. (collectively, NP) appeal from the judgment of the United States District Court for the Northern District of Illinois holding that . . . (3) NP was not entitled to JMOL or, in the alternative, a new trial following the jury verdict in favor of 3I [Implant Innovations Inc.] on its antitrust counterclaim against NP, Dr. Per-Ingvar Branemark, and the Institute for Applied Biotechnology. We conclude that the district court did not err in . . . denying NP’s motion for JMOL or a new trial on the antitrust counterclaim. Accordingly, the decision of the district court is affirmed.

BACKGROUND

Drs. Branemark and Bo-Thureson of Ekenstam are the named inventors on the ’891 patent, the application for which was filed in 1980 and claimed priority from a Swedish patent application that was filed in 1979. The patent claims “an element intended for implantation into bone tissue.” This “element,” when used as part of a dental implant, is placed directly into the jawbone where it acts as a tooth root substitute. The implants described and claimed in the patent are preferably made of titanium and have a network of particularly-sized and particularly-spaced “micropits.” These micropits, which have diameters in the range of about 10 to 1000 nanometers or, preferably, 10

to 300 nanometers, allow a secure connection to form between the implant and growing bone tissue through a process called “osseointegration.”

Branemark is also one of the authors of a book published in 1977, entitled “Osseointegrated Implants in the Treatment of the Edentulous Jaw Experienced from a 10-Year Period” (hereinafter “the 1977 Book”). As its title suggests, this book describes a decade-long clinical evaluation of patients who had received dental implants. The 1977 Book includes a single page containing four scanning electron micrographs (SEMs) of titanium implants that exhibit micropits. The caption describing these SEMs reads, in part: “Irregularities are produced during manufacturing in order to increase the retention of the implants within the mineralized tissue.” 3I determined, based on measurements and calculations that it presented to the trial court, that the micropits shown in the 1977 Book have diameters within the range claimed in the ’891 patent. However, the 1977 Book does not specifically refer to “micropits.”

In preparing to file the Swedish patent application, af Ekenstam submitted a draft written description of the invention to the inventors’ Swedish patent agent, Mr. Barnieske. This draft referred to the 1977 Book in the following translated passage:

In ten years of material pertaining to titanium jaw implants in man, Branemark et al. [in the 1977 Book] have shown that a very high frequency of healing, as stated above, can be achieved by utilizing a carefully developed surgical technique and adequately produced implants.

However, Barnieske deleted all reference to the 1977 Book from the patent application that was ultimately filed in Sweden. Similarly, the 1977 Book is not mentioned in the U.S. patent application filed by Barnieske on behalf of Branemark and af Ekenstam.

In June 1980, while the U.S. patent application was pending, Branemark entered into an exclusive license agreement with NP covering the claimed technology. Barnieske kept NP informed of the prosecution of the U.S. patent application and received assistance from NP’s U.S. patent agent. The ’891 patent issued in 1982; NP has since asserted it in at least three patent infringement suits.

In July 1991, while Branemark was a member of NP’s Board of Directors, NP brought this suit alleging that certain of 3I’s dental implants infringed the ’891 patent. 3I defended on the grounds of invalidity, unenforceability, and non-infringement. 3I also brought an antitrust counterclaim, based in part on the assertion that NP attempted to enforce a patent that it knew was invalid and unenforceable. Specifically, 3I alleged that when NP brought suit, NP was aware that the inventors’ intentional failure to disclose the 1977 Book to the U.S. Patent and Trademark Office (PTO) would render the ’891 patent unenforceable.

During its case-in-chief, NP introduced portions of a deposition of Branemark that apparently was conducted several years before this trial began in connection with a lawsuit involving neither NP nor 3I. NP also introduced into evidence portions of that deposition that were counter-designated for introduction by 3I. Branemark’s deposition testimony included his admissions that one “could consider” the procedure used to manufacture the micropitted surface a trade secret, and “it might be” that there are details “important to

making” the micropitted surface that are not disclosed in the patent. At the close of NP’s case-in-chief, the district court granted 3I’s motion for JMOL of invalidity and non infringement. The court held that the patent was invalid under § 112, ¶ 1, for failure to disclose the best mode and that NP had failed to prove infringement. The court then denied NP’s motion for JMOL on 3I’s antitrust counterclaim, proceeded to inform the jury that the court had held the patent invalid, and allowed 3I to present the counterclaim to the jury.

After trial limited to the antitrust issue, the jury found in special verdicts, *inter alia*, that 3I had proven that (1) “the inventors or their agents or attorneys obtained the ’891 patent through fraud,” (2) NP “had knowledge that the ’891 patent was obtained by fraud at the time this action was commenced against 3I,” and (3) NP “brought this lawsuit against 3I knowing that the ’891 patent was either invalid or unenforceable and with the intent of interfering directly with 3I’s ability to compete in the relevant market.” The jury awarded 3I approximately \$3.3 million in compensatory damages, an amount the court trebled pursuant to section 4 of the Clayton Act, 15 U.S.C. § 15 (1994). The court declined to rule on whether the patent was unenforceable for inequitable conduct, concluding that its judgment of invalidity rendered the issue of enforceability moot.

NP appealed to this court, challenging the district court’s grant of 3I’s motion for JMOL of invalidity and non-infringement and its denial of the post-verdict motion for JMOL or a new trial.

DISCUSSION

* * *

B. Antitrust Liability

I.

After the jury returned its verdict in favor of 3I on its counterclaim that NP violated the antitrust laws by bringing suit against 3I, the court denied NP’s motion for JMOL or, in the alternative, for a new trial under Fed. R. Civ. P. 50(b). In denying NP’s motion, the district court held that the verdict was supported, *inter alia*, by the jury’s factual findings that the patent was obtained through “NP’s knowing fraud upon, or intentional misrepresentations to, the [PTO]” and that “NP maintained and enforced the patent with knowledge of the patent’s fraudulent derivation” and with the intent of interfering directly with 3I’s ability to compete in the relevant market. The court further held, based on these findings, that the jury need not have considered whether NP’s suit was “objectively baseless.”

In support of its position that the court erred in denying its renewed motion for JMOL, NP argues that there was a lack of substantial evidence to support the jury’s findings that the patent was obtained through “fraud” and that NP was aware of that conduct when it brought suit against 3I. NP also argues that these findings, even if supported by substantial evidence, do not provide a legal basis for the imposition of antitrust liability. Finally, NP argues

that it is entitled to a new trial because the court failed to instruct the jury that bringing a lawsuit cannot be the basis for antitrust liability if that suit is not “objectively baseless.”

3I responds that the jury’s explicit findings that the patent was procured through fraudulent conduct and that NP knew of that conduct when it brought suit were supported by substantial evidence, and that these findings provide a sound basis for imposing antitrust liability on NP. Responding to NP’s arguments for a new trial, 3I argues that an “objectively reasonable” or “objectively baseless” jury instruction was not necessary because the district court required that 3I prove that NP had actual knowledge of the fraud when it brought suit and that even if such an instruction had been necessary, NP waived this argument by failing to propose a jury instruction relating to an “objectively baseless” standard. We agree with 3I that the court did not err in denying NP’s motion for JMOL because substantial evidence supports the jury’s findings that the patent was fraudulently obtained and that NP sought to enforce the patent with knowledge of its fraudulent origin. Similarly, the court did not err in denying NP’s motion for a new trial because NP was not prejudiced by any legally erroneous jury instruction.

II.

* * *

Whether conduct in the prosecution of a patent is sufficient to strip a patentee of its immunity from the antitrust laws is one of those issues that clearly involves our exclusive jurisdiction over patent cases. It follows that whether a patent infringement suit is based on a fraudulently procured patent impacts our exclusive jurisdiction.

Moreover, an antitrust claim premised on stripping a patentee of its immunity from the antitrust laws is typically raised as a counterclaim by a defendant in a patent infringement suit. See *Argus Chem. Corp. v. Fibre Glass-Evercoat Co.*, 812 F.2d 1381, 1383 (Fed. Cir. 1987) (“*Walker Process*, like the present case, was a patent infringement suit in which an accused infringer filed an antitrust counterclaim”). Because most cases involving these issues will therefore be appealed to this court, we conclude that we should decide these issues as a matter of Federal Circuit law, rather than rely on various regional precedents. We arrive at this conclusion because we are in the best position to create a uniform body of federal law on this subject and thereby avoid the “danger of confusion [that] might be enhanced if this court were to embark on an effort to interpret the laws” of the regional circuits. *Forman v. United States*, 767 F.2d 875, 880 n.6 (Fed. Cir. 1985). Accordingly, we hereby change our precedent and hold that whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law. This conclusion applies equally to all antitrust claims premised on the bringing of a patent infringement suit. Therefore, *Cygnus*, 92 F.3d at 1161, *Loctite*, 781 F.2d at 875, and *Atari*, 747 F.2d at 1438-40, are expressly overruled to the extent they hold otherwise.

However, we will continue to apply the law of the appropriate regional circuit to issues involving other elements of antitrust law such as relevant market, market power, damages, etc., as those issues are not unique to patent law, which is subject to our exclusive jurisdiction.

III.

A patentee who brings an infringement suit may be subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves (1) that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965), or (2) that the infringement suit was “a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor,” *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961); *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (holding that *Noerr* “governs the approach of citizens or groups of them . . . to courts, the third branch of Government”). See *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62 n.6 (1993) (PRE) (declining to decide “whether and, if so, to what extent *Noerr* permits the imposition of antitrust liability for a litigant’s fraud or other misrepresentations”).

In *Walker Process*, the Supreme Court held that in order “to strip [a patentee] of its exemption from the antitrust laws” because of its attempting to enforce its patent monopoly, an antitrust plaintiff is first required to prove that the patentee “obtained the patent by knowingly and willfully misrepresenting facts to the [PTO].” 382 U.S. at 177. The plaintiff in the patent infringement suit must also have been aware of the fraud when bringing suit. *Id.* at 177 & n.6. The Court cited prior decisions that involved the knowing and willful misrepresentation of specific facts to the Patent Office: *Precision Instrument Manufacturing v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945) (misrepresenting that the inventor had conceived, disclosed, and reduced to practice the invention on certain dates); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944) (misrepresenting that a widely known expert had authored an article praising the invention); and *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933) (involving an agreement to suppress evidence in the course of litigation). These cases indicate the context in which the Court established the knowing and willful misrepresentation test.

Justice Harlan, in a concurring opinion, emphasized that to “achiev[e] a suitable accommodation in this area between the differing policies of the patent and antitrust laws,” a distinction must be maintained between patents procured by “deliberate fraud” and those rendered invalid or unenforceable for other reasons. *Walker Process*, 382 U.S. at 179-80. He then stated:

[T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be

deemed available to reach [Sherman Act] § 2 monopolies carried on under a nonfraudulently procured patent.

Id. at 180.

Consistent with the Supreme Court's analysis in *Walker Process*, as well as Justice Harlan's concurring opinion, we have distinguished "inequitable conduct" from *Walker Process* fraud, noting that inequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim. Inequitable conduct in fact is a lesser offense than common law fraud, and includes types of conduct less serious than "knowing and willful" fraud.

In *Norton v. Curtiss*, 433 F.2d 779, 792-94 & n.12 (1970), our predecessor court explicitly distinguished inequitable conduct from "fraud," as that term was used by the Supreme Court in *Walker Process*. The court noted that

the concept of "fraud" has most often been used by the courts, in general, to refer to a type of conduct so reprehensible that it could alone form the basis of an actionable wrong (e.g., the common law action for deceit.). . . . Because severe penalties are usually meted out to the party found guilty of such conduct, technical fraud⁵ is generally held not to exist unless the following indispensable elements are found to be present: (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.

Id. at 792-93. The court then contrasted such independently actionable common law fraud with lesser misconduct, including what we now refer to as inequitable conduct, which "fail[s], for one reason or another, to satisfy all the elements of the technical offense." *Norton*, 433 F.2d at 793. Regarding such misconduct, "the courts appear to look at the equities of the particular case and determine whether the conduct before them . . . was still so reprehensible as to justify the court's refusing to enforce the rights of the party guilty of such conduct." *Id.*

Inequitable conduct is thus an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword. Antitrust liability can include treble damages. In contrast, the remedies for inequitable conduct, while serious enough, only include unenforceability of the affected patent or patents and possible attorney fees. *See* 35 U.S.C. §§ 282, 285 (1994). Simply put, *Walker Process* fraud is a more serious offense than inequitable conduct.

In this case, the jury was instructed that a finding of fraud could be premised on "a knowing, willful and intentional act, misrepresentation or omission before the [PTO]." This instruction was not inconsistent with various opinions of the courts stating that omissions, as well as misrepresentations, may in limited circumstances support a finding of *Walker Process* fraud. We

5. We understand from the enumeration of elements that the term "technical fraud" was used by the court to mean common law fraud.

agree that if the evidence shows that the asserted patent was acquired by means of either a fraudulent misrepresentation or a fraudulent omission and that the party asserting the patent was aware of the fraud when bringing suit, such conduct can expose a patentee to liability under the antitrust laws. We arrive at this conclusion because a fraudulent omission can be just as reprehensible as a fraudulent misrepresentation. In addition, of course, in order to find liability, the necessary additional elements of a violation of the antitrust laws must be established. See *Walker Process*, 382 U.S. at 178.

Such a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent. See *id.* at 794 (“[T]he fact misrepresented must be ‘the efficient, inducing, and proximate cause, or the determining ground’ of the action taken in reliance thereon.”) (quoting 37 C.J.S. Fraud § 18 (1943)). In contrast, a conclusion of inequitable conduct may be based on evidence of a lesser misrepresentation or an omission, such as omission of a reference that would merely have been considered important to the patentability of a claim by a reasonable examiner. A finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. Moreover, unlike a finding of inequitable conduct, a finding of *Walker Process* fraud may not be based upon an equitable balancing of lesser degrees of materiality and intent. Rather, it must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission. Therefore, for an omission such as a failure to cite a piece of prior art to support a finding of *Walker Process* fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the PTO will not suffice.

IV.

The district court observed that the Supreme Court, in footnote six of its *PRE* opinion, “left unresolved the issue of how ‘*Noerr* applies to the ex parte application process,’ and in particular, how it applies to the *Walker Process* claim.” 930 F. Supp. at 1253. The court also accurately pointed out that we have twice declined to resolve this issue. Therefore, after reviewing three opinions from the Ninth and District of Columbia Circuit Courts of Appeals, the district court made its own determination that *PRE*’s two-part test for a sham is inapplicable to an antitrust claim based on the assertion of a patent obtained by knowing and willful fraud. We do not agree with that determination. *PRE* and *Walker Process* provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws; both legal theories may be applied to the same conduct. Moreover, we need not find a way to merge these decisions. Each provides its own basis for depriving a patent owner of immunity from the antitrust laws; either or both may be applicable to a particular party’s conduct in obtaining and enforcing a patent. The Supreme Court saw no need to merge these separate lines of cases and neither do we.

Consequently, if the above-described elements of *Walker Process* fraud, as well as the other criteria for antitrust liability, are met, such liability can be imposed without the additional sham inquiry required under *PRE*. That is

because *Walker Process* antitrust liability is based on the knowing assertion of a patent procured by fraud on the PTO, very specific conduct that is clearly reprehensible. On the other hand, irrespective of the patent applicant's conduct before the PTO, an antitrust claim can also be based on a *PRE* allegation that a suit is baseless; in order to prove that a suit was within *Noerr*'s "sham" exception to immunity, an antitrust plaintiff must prove that the suit was both *objectively* baseless and *subjectively* motivated by a desire to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy. *PRE*, 508 U.S. at 60-61. As the Supreme Court stated:

First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals "an attempt to interfere *directly* with the business relationships of a competitor," through the "use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." . . . Of course, even a plaintiff who defeats the defendant's claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham must still prove a substantive antitrust violation. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.

Id. Thus, under *PRE*, a sham suit must be both subjectively brought in bad faith and based on a theory of either infringement or validity that is objectively baseless. Accordingly, if a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial. *Id.* In contrast with a *Walker Process* claim, a patentee's activities in procuring the patent are not necessarily at issue. It is the bringing of the lawsuit that is subjectively and objectively baseless that must be proved.

V.

As for the present case, we conclude that there exists substantial evidence upon which a reasonable fact finder could strip NP of its immunity from antitrust liability. In particular, there exists substantial evidence that the 1977 Book was fraudulently kept from the PTO during patent prosecution. The jury could reasonably have found that the 1977 Book was fraudulently withheld and that it disclosed the claimed invention. First, the jury could reasonably have concluded that Branemark, through his Swedish patent agent, Barnieske, withheld the 1977 Book with the requisite intent to defraud the PTO. The initial disclosure to Barnieske, provided by Branemark's co-inventor, af Ekenstam, indicated that the studies described in the 1977 Book verified the utility of the claimed invention. While Barnieske did testify that he did not recall his thoughts during the prosecution of the patent and that he would have submitted the 1977 Book to the PTO if he had considered it relevant, the jury was free to disbelieve him. Barnieske could not explain, even in retrospect, why he deleted all reference to the 1977 Book. Importantly, the 1977 Book was thought by at least one inventor to be relevant, as evidenced by the

initial disclosure to the patent agent, but it was inexplicably not later disclosed to the PTO. Also, as the author of the 1977 Book and an inventor, Branemark presumably knew of the book's relevance to the invention and could have directed Barnieske not to disclose the book to the PTO. Thus, the jury could properly have inferred that Branemark had the requisite intent to defraud the PTO based on his failure to disclose the reference to the PTO. Such a scheme to defraud is the type of conduct contemplated by *Walker Process*.

Second, substantial evidence upon which a reasonable jury could have relied also indicates that the 1977 Book was sufficiently material to justify a finding of fraud. 3I's expert witness, Dr. Donald Brunette, testified that the SEMs of the 1977 Book depict dental implants having all the elements of the claims asserted by NP. Specifically, he explained how he had determined that the SEMs depict a "biologically flawless material" suitable for use as a dental implant. He also explained how he determined that the depicted micropits have diameters within the claimed range of approximately 10 to 1000 nanometers. Even Branemark, in this deposition testimony, conceded that it would not have been difficult to calculate the size of the micropits depicted in the 1977 Book, given the magnification factors provided in the captions to the SEMs. Accordingly, a reasonable jury could have found, based on the unambiguous claim language, that the 1977 Book anticipated the patent and that the examiner would not have granted the patent if he had been aware of the 1977 Book.

Third, the record indicates that a reasonable jury could have found that NP brought suit against 3I with knowledge of the applicants' fraud. A reasonable jury could have found that two of NP's then-officers, Dr. Ralph Green, Jr. and Mr. Mats Nilsson, were aware of the fraud based on Green's testimony that Nilsson told him: "[I]f the Patent Office did not receive a copy of [the 1977 Book], and if that were true, then we would have a larger problem and that was fraud." Green's testimony also indicates that NP was aware that the 1977 Book was highly material and, in fact, likely rendered the patent invalid. Green testified that he, Nilsson, and Mr. George Vande Sande obtained a legal opinion from NP's attorney, Mr. David Lindley, who indicated that if "we were to sue anyone on the patent we would lose in the first round. . . . [T]here was prior art, not the least of which was this textbook [the 1977 Book] that would invalidate the patent."

Regarding NP's motion for a new trial, we have concluded that the court's instructions to the jury regarding fraud, to which NP did not object, substantially comport with the law. Specifically, the court emphasized to the jury that to strip NP of its immunity from the antitrust laws, 3I "must prove that the '891 patent was fraudulently . . . obtained by clear and convincing 'evidence.'" The court also pointed out that only "knowing, willful and intentional acts, misrepresentations or omission" may support a finding of fraud and that the jury should approach such a finding with "great care." As to reliance, the court instructed the jury that "[m]ateriality is shown if but for the misrepresentation or omission the '891 patent would not have been issued." These instructions were not legally erroneous.

Because we conclude that the finding of *Walker Process* fraud was supported by substantial evidence and was based upon a jury instruction that was not legally erroneous or prejudicial, we affirm the denial of NP's motion for JMOL. NP was properly deprived of its immunity from the antitrust laws

under *Walker Process*, and it could not have benefited from additional jury instructions regarding *PRE* or *Noerr*. The court's refusal to so instruct the jury therefore does not require a new trial.

We have also considered NP's alternative arguments in support of its motion for a new trial, including its assertions that the district court erred in permitting Green to testify, in prohibiting Dr. Hodosh and Messrs. Vande Sande and Martens from testifying, in allowing 3I to present a theory of joint venture liability to the jury, and in impugning the credibility of NP's arguments before the jury. We do not find these arguments persuasive. The district court did not abuse its discretion or misapply the law of attorney-client privilege in making its evidentiary rulings, nor did it prejudice NP's substantive rights by allowing the jury to consider a joint venture theory of liability or by commenting on NP's arguments during the trial. Accordingly, the court did not abuse its discretion in denying NP's motion for a new trial.

CONCLUSION

The district court did not err . . . in denying NP's motion for JMOL or a new trial on 3I's antitrust counterclaim. A reasonable jury, applying the correct law, could have found that the facts of this case were sufficient to constitute fraud within the meaning of *Walker Process*.

Comments

1. **Noerr-Pennington Immunity.** A basic principle of antitrust law is that the act of invoking the machinery of government (*e.g.*, executive agencies or courts) is, by itself, not a violation of the antitrust laws. This immunity is referred to as the *Noerr-Pennington* doctrine. *See Eastern R.R. President's Conf. v. Noerr Motor Freight*, 365 U.S. 127, 135 (1961) ("We accept the same basic construction of the Sherman Act adopted by the courts below that no violation of the Act can be predicated upon mere attempts to influence the passage or enforcement of laws"), and *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965) ("*Noerr* shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose."). The doctrine is ground in First Amendment principles under the assumption that petitioning the government should not give rise to liability. *See Noerr*, 365 U.S. at 137 ("In a representative democracy . . . the whole concept of representation depends upon the ability of the people to make their wishes known to their representatives. To hold that the government retains the power to act in this representative capacity and yet hold, at the same time, that the people cannot freely inform the government of their wishes would impute to the Sherman Act a purpose to regulate, not business activity, but political activity, a purpose which would have no basis whatever in the legislative history of that Act"); Herbert Hovenkamp, *Standards Ownership and Competition Policy*, 48 B.C. L. REV. 87, 107 (2007) ("The Supreme Court applied the historical *Noerr* rule that private parties have a right, essentially protected by the First Amendment of the U.S. Constitution, to petition the government for even anticompetitive actions.").

Immunity extends to the petitioning of all branches of government, including the courts. *See California Motor Transport Co. v. Trucking Unlimited*,

404 U.S. 508, 612 (1972) (“Certainly the right to petition extends to all departments of the Government. The right of access to the courts is indeed but one aspect of the right of petition.”). Thus, a patentee’s filing an infringement action in federal district court is — by itself — not a violation of antitrust law. An exception to *Noerr-Pennington* immunity is the so-called “sham” petition; that is, invoking the judiciary, not to legitimately influence a court, but to interfere with the business relationships of a competitor. See Comment 3 and the discussion of *Handgards* claims. Importantly, absence of immunity does not necessarily lead to an antitrust violation; the antitrust plaintiff must still meet his burden of proof, showing the existence of the requisite elements of an antitrust cause of action.

2. **Walker Process Claim.** A *Walker Process* antitrust claim can be traced to *Walker Process Equipment v. Food Machinery & Chemical*, 382 U.S. 172 (1965). In *Walker Process*, the Court “concluded that the enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present.” *Id.* at 174. The underlying contention of a *Walker Process* claim is that a patentee who engaged in fraud to obtain a patent and thereafter enforced it should not be able to seek refuge in *Noerr-Pennington* immunity. See *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007) (stating “[p]roof that a patentee has ‘obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office . . . [is] sufficient to strip [the patentee] of its exemption from the antitrust laws.’” (quoting *Walker Process*)).

Nobelpharma applied principles of common law fraud, which is narrower and more serious than what is required for inequitable conduct. (Inequitable conduct is discussed in the *Agfa* case in the next section.) The fraud for *Walker Process* “must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant the patent.” Common law fraud consists of:

- (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.

In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 807 (Fed. Cir. 2000). Thus, mere omission of a prior art reference is not enough to constitute *Walker Process* fraud. See *Dippin’ Dots*, 476 F.3d at 1347 (stating “to find a prosecution omission fraudulent there must be evidence of intent separable from the simple fact of the omission. A false or clearly misleading prosecution statement may permit an inference that the statement was made with deceptive intent. For instance, evidence may establish that a patent applicant knew one fact and presented another, thus allowing the factfinder to conclude that the applicant intended by the misrepresentation to deceive the examiner. That is not the case with an omission, which could happen for any number of nonfraudulent reasons—the applicant could have had a good-faith belief that disclosure was not necessary, or simply have forgotten to make the required disclosure”).

Once immunity is stripped, a *Walker Process* claimant must then prove “the other elements necessary to a § 2 [Sherman Act] case.” In *Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1355 (Fed. Cir. 2004), the Federal Circuit stated:

The elimination of [the patentee’s] antitrust immunity would mark only the beginning of the antitrust inquiry, not its endpoint. To establish monopolization or attempt to monopolize a part of trade or commerce under § 2 of the Sherman Act, it would then be necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved. Without a definition of that market there is no way to measure [the patentee’s] ability to lessen or destroy competition. It may be that the patented process “does not comprise a relevant market. There may be effective substitutes . . . which do not infringe the patent.”

In order to prevail on its *Walker Process* claim, [the plaintiff] must therefore establish: that [the patentee] attempted to enforce the patent; that the patent issued because [the patentee] defrauded the PTO; that ConAgra’s attempted enforcement threatened to lessen competition in a relevant antitrust market; that [the plaintiff] suffered antitrust damages; and that all other elements of attempted monopolization are met. These requirements frame our antitrust inquiry.

3. **Handgards Claim.** *Walker Process* dealt with the enforcement of a fraudulently obtained patent. A *Handgards* claim differs from *Walker Process* in that the former relates to the enforcement of a patent that was not obtained by fraud, but was asserted with knowledge that it was either invalid or not infringed. In other words, the focus is on the patentee’s bad-faith enforcement or sham litigation, irrespective of his conduct before the PTO. See *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979).

A patentee who engages in sham litigation does not enjoy *Noerr-Pennington* immunity. See *Noerr*, 365 U.S. at 144 (concluding that “application of the Sherman Act would be justified” where petitioning the government, “ostensibly directed toward influencing governmental action, is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor. . . .”); *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991) (“The ‘sham’ exception to *Noerr* encompasses situations in which persons use the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon. A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay.”); *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 515 (1972) (“First Amendment rights may not be used as the means or the pretext for achieving ‘substantive evils’ . . . which the legislature has the power to control.”).

In *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (*PRE*), the Supreme Court provided a framework to prove a *Handgards* claim. The *PRE* Court set forth a two-part test, comprising an objective and subjective component. According to the Court, “the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” If an antitrust plaintiff is able to prove that the lawsuit was objectively meritless, “may a court examine the litigant’s subjective motivation. Under this second part of our definition of

sham, the court should focus on whether the baseless lawsuit conceals ‘an attempt to interfere *directly* with the business relationships of a competitor, through the use [of] the governmental *process* — as opposed to the *outcome* of that process — as an anticompetitive weapon.’” 508 U.S. at 60-61.

3. Settlements

As a general policy, settlement is encouraged as an efficient alternative to litigation. Patent litigation is very expensive, and judicial resources are increasingly strained. Moreover, a consensual settlement between private parties is likely to accurately reflect the preferences of the parties, add prospective certainty to business dealings, and enhance social welfare. But patent settlements — which are usually horizontal (*i.e.*, between competitors) — can also be anticompetitive. One particular form of settlement that has come under heavy antitrust scrutiny in the pharmaceutical industry involves so-called “exclusion payments” — payments made by the patentee to the alleged infringer to abandon the market. This type of settlement was at issue in *In re Tamoxifen*.

IN RE TAMOXIFEN CITRATE ANTITRUST LITIGATION

466 F.3d 187 (2d Cir. 2006)

SACK, Circuit Judge.

This appeal, arising out of circumstances surrounding a lawsuit in which a drug manufacturer alleged that its patent for the drug tamoxifen citrate (“tamoxifen”) was about to be infringed, and the suit’s subsequent settlement, requires us to address issues at the intersection of intellectual property law and antitrust law. Although the particular factual circumstances of this case are unlikely to recur, the issues presented have been much litigated and appear to retain their vitality.

The plaintiffs claim that the defendants conspired, under an agreement settling a patent infringement lawsuit among the defendants in 1993 while an appeal in that lawsuit was pending, to monopolize the market for tamoxifen — the most widely prescribed drug for the treatment of breast cancer — by suppressing competition from generic versions of the drug. The settlement agreement included, among other things, a so-called “reverse payment” of \$21 million from the defendant patent-holders Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC (collectively “Zeneca”) to the defendant generic manufacturer Barr Laboratories, Inc. (“Barr”), and a license from Zeneca to Barr allowing Barr to sell an unbranded version of Zeneca-manufactured tamoxifen. The settlement agreement was contingent on obtaining a *vacatur* of the judgment of the district court that had heard the infringement action holding the patent to be invalid.

The district court in the instant case concluded that the settlement did not restrain trade in violation of the antitrust laws, and that the plaintiffs suffered no antitrust injury from that settlement. Because we conclude that we have jurisdiction to hear the appeal and that the behavior of the defendants alleged in the complaint would not violate antitrust law, we affirm the judgment of the district court.

REGULATORY BACKGROUND

Before setting forth the salient facts of this case and addressing the merits of the plaintiffs' appeal, it may be helpful to outline the relevant regulatory background.

The Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified at scattered sections of title 21 of the United States Code), prohibits the introduction or delivery for introduction into interstate commerce of "any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of [21 U.S.C. § 355] is effective with respect to such drug." 21 U.S.C. § 355(a). Subsection (b) describes the process of filing a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA"), which is typically a costly and time-consuming procedure in which the applicant attempts to establish the safety and effectiveness of the drug. *Id.* § 355(b). In 1984, in order to accelerate the approval process for low-cost generic versions of established drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). Among other things, the Act added subsection (j) to section 355. Hatch-Waxman Act § 101. Subsection (j) provides for an Abbreviated New Drug Application ("ANDA") to the FDA for the bioequivalent form of a drug already approved for safety and effectiveness. 21 U.S.C. § 355(j)(1), (j)(2)(A), (j)(7)(A). Subsection (j)(7)(A) further provides that the Secretary of the FDA will create and maintain a list of such approved drugs. *Id.* § 355(j)(7)(A). This list, *Approved Drug Products with Therapeutic Equivalence Evaluations*, is commonly known as the "Orange Book"²; <http://www.fda.gov/cder/orange/default.htm>.

An ANDA filer must certify, with respect to each patent that claims the listed drug for the bioequivalent of which the ANDA filer is seeking approval, either that no patent was filed for the listed drug (a "paragraph I" certification), that the patent has expired (a "paragraph II" certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a "paragraph III" certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a "paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii).

An ANDA filer that elects a paragraph IV certification must notify each affected patent owner of the certification. *Id.* § 355(j)(2)(B)(i). The patent owner then has forty-five days after the date it receives such notice to bring suit against the ANDA filer for patent infringement. *Id.* § 355(j)(5)(B)(iii). If no patent owner brings such a lawsuit during this period, the FDA may immediately approve the ANDA. *Id.* If, however, the patent owner brings suit during this period, the FDA's final approval of the ANDA is stayed for thirty months after the date the patent owner received the requisite notice or until a district court returns a decision as to the validity of the patent or its infringement if it does so before the thirty-month period expires. *Id.*

2. The ANDA process was intended to be available to manufacturers of generic versions of approved drugs. "A generic version . . . contains the same active ingredients, but not necessarily the same inactive ingredients, as the pioneer drug. A generic drug, as the name implies, is ordinarily sold without a brand name and at a lower price." *Andrx Pharms.*, 256 F.3d at 801 n.1. Filing an ANDA allows a generic drug manufacturer to avoid the costly and time-consuming process of demonstrating safety and efficacy, allowing the manufacturer to rely on the FDA's earlier findings concerning the brand-name drug's NDA, and thereby facilitates quicker market entry by generic manufacturers. *See id.* at 801.

Any approval letter sent by the FDA before the expiration of the prescribed stay and before a court ruling of patent invalidity or non-infringement is tentative. *See* 21 C.F.R. § 314.105(d). If before the thirty months expire a court rules that the patent is either invalid or not infringed, the tentative approval of the ANDA is made effective as of the date of judgment. 21 U.S.C. § 355(j)(5)(B)(iii)(I). If after thirty months there has been no ruling on patent validity or infringement and the stay expires, the ANDA filer can distribute and market the drug but, depending on the court's later patent ruling, an ANDA filer that chooses to follow this course may thereafter become liable for infringement damages if infringement is found.

As an incentive for generic manufacturers to choose the paragraph IV certification route and, in the course of pursuing such applications, to challenge weak patents, the Hatch-Waxman Act offers the first ANDA filer with a paragraph IV certification, under certain conditions, the opportunity to market its generic drug exclusively for 180 days. To this end, the FDA may not approve the ANDA of a subsequent filer until 180 days after the earlier of the date (1) the first ANDA filer commercially markets the generic drug or (2) a court of competent jurisdiction concludes that the patent in question is invalid or not infringed.⁵ 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II).

Until 1998 (and, therefore, at the time of the settlement that is the subject of this appeal), the 180-day exclusivity period was available to the first ANDA filer to elect a paragraph IV certification, but only if the ANDA filer successfully defended against a lawsuit for infringement of the relevant patent. *See* 21 C.F.R. § 314.107(c)(1) (1995). This so-called "successful defense" requirement was challenged in 1997 in two separate lawsuits. In each, the circuit court rejected the requirement as inconsistent with the Hatch-Waxman Act.

In June 1998, in response to these decisions, the FDA published a "Guidance for Industry." In the "Guidance," the FDA expressed its intention to remove the "successful defense" requirement formally through rulemaking and made clear that thereafter even ANDA paragraph IV filers that are not the subject of lawsuits will be eligible for the 180-day exclusivity period. "Until such time as the rulemaking process [was] complete, FDA . . . regulate[d] directly from the statute, and . . . ma[de] decisions on 180-day generic drug exclusivity on a case-by-case basis." *Id.* at 4. Later that year, the FDA formally revoked the "successful defense" requirement.

FACTUAL AND PROCEDURAL BACKGROUND

Tamoxifen, the patent for which was obtained by Imperial Chemical Industries, PLC ("ICI") on August 20, 1985, is sold by Zeneca (a former subsidiary of ICI which succeeded to the ownership rights of the tamoxifen patent) under the trade name Nolvadex®. Tamoxifen is the most widely prescribed drug for the treatment of breast cancer. Indeed, it is the most prescribed cancer drug in the world. In December 1985, four months after ICI

5. Like its interpretation of the type of court decision sufficient to end the 30-month stay of final FDA approval described above, at the time of the settlement in this case and until 2000, the FDA interpreted a court decision required to trigger the 180-day period to mean only a court decision "from which no appeal can be or has been taken." *See* CDER, *Court Decisions*, *supra*, at 2 (quoting 21 C.F.R. § 314.107(e)(1) (1999)). That interpretation was subsequently changed in 2000, when the FDA concluded that a patent invalidity decision by a district court would be sufficient to trigger the commencement of the 180-day period. *See id.* at 3-5.

was awarded the patent, Barr filed an ANDA with the FDA requesting the agency's approval for Barr to market a generic version of tamoxifen that it had developed. Barr amended its ANDA in September 1987 to include a paragraph IV certification.

In response, on November 2, 1987—within the required forty-five days of Barr's amendment of its ANDA to include a paragraph IV certification—ICI filed a patent infringement lawsuit against Barr and Barr's raw material supplier, Heumann Pharma GmbH & Co. ("Heumann"), in the United States District Court for the Southern District of New York. On April 20, 1992, the district court (Vincent L. Broderick, *Judge*) declared ICI's tamoxifen patent invalid based on the court's conclusion that ICI had deliberately withheld "crucial information" from the Patent and Trademark Office regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug. *See Imperial Chem. Indus., PLC v. Barr Labs., Inc.*, 795 F.Supp. 619, 626-27 (S.D.N.Y. 1992) ("*Tamoxifen I*"). Those tests had revealed hormonal effects "opposite to those sought in humans," which, the court found, could have "unpredictable and at times disastrous consequences." *Id.* at 622.

ICI appealed the district court's judgment to the United States Court of Appeals for the Federal Circuit. In 1993, while the appeal was pending, the parties entered into a confidential settlement agreement (the "Settlement Agreement") which is the principal subject of this appeal. In the Settlement Agreement, Zeneca (which had succeeded to the ownership rights of the patent) and Barr agreed that in return for \$21 million and a non-exclusive license to sell Zeneca-manufactured tamoxifen in the United States under Barr's label, rather than Zeneca's trademark Nolvadex[®], Barr would change its ANDA paragraph IV certification to a paragraph III certification, thereby agreeing that it would not market its own generic version of tamoxifen until Zeneca's patent expired in 2002. *See In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 125-26 (E.D.N.Y. 2003) ("*Tamoxifen II*"). Zeneca also agreed to pay Heumann \$9.5 million immediately, and an additional \$35.9 million over the following ten years. The parties further agreed that if the tamoxifen patent were to be subsequently declared invalid or unenforceable in a final and (in contrast to the district court judgment in *Tamoxifen I*) unappealable judgment by a court of competent jurisdiction, Barr would be allowed to revert to a paragraph IV ANDA certification. Thus if, in another lawsuit, a generic marketer prevailed as Barr had prevailed in *Tamoxifen I*, and that judgment was either not appealed or was affirmed on appeal, Barr would have been allowed to place itself in the same position (but for the 180-day head start, if it was available) that it would have been in had it prevailed on appeal in *Tamoxifen I*, rather than settling while its appeal was pending in the Federal Circuit.

The plaintiffs allege that as a part of the Settlement Agreement, Barr "understood" that if another generic manufacturer attempted to market a version of tamoxifen, Barr would seek to prevent the manufacturer from doing so by attempting to invoke the 180-day exclusivity right possessed by the first "paragraph IV" filer. Compl. ¶ 58. According to the plaintiffs, this understanding among the defendants effectively forestalled the introduction of any generic version of tamoxifen, because, five years later—only a few

weeks before other generic manufacturers were to be able to begin marketing their own versions of tamoxifen — Barr did in fact successfully claim entitlement to the exclusivity period. It thereby prevented those manufacturers from entering the tamoxifen market until 180 days after Barr triggered the period by commercially marketing its own generic version of the drug. In fact, Barr had not yet begun marketing its own generic version and had little incentive to do so because, pursuant to the Settlement Agreement, it was already able to market Zeneca's version of tamoxifen.

Meanwhile, pursuant to the Settlement Agreement which was contingent on the *vacatur* of the district court judgment in *Tamoxifen I*, Barr and Zeneca filed a “Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below.” The Federal Circuit granted the motion, thereby vacating the district court's judgment that the patent was invalid. Such a *vacatur*, while generally considered valid as a matter of appellate procedure by courts at the time of the Settlement Agreement, was shortly thereafter held to be invalid in nearly all circumstances by the Supreme Court, see *U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 27-29 (1994).

In the years after the parties entered into the Settlement Agreement and the Federal Circuit vacated the district court's judgment,⁹ three other generic manufacturers filed ANDAs with paragraph IV certifications to secure approval of their respective generic versions of tamoxifen: Novopharm Ltd., in June 1994, Mylan Pharmaceuticals, Inc., in January 1996, and Pharmachemie, B.V., in February 1996. Zeneca responded to each of these certifications in the same manner that it had responded to Barr's: by filing a patent infringement lawsuit within the forty-five day time limit provided by 21 U.S.C. § 355(j)(5)(B)(iii). In each case, the court rejected the generic manufacturer's attempt to rely on the vacated *Tamoxifen I* decision, and — contrary to the *Tamoxifen I* judgment — upheld the validity of Zeneca's tamoxifen patent.

While Mylan and Pharmachemie's lawsuits were pending in district court, the FDA's “successful defense” rule, requiring that a generic manufacturer seeking to market an allegedly patented drug “successfully defend” its patent infringement lawsuit in order to receive the 180-day exclusivity period — which at the time the Settlement Agreement was entered into would have excluded Barr from benefitting from the exclusivity period — was, as noted, held invalid. In June 1998, at the time the FDA removed the requirement, Barr — armed with the new rule rendering the first ANDA paragraph IV filer eligible for the 180-day exclusivity period even if it had not successfully defended a patent infringement suit — attempted to block final FDA approval of other generic versions of tamoxifen by claiming entitlement to the 180-day exclusivity period.

At the time, Pharmachemie had received tentative approval from the FDA to distribute its version of the drug, Mylan was awaiting approval to do the same, and both Pharmachemie and Mylan's thirty-month stays under section 355(j)(5)(B)(iii), triggered by Zeneca's infringement lawsuits, were soon to

9. After the Settlement Agreement was entered into and the *vacatur* ordered, Barr began to market its licensed version of Zeneca's tamoxifen, selling its product to distributors and wholesalers at a 15 percent discount to the brand-name price, which translated into a price to consumers about five percent below Zeneca's otherwise identical Nolvadex[®] brand-name version. Barr soon captured about 80 percent of the tamoxifen market.

expire. *See* Compl. ¶¶ 61-63 (stating that the 30-month stay for Mylan was scheduled to expire on July 10, 1998, and for Pharmachemie in August 1998). Because of the rule change, however, the FDA was able to, and on March 2, 1999, did, grant Barr's petition to confirm its entitlement to the exclusivity period despite the fact that it had settled, rather than "successfully defended" against, Zeneca's lawsuit. The FDA's action effectively delayed the marketing of other generic versions of tamoxifen unless and until Barr triggered and exhausted its 180-day exclusivity period by selling its own generic form of the drug, rather than the version manufactured by Zeneca. As noted, Barr had little incentive to do so because it was already distributing Zeneca's version of tamoxifen.

Pharmachemie and Mylan challenged the FDA's decision. On March 31, 2000, in *Mylan Pharmaceuticals*, the United States District Court for the District of Columbia ruled in Pharmachemie's and Mylan's favor. 94 F. Supp. 2d at 54. It concluded that, although Judge Broderick's ruling of invalidity in *Tamoxifen I* had been vacated by the Settlement Agreement, that ruling was still a court decision sufficient to trigger Barr's 180-day exclusivity period, which therefore had already expired. *See Mylan Pharms.*, 94 F. Supp. 2d at 54. As a result, on June 26, 2000, the FDA revoked Barr's claim to the 180-day exclusivity period.

On appeal, however, the District of Columbia Circuit vacated the district court's decision as moot. The court noted that subsequent to the FDA's decision to approve Barr's application, the district court had ruled against Pharmachemie in Zeneca's patent infringement lawsuit against it. Thus, even if, as the district court held in *Mylan*, Barr's 180-day exclusivity period had run, Pharmachemie and Mylan were prohibited by the judgments against them in the patent litigation from marketing their generic versions of tamoxifen until Zeneca's patent expired. Zeneca's patent on tamoxifen expired on August 20, 2002, and generic manufacturers began marketing their own versions of tamoxifen soon thereafter.

* * *

The district court dismissed the plaintiffs' Sherman Act claims.

DISCUSSION

* * *

III. The Plaintiffs' Antitrust Claims

A. The Tension between Antitrust Law and Patent Law

With the ultimate goal of stimulating competition and innovation, the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States,"¹³ 15 U.S.C. § 1, and "monopoliz[ation], or attempt[s] to monopolize,

13. "Although the Sherman Act, by its terms, prohibits every agreement 'in restraint of trade,' th[e] Supreme] Court has long recognized that Congress intended to outlaw only unreasonable restraints." *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S. Ct. 275, 139 L. Ed. 2d 199 (1997). Conduct may be deemed an unreasonable restraint of trade in two ways. Conduct may be considered *per se* unreasonable because it has "such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." *Id.*

or combin[ations] or conspir[acies] . . . to monopolize any part of the trade or commerce among the several States,” *id.* § 2.¹⁴ By contrast, also with the ultimate goal of stimulating competition and innovation, patent law grants an innovator “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited term of years. 35 U.S.C. § 154(a)(1)-(2); *see also Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (“[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.”). It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal. *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) (“[T]he possession of a valid patent . . . does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.”) *cf. Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 802 (D.C. Cir. 2001) (“Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants.”); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1067 (11th Cir. 2005) (“Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes.”).

B. The Plaintiffs’ Allegations

1. *Settlement of a Patent Validity Lawsuit.* The plaintiffs contend that several factors—including that *Tamoxifen I* was settled after the tamoxifen patent had been held invalid by the district court, making the patent unenforceable at the time of settlement—indicate that if their allegations are proved, the defendants violated the antitrust laws. They argue that the district court in the case before us erred by treating the tamoxifen patent as valid and enforceable. Instead, they say, in accordance with the never-reviewed judgment in *Tamoxifen I*, the district court in this case should have treated the patent as presumptively invalid for purposes of assaying the sufficiency of the plaintiffs’ complaint.

In most cases, however, conduct will be evaluated under a “rule of reason” analysis, “according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.” *Id.* (citation omitted).

The rule-of-reason analysis has been divided into three steps. First, a plaintiff must demonstrate “that the challenged action has had an *actual* adverse effect on competition as a whole in the relevant market.” *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 543 (2d Cir.) (emphasis in original), *cert. denied*, 510 U.S. 947 (1993). If the plaintiff succeeds in doing so, “the burden shifts to the defendant to establish the ‘pro-competitive “redeeming virtues”’ of the action.” *K.M.B. Warehouse Distributions, Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 127 (2d Cir. 1995) (quoting *Capital Imaging Assocs.*, 996 F.2d at 543). If the defendant succeeds in meeting its burden, the plaintiff then has the burden of “show[ing] that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.” *Id.*

14. “The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

We begin our analysis against the backdrop of our longstanding adherence to the principle that “courts are bound to encourage” the settlement of litigation. “Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement. The trial court must protect the public interest, as well as the interests of the parties, by encouraging the most fair and efficient resolution.” *United States v. Glens Falls Newspapers, Inc.*, 160 F.3d 853, 856-57 (2d Cir.1998). As the Eleventh Circuit recently noted in drug patent litigation similar to the one before us, “There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.” *Schering-Plough*, 402 F.3d at 1075.

It is well settled that “[w]here there are legitimately conflicting [patent] claims . . . , a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act,” although such a settlement may ultimately have an adverse effect on competition. *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931); cf. *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) (“[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of litigation is more strongly favored by the law.”).

Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation. Although forcing patent litigation to continue might benefit consumers in some instances, “patent settlements can . . . promote efficiencies, resolving disputes that might otherwise block or delay the market entry of valuable inventions.”¹⁵ As the Fourth Circuit has observed, “It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations may occur.” *Duplan Corp.*, 540 F.2d at 1220.

We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca’s success had it not settled but rather pursued its appeal. As the Supreme Court noted in another context, “[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.” *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990). . . . The fact that the settlement here occurred after the district court ruled against Zeneca seems to us to be of little moment. There is a risk of loss in all appeals that may give rise to a desire on the part of both the appellant and the appellee to settle before the appeal is decided. Settlements of legiti-

15. It is true that had the defendants not settled the underlying patent litigation and had the district court’s judgment been affirmed on appeal, Zeneca would have been estopped from asserting the validity of its patent against others seeking to enter the market. See *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971). However, it is clearly a permissible byproduct of settlement that future hypothetical plaintiffs might be forced to relitigate the same issues involved in the settled case. Furthermore, before 1994, when district court judgments were vacated as a matter of course upon settlement, see *U.S. Bancorp*, 513 U.S. at 29 (virtually ending this practice), there was similarly and permissibly no collateral estoppel effect accorded these judgments for the benefit of future hypothetical plaintiffs. See *Nestle*, 756 F.2d at 284 (“Drum-beating about the need to protect other unknown users of the trademark [in question] will ring hollow indeed in the ears of the present defendants if the peril of a reversal is realized. . . . We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation.”).

mate disputes, even antitrust and patent disputes of which an appeal is pending, in order to eliminate that risk, are not prohibited. That Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first should hardly weigh against it.

We conclude, then, that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court that would tend to establish that the Settlement Agreement was unlawful, the assertion that there was a bar — antitrust or otherwise — to the defendants' settling the litigation at the time that they did is unpersuasive.

2. *Reverse Payments.* Payments pursuant to the settlement of a patent suit such as those required under the Settlement Agreement are referred to as "reverse" payments because, by contrast, "[t]ypically, in patent infringement cases the payment flows from the alleged infringer to the patent holder." Here, the patent holder, which, if its patent is valid, has the right to prevent the alleged infringer from making commercial use of it, nonetheless pays that party not to do so. Seeking to supply the "something more" than the fact of settlement that would render the Settlement Agreement unlawful, the plaintiffs allege that the value of the reverse payments from Zeneca to Barr thereunder "greatly exceeded the value of Barr's 'best case scenario' in winning the appeal . . . and entering the market with its own generic product." Appellants' Br. at 27.

It is the size, not the mere existence, of Zeneca's reverse payment that the plaintiffs point to in asserting that they have successfully pleaded a Sherman Act cause of action. In explaining our analysis, though, it is worth exploring the notion advanced by others that the very existence of reverse payments establishes unlawfulness. See Herbert Hovenkamp *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1751 (2003) ("[T]he problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent.").

Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are *per se* violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation. See *Valley Drug*, 344 F.3d at 1309 (concluding that the presence of a reverse payment, by itself, does not transform an otherwise lawful settlement into an unlawful one); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1807 (2003) (noting that "the plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial," which "suggests that reverse payments should not be *per se* illegal, since they are just as consistent with a high probability of validity and infringement as they are with a low probability. It also suggests that reverse payments should not be *per se* legal for the same reason."). But see *Cardizem*, 332 F.3d at 911 (calling a forty-million-dollar reverse payment to a generic manufacturer "a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers").

As other courts have noted, moreover, reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them. In the typical patent infringement case, the alleged infringer enters the market with its drug after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like. The patent holder then brings suit against the alleged infringer seeking damages for, *inter alia*, its lost profits. If the patent holder wins, it receives protection for the patent and money damages for the infringement. And in that event, the infringer loses not only the opportunity to continue in the business of making and selling the infringing product, but also the investment it made to enter the market for that product in the first place. And it must pay damages to boot. It makes sense in such a circumstance for the alleged infringer to enter into a settlement in which it pays a significant amount to the patent holder to rid itself of the risk of losing the litigation.

By contrast, under the Hatch-Waxman Act, the patent holder ordinarily brings suit shortly after the paragraph IV ANDA has been filed—*before* the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug. Conversely, there are no infringement damages for the patent holder to recover, and there is therefore little reason for it to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place.

Accordingly, a generic marketer has few disincentives to file an ANDA with a paragraph IV certification. The incentive, by contrast, may be immense: the profits it will likely garner in competing with the patent holder without having invested substantially in the development of the drug, and, in addition, possible entitlement to a 180-day period (to be triggered at its inclination) during which it would be the exclusive seller of the generic drug in the market.¹⁹

The patent holder's risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly. At the same time, it stands to gain little from winning other than the continued protection of its lawful monopoly over the manufacture and sale of the drug in question. "Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic challengers] gain[] considerable leverage in patent litigation: the exposure to liability amount[s] to litigation costs,

19. In this case, Barr could not at the time of the Settlement Agreement count on obtaining the 180-day exclusive period from the FDA because, as a settler rather than a "successful defender," it at least appeared that it was unlikely to be entitled to the period of exclusivity—in other words, it appeared that, by settling, Barr was trading away its exclusivity period. It is noteworthy, nonetheless, that the 180-day period is of substantial benefit to the generic drug manufacturer who obtains it because it gives that manufacturer a significant head start over other manufacturers. *See, e.g., Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 494, 510 (2d Cir. 2004) (considering claim that defendant's first-mover status converted a transitory advantage into a permanent one, where plaintiffs provided testimony that "even though its offer price to the Eckerd and CVS drugstore chains was as much as 25 percent below [the first mover's price], neither chain was willing to leave [the first mover] after having devoted substantial time to switching patients and getting their pharmacists comfortable with the new product").

but pale[s] in comparison to the immense volume of generic sales and profits.” *Schering-Plough*, 402 F.3d at 1074 (citation omitted).

Under these circumstances, we see no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder’s patent.²⁰

3. “Excessive” Reverse Payments. As we have noted, although there are those who contend that reverse payments are in and of themselves necessarily unlawful, the plaintiffs are not among them. They allege instead that “[t]he value of the consideration provided to keep Barr’s product off the market . . . greatly exceeded the value Barr could have realized by successfully defending its trial victory on appeal and entering the market with its own competitive generic product.” Appellants’ Br. at 15. The plaintiffs assert that it is that excessiveness that renders the Settlement Agreement unlawful.²¹ We agree that even if “reverse payments are a natural by-product of the Hatch-Waxman process,” *Cipro II*, 261 F. Supp. 2d at 252, it does not follow that they are necessarily lawful, see *Hovenkamp et al.*, *supra*, at 1758 (“We do not think it follows that because it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive. Far from it.”). But [o]nly if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit. Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices—masks—for fixing prices, in violation of antitrust law. *Asahi Glass*, 289 F. Supp. 2d at 991. “If, however, there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation.” *Id.* at 992.

20. It has been observed that even the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment. See *Cipro II*, 261 F. Supp. 2d at 252 (“[E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer.”); cf. *Asahi Glass*, 289 F. Supp. 2d at 994 (“[A]ny settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements.” (emphasis in original)); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L. Rev. 698, 700 (2004) (“It makes no sense to single out exclusion payments for disfavor when the same potential for collusion arises in any settlement involving the defendant’s exit.”). A blanket rule that all settlements involving reverse payments are unlawful could thus conceivably endanger many ordinary settlements of patent litigation.

21. The Federal Trade Commission and some commentators have proposed similar or even more stringent rules. See *In re Schering-Plough Corp.*, No. 9297, final order at 4, 2003 WL 22989651 (Fed. Trade Comm’n Dec. 8, 2003), 2003 FTC LEXIS 187 (applying a rule under which generic manufacturers would not be permitted to receive reverse payments that exceeded “the lesser of the [patent] [h]older’s expected future litigation costs to resolve the Patent Infringement Claim or \$2 million”), *vacated*, 402 F.3d 1056 (11th Cir. 2005); *Hovenkamp et al.*, *supra*, at 1759 (proposing that “[i]n an antitrust challenge, a payment from a patentee to an infringement defendant for the latter’s exit from the market is presumptively unlawful,” and that the “infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit”).

There is something on the face of it that does seem “suspicious” about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder. Why, after all—viewing the settlement through an antitrust lens—should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers? We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.²²

If the patent holder loses its patent monopoly as a result of defeat in patent litigation against the generic manufacturer, it will likely lose some substantial portion of the market for the drug to that generic manufacturer and perhaps others. The patent holder might also (but will not necessarily) lower its price in response to the competition. The result will be, unsurprisingly, that (assuming that lower prices do not attract significant new purchasers for the drug) the *total* profits of the patent holder and the generic manufacturer on the drug in the competitive market will be *lower* than the total profits of the patent holder alone under a patent-conferred monopoly. In the words of the Federal Trade Commission: “The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete.” *In re Schering-Plough Corp.*, slip op. at 27, 2003 WL 22989651 (Fed. Trade Comm’n Dec. 8, 2003), 2003 FTC LEXIS 187, *vacated*, 402 F.3d 1056 (11th Cir. 2005). It might therefore make economic sense for the patent holder to pay some portion of that difference to the generic manufacturer to maintain the patent-monopoly market for itself. And, if that amount exceeds what the generic manufacturer sees as its likely profit from victory, it seems to make obvious economic sense for the generic manufacturer to accept such a payment if it is offered.²⁴ We

22. The dissent questions what it sees as our reliance on the presumption of validity of the patent at the time of the settlement. Even after a district court holds a patent invalid, it is treated as presumptively valid under 35 U.S.C. § 282 on appeal. *See Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1377-78 (Fed. Cir. 2002). But irrespective of whether there was a presumption or where any such presumption lay at the time of settlement, we think that Zeneca was then entitled to protect its tamoxifen patent monopoly through settlement. The question for this Court is whether the settlement extended the patent’s scope. If the judgment of the district court against a patent’s validity put an end to the patent monopoly that the patent holder was entitled to protect, then *any* settlement after judgment of the district court holding the patent invalid would extend the patent monopoly beyond the patent’s scope and therefore be unlawful.

24. To illustrate using a vastly oversimplified hypothetical example (ignoring, for example, legal fees and costs): Suppose the patent holder is selling 1,000,000 pills per year at a \$1 profit per pill (for a total profit of \$1,000,000). The generic manufacturer files a paragraph IV ANDA, and the patent holder responds by bringing suit to protect its patent. If the patent holder projects that, should it lose the suit, it will thereafter sell only 250,000 pills per year at a \$.90 profit per pill (for a total profit of \$225,000) in the competitive market, and the generic will sell 750,000 pills per year at a profit of \$.60 per pill (for a total profit of \$450,000)—so that total market profits are now down from \$1,000,000 to \$675,000—it would make economic sense for the patent holder to pay the generic manufacturer something more than the \$450,000 the generic manufacturer would make in a competitive market to settle the litigation. If it paid \$500,000 a year to the generic manufacturer—\$50,000 more than the generic manufacturer could earn in the market in a “best case scenario”—for example, it would thereby retain the ability to make \$500,000 per year selling its branded pills (\$1,000,000 profit less \$500,000 per

think we can safely assume that the patent holder will seek to pay less if it can, but under the circumstances of a paragraph IV Hatch-Waxman filing, as we have discussed, the ANDA filer might well have the whip hand. *Cf. Valley Drug*, 344 F.3d at 1310 (“Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”).

Of course, the law could provide that the willingness of the patent holder to settle at a price above the generic manufacturer’s projected profit betrays a fatal disbelief in the validity of the patent or the likelihood of infringement, and that the patent holder therefore ought not to be allowed to maintain its monopoly position. Perhaps it is unwise to protect patent monopolies that rest on such dubious patents. But even if large reverse payments indicate a patent holder’s lack of confidence in its patent’s strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder’s fear of losing it.

[T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent’s validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment. It is not “bad faith” to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit.

Asahi Glass, 289 F. Supp. 2d at 992-93 (citation omitted) (emphasis in original).

Such a rule would also fail to give sufficient consideration to the patent holder’s incentive to settle the lawsuit without reference to the amount the generic manufacturer might earn in a competitive market, even when it is relatively confident of the validity of its patent—to insure against the possibility that its confidence is misplaced, or, put another way, that a reviewing court might (in its view) render an erroneous decision. *Cf. Schering-Plough*, 402 F.3d at 1075-76. Whatever the degree of the patent holder’s certainty, there is always some risk of loss that the patent holder might wish to insure against by settling.

This case is illustrative. It is understandable that however sure Zeneca was at the outset that its patent was valid, settlement might have seemed attractive once it lost in the district court, especially in light of the deferential standard the Federal Circuit was expected to apply on review. But its desire to settle does not necessarily belie Zeneca’s confidence in the patent’s validity. Indeed, Zeneca’s pursuit of subsequent litigation seeking to establish the tamoxifen patent’s validity, and the success of that litigation, strongly suggest that such

year paid to the generic), \$275,000 *more* per year than it would earn if it paid nothing to the generic but lost the patent litigation and with it the patent monopoly. It might well be sensible for the patent holder to enter into this sort of settlement, depending in part on its perceived prospects for winning the litigation, and it would seem difficult for the generic manufacturer to refuse. The \$325,000 of yearly monopoly profits which accrued to the patent holder before the litigation began would thereafter be divided between the patent holder and the generic manufacturer.

confidence persisted and was not misplaced. Neither do we think that the settlement's entry after the district court rendered a judgment against Zeneca should counsel against the settlement's propriety. It would be odd to handicap the ability of Zeneca to settle after it had displayed sufficient confidence in its patent to risk a finding of invalidity by taking the case to trial.

We are unsure, too, what would be accomplished by a rule that would effectively outlaw payments by patent holders to generic manufacturers greater than what the latter would be able to earn in the market were they to defend successfully against an infringement claim. A patent holder might well prefer such a settlement limitation—it would make such a settlement cheaper—while a generic manufacturer might nonetheless agree to settle because it is less risky to accept in settlement all the profits it expects to make in a competitive market rather than first to defend and win a lawsuit, and then to enter the marketplace and earn the profits. If such a limitation had been in place here, Zeneca might have saved money by paying Barr the maximum such a rule might allow—what Barr was likely to earn if it entered the market—and Barr would have received less than it could have if it were free to negotiate the best deal available—as it did here. But the resulting level of competition, and its benefit to consumers, would have been the same. The monopoly would have nonetheless endured—but, to no apparent purpose, at less expense to Zeneca and less reward for Barr.

It strikes us, in other words, as pointless to permit parties to enter into an agreement settling the litigation between them, thereby protecting the patent holder's monopoly even though it may be based on a relatively weak patent, but to limit the amount of the settlement to the amount of the generic manufacturer's projected profits had it won the litigation.

We are not unaware of a troubling dynamic that is at work in these cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent. But the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly. So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.

We also agree with the *Cipro III* court's observation that:

If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.

Cipro III, 363 F. Supp. 2d at 534. There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-

gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt, however, that this scenario is realistic.

Every settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. The point will come when there are simply no monopoly profits with which to pay the new generic challengers. “[I]t is unlikely that the holder of a weak patent could stave off *all* possible challengers with exclusion payments because the economics simply would not justify it.” *Cipro III*, 363 F. Supp. 2d at 535 (emphasis supplied). We note in this regard that Zeneca settled its first tamoxifen lawsuit against the first generic manufacturer, Barr, but did not settle, and, as far as we know, did not attempt to settle, the litigation it brought against the subsequent challenging generics, Novopharm, Pharmachemie, and Mylan. (To be sure, the settlement with Barr came after a judgment *against* Zeneca, while the judgments in Novopharm, Pharmachemie, and Mylan’s challenges were *for* Zeneca.)²⁵

An alternative rule is, of course, possible. As suggested above, the antitrust laws could be read to outlaw all, or nearly all, settlements of Hatch-Waxman infringement actions. Patent holders would be required to litigate each threatened patent to final, unappealable judgment. Only patents that the courts held were valid would be entitled to confer monopoly power on their proprietors. But such a requirement would be contrary to well-established principles of law. As we have rehearsed at some length above, settlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents. It is too late in the journey for us to alter course.

We generally agree, then, with the Eleventh Circuit insofar as it held in *Valley Drug* that “‘simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,’ unless the ‘exclusionary effects of the agreement’ exceed the ‘scope of the patent’s protection.’” *Cipro III*, 363 F. Supp. 2d at 538 (quoting *Schering-Plough*, 402 F.3d at 1076). Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly. “Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.” *Cipro III*, 363 F. Supp. 2d at 535.

We further agree with the *Cipro III* court that absent an extension of the monopoly beyond the patent’s scope, an issue that we address in the next section of this opinion, and absent fraud, which is not alleged here, the question is whether the underlying infringement lawsuit was “objectively

25. It seems to us odd for the dissent to urge, in the context of this case, that we have not given proper weight to “the public interest in having the validity of patents litigated.” The Settlement Agreement was a virtual invitation to other generic manufacturers to file paragraph IV certifications and thereby court litigation as to the validity of the tamoxifen patent. It was an invitation that was accepted three times leading to three lawsuits, two of them litigated to judgment, as to the validity of the tamoxifen patent. Accepting the value of litigating the validity of patents in these circumstances, it has hardly been undermined here.

baseless in the sense that no reasonable litigant could realistically expect success on the merits.” *Profl Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60, (1993). In this case, the plaintiffs do not contend that they can—and we conclude that in all likelihood they cannot—establish that Zeneca’s patent litigation was baseless, particularly in light of the subsequent series of decisions upholding the validity of the same patent. Payments, even “excessive” payments, to settle the dispute were therefore not necessarily unlawful.

4. *The Terms of the Settlement Agreement.* Inasmuch as we conclude that neither the fact of settlement nor the amount of payments made pursuant thereto as alleged by the plaintiffs would render the Settlement Agreement unlawful, we must assess its other terms to determine whether they do. As we have explained in the previous section of this opinion, we think that the question is whether the “exclusionary effects of the agreement” exceed the “scope of the patent’s protection.” *Schering-Plough*, 402 F.3d at 1076. Looking to other courts that have addressed similar cases for guidance, and accepting the plaintiffs’ allegations as true, we conclude that the Settlement Agreement did not unlawfully extend the reach of Zeneca’s tamoxifen patent.

First, the Settlement Agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products. It is thus unlike the agreement the Sixth Circuit held *per se* illegal in *Cardizem*, 332 F.3d at 908, which included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market non-infringing products. *See id.* at 902, 908 & n.13 (quoting the court in *Cipro II*, 261 F. Supp. 2d at 242, which observed that the *Cardizem* district court, in condemning the settlement agreement in that case, “emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, Thus, the court found that the agreement’s restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.”); *see also Valley Drug*, 344 F.3d at 1306 n.18 (observing that if the agreement “also prohibited the marketing of non-infringing terazosin products, prohibited [the generic manufacturer] from marketing infringing products beyond the date a district court held the [relevant] patent invalid, and prohibited [the generic manufacturer] from waiving its 180-day exclusivity period” then the agreement “may be beyond the scope of [the patent holder’s] lawful right to exclude and, if so, would expose appellants to antitrust liability”).

Like the patent for the compound ciprofloxacin hydrochloride, which was the subject of dispute in the *Cipro* cases, and unlike the patents at issue in *Cardizem* and *Valley Drug*, Zeneca’s tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug. Because Zeneca’s patent therefore precludes all generic versions of tamoxifen, so that any such competing version would, as we understand it, necessarily infringe the patent, the Settlement Agreement did not, by precluding the manufacture of a generic version of tamoxifen, restrain the marketing of any non-infringing products.

Second, the Settlement Agreement ended all litigation between Zeneca and Barr and thereby opened the tamoxifen patent to immediate challenge

by other potential generic manufacturers, which did indeed follow—spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit, since by vacating the district court judgment and amending its ANDA to remove its paragraph IV certification, Barr appeared to ensure (under procedures in effect at the time) that it was not eligible for the exclusivity period. *See Cipro II*, 261 F. Supp. 2d at 242-43 (emphasizing that the settlement in that case extinguished the litigation between Barr and Bayer and that Barr agreed to withdraw its paragraph IV certification, thus removing any “bottleneck” to future generic entrants). The Agreement thus avoided a “bottleneck” of the type created by the agreements in *Valley Drug* and *Cardizem*, which prevented other generic manufacturers from obtaining approval for their own generic versions from the FDA. Rather than resolve the litigation, the settlements in those cases prolonged it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly. In *Cardizem*, for example, the settlement included periodic payments to the generic manufacturer during the pendency of the lawsuit in exchange for its promise not to market a generic drug for which it had already received FDA approval, thereby delaying the market entry of other generic manufacturers “who could not enter until the expiration of [the first-moving generic manufacturer’s] 180-day period of marketing exclusivity, which [the generic] had agreed not to relinquish or transfer.” *Cardizem*, 332 F.3d at 907.

The disadvantage purportedly suffered by the plaintiffs is not that Barr somehow prevented others from challenging the patent and obtaining FDA approval; nor is it that no other generic manufacturer tried to do so. It is instead that each of the subsequent challenges failed. While it is true that, had the district court’s decision in Zeneca’s patent infringement lawsuit against Barr been affirmed, other generic manufacturers would have been allowed to market their drugs, there is no legal requirement that parties litigate an issue fully for the benefit of others.

Thus the stated terms of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca’s patent: The Settlement Agreement did not have an impact on the marketing of non-infringing or unrelated products, and the Agreement fully resolved the litigation between Zeneca and Barr, clearing the way for other generic manufacturers to seek to enter the market.

Finally, the Settlement Agreement did not entirely foreclose competition in the market for tamoxifen. It included a license from Zeneca to Barr that allowed Barr to begin marketing Zeneca’s version of tamoxifen eight months after the Settlement Agreement became effective. The license ensured that money also flowed from Barr to Zeneca, decreasing the value of the reverse payment. By licensing tamoxifen to Barr, Zeneca added a competitor to the market, however limited the competition may have been. Unlike reverse payment settlements that leave the competitive situation as it was prior to the litigation, the reverse payment in this case was pursuant to an agreement that increased competition in the market for tamoxifen—even if only a little—almost nine years before the tamoxifen patent was to expire.

The Settlement Agreement almost certainly resulted in less price competition than if Barr had introduced its own generic version, of course. The

plaintiffs allege that the Barr-distributed, Zeneca-manufactured tamoxifen sold at retail for just five percent less than the Zeneca-branded version, compared with what the plaintiffs allege is a typical initial drop of sixteen percent or more, and an eventual drop in a truly competitive market of thirty to eighty percent, Compl. ¶ 75. *See also* Congr. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 32 (July 1998) (describing one study that estimated that the average price of a generic drug fell from sixty percent of the brand-name price to thirty-four percent of the brand-name price as the number of generic manufacturers increased from one to ten). This was competition nonetheless. It was certainly more competition than would have occurred had there been no settlement and had Zeneca prevailed on appeal.

We conclude that the facts as alleged in the plaintiffs' complaint, if proved, would not establish that the terms of the Settlement Agreement violated the antitrust laws. In the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside the scope of the tamoxifen patent, the plaintiffs have not stated a claim for relief with respect to the Settlement Agreement.

* * *

POOLER, Circuit Judge, dissenting.

I respectfully dissent. I believe that the opinion of the court, which dismisses plaintiffs' complaint, shortcuts a process necessary to balance the interests at stake in this litigation. These interests include, on one side, the encouragement of innovation fostered by the patent laws, the public and private interest in amicable settlements, and judicial economy; and, on the other side, an interest in vigorous competition protected by the Sherman Act as well as the interest of consumers in having the validity of a patent litigated.

* * *

DISCUSSION

I differ with both the majority's standard for pleading a Hatch-Waxman-settlement antitrust violation and with several subsidiary holdings, conclusions, or assumptions. The requirement that—unless an antitrust plaintiff demonstrates that a settlement agreement exceeds the scope of the patent—it must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws. Beyond that overarching difference, the majority has, in my view, wrongly (1) accorded dispositive deference to Zeneca's patent rights when its patent had been declared invalid at the time of the settlement; (2) focused on subsequent litigation concerning patent validity rather than the litigation posture at the time of settlement; (3) held that the district court could not assess the likelihood that Zeneca would succeed on appeal; (4) held that plaintiffs insufficiently alleged a conspiracy between Barr and Zeneca to deploy Barr's paragraph IV certification when it would delay the market entry of another generic manufacturer; and (5) failed to recognize that whether plaintiffs' injuries stem from the alleged Barr/Zeneca conspiracy or from the

failure of other generics to invalidate the patent cannot be resolved on the pleadings.

I. The pleading standard.

Relying principally on *Professional Real Estate Investors*, the majority concludes that, in order to attack a Hatch-Waxman settlement on antitrust grounds, plaintiffs must allege either that the agreement gave the patent holder benefits beyond the scope of the patent or that the agreement was a sham, that it was “objectively baseless in the sense that no reasonable litigant would realistically expect success on the merits.” I agree that a settlement agreement that confers on the patent holder a greater monopoly benefit than does the patent itself is illegal. However, I do not agree that, absent a showing of benefits exceeding the scope of the patent, the antitrust plaintiff must show that the settled litigation was objectively baseless.

Professional Real Estate Investors is not apposite because it did not involve the settlement of Hatch-Waxman patent litigation. Rather, plaintiffs brought a copyright infringement case, and defendants countersued, alleging that the suit was a sham and a violation of §§ 1 and 2 of the Sherman Act. 508 U.S. at 52. The district court held that while no infringement occurred, no antitrust violation occurred either because the plaintiffs were entitled to immunity under *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), as their litigation “was clearly a legitimate effort and therefore not a sham.” 508 U.S. at 53. Both the Court of Appeals and the Supreme Court agreed, and the Supreme Court defined “sham” for the purposes of defeating *Noerr-Pennington* immunity, as the majority does here. *Id.* at 60. The Court was not called upon to decide and did not decide the standard for pleading an antitrust violation; it simply defined “sham,” in a context in which it was already clear that the required standard was sham litigation. It is ill-advised, I think, to import the definition of “sham” used where a party must concededly establish that litigation was “sham” to avoid a well-established immunity from antitrust liability to a context in which we are defining antitrust liability in the first instance. Although Zeneca’s original suit was likely protected under the standard set out in *Professional Real Estate Investors*, it does not necessarily follow that the settlement of that suit should be judged on the same grounds.

In fact, other leading cases cited in the majority opinion suggest, although I concede they do not mandate, a contrary conclusion. See *Standard Oil*, 283 U.S. at 180, 51 S. Ct. 421 (noting in the context of upholding cross-licensing agreements for patents against an antitrust challenge that a “master found, after an elaborate review of the entire art, that the presumption of validity attaching to the patents had not been negated in any way; that they merited a broad interpretation; that they had been acquired in good faith; and that the scope of the several groups of patents overlapped sufficiently to justify the threats and fears of litigation.”); *United States v. Singer Mfg Co.*, 374 U.S. 174, 197 (1963) (White, *Justice, concurring*) (noting that the majority had not reached issue of whether “collusive termination of a Patent Office interference proceeding pursuant to an agreement between [certain parties] to help one another to secure as broad a patent monopoly as possible, invalidity considerations, notwithstanding” was sufficient, standing alone, to state an antitrust claim and indicating that he believed it was). Both the majority opinion

in *Standard Oil* and the concurrence in *Singer* suggest that an antitrust court must go beyond deciding that a lawsuit was not a sham, that is objectively baseless, before it can dismiss an antitrust challenge to the lawsuit's settlement—as opposed to the initiation of the lawsuit—and, in fact, must consider the strength of the patent.

Holding that a Hatch-Waxman settlement agreement cannot violate antitrust laws unless the underlying litigation was a sham also ill serves the public interest in having the validity of patents litigated. See *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973). This interest exists because “[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.” *Id.* at 58. Litigating the validity of drug company patents is critically important to the general well being in light of the recent trend toward capping the maximum amounts insurers and public benefit plans will spend on medications.

A Hatch-Waxman settlement, by definition, protects the parties' interests as they see them. Whether it also promotes the public's interest depends on the facts. If the validity of the patent is clear, and the generic company receives a license to market the patent holder's product, competition is increased. However, if, as in this case, the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its generic product off the market, it is hard to see how the public benefits.

The Hatch-Waxman Act provides an incentive for the second kind of agreement that other patent laws do not provide. Patent litigation other than Hatch-Waxman patent litigation generally proceeds along familiar lines. A patent holder sues an alleged infringer, and the infringer either chooses to go to trial to vindicate its view that the patent is invalid or pays the patent holder money as compensation for damages the patent holder has suffered or as the price of a license. In this context, one can perhaps assume that the parties' relative views on the strength of a patent will result in a pro-competitive or neutral result. If the patent holder believes its patent is strong, it will proceed to trial, knowing that it can collect damages at the end. The generic manufacturer, if it believes the patent holder's patent is weak, may be willing to risk damages and market its product during the litigation, thereby promoting competition. And if the claims are in relative equipoise, a licensing arrangement may well result.

In contrast, a generic competitor subject to Hatch-Waxman cannot enter the market for the first thirty months after litigation is commenced against it. See 21 U.S.C. § 355(j)(5)(B)(iii). In addition, whether its attack against the patent is strong or weak, the benefit it will obtain by successfully litigating to the finish is not great. At best, it will obtain 180 days in which it will be the exclusive generic on the market. See 21 U.S.C. § 355(j)(5)(B)(iv). On the other hand, the benefits to the public from the completion of litigation can be enormous if the generic challenger prevails as it did, at least initially, here. Once the 180-day exclusivity period is over, any generic that wishes to market a generic product and that can establish its product is bioequivalent to the patented product can enter the market, thus providing increased competition.

Moreover, the thirty-month stay provides an incentive to the patent holder to pay its generic competitor more than the generic company could have realized from winning the lawsuit. This is so because once the settlement is

reached and the litigation dismissed, another generic manufacturer will have to wait at least thirty months after litigation is commenced against it to begin production. Thus, the patent holder will be protected against all generic competition for thirty months after the first lawsuit is terminated. This problem is aggravated when the agreement between the putative competitors provides that the generic company can deploy its exclusivity period after sitting on it until another ANDA applicant attempts to enter the market. These anti-competitive effects—and others not present in this case—have caused antitrust scholars to propose various analytical frameworks for determining whether an antitrust violation has occurred when a patent holder makes a reverse payment to settle patent litigation. The analytical frameworks proposed vary both as to burden of proof and as to the evidence necessary to find a reverse payment illegal.

For instance, Herbert Hovenkamp, Mark Janis, and Mark A. Lemley propose that a Hatch Waxman Act settlement that includes a reverse payment be presumed illegal with the patent holder being allowed to rebut this presumption “by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.” Herbert Hovenkamp et al, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2004).

Thomas F. Cotter’s approach would leave on the antitrust defendants the burden of demonstrating the legality of a reverse-payment settlement, but he does not adopt Hovenkamp’s position that the reverse payment must be limited to litigation costs. See Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 MINN. L. REV. 1789, 1795-97, 1802 (2003). Rather, he argues that “when the antitrust defendants can show that the payment is below the expected amount of the patent defendant’s loss if an injunction were to issue, the burden of proving validity and infringement should be somewhat easier to satisfy than at a full-blown infringement trial.” *Id.* at 1814. Cotter rejects, and the other commentators implicitly reject, the approach adopted by the majority. See *id.* at 1811 (noting that requiring antitrust plaintiffs to show that patent litigation is a sham “would permit too many anticompetitive settlements to escape scrutiny. A suit with only a 25% chance of success may not be a sham, but a settlement based upon such a low probability estimate reduces consumer welfare for no apparent offsetting benefit.”).

Thus, commentators, precedent, and policy suggest the majority’s requirement that an antitrust plaintiff show that a Hatch-Waxman lawsuit settled by agreement was a sham—assuming that the agreement did not convey benefits beyond the scope of the patent—is unjustified. A more searching inquiry and a less stringent standard are required to properly protect all interests. I see no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context.⁵ In assessing reasonableness, the fact-finder must consider all the

5. The majority argues that applying the general rule of reasonableness would “mak[e] every settlement of patent litigation, at least in the Hatch-Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a

circumstances affecting a restrictive agreement. *Id.* Of course, the strength of the patent must be central to any antitrust analysis involving a patent. Thus, in assessing the reasonability of a Hatch-Waxman settlement, I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period. Because plaintiffs allege that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants, I believe that their pleading is adequate.

* * *

Comments

1. ***Settlement of Patent Litigation.*** Recent empirical scholarship on patent litigation suggests that only about 1 percent of patents are litigated. See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. L. REV. 1495, 1501 (2001). Of this small percentage, 5 percent of patent cases go to trial, see Jean O. Lanjouw & Mark Schankerman, *Protecting Intellectual Property Rights: Are Small Firms Handicapped?*, 47 J.L. ECON. 45 (2004), an additional 6-9 percent are resolved on the merits through summary judgment, and the remaining are resolved through some form of settlement. See Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237 (2006); Paul Janicke, *Patent Litigation Remedies: Some Statistical Observations* (2007) at http://www.patstats.org/editors_page.rev6.html (showing in 2006, 86.5 percent of patent cases were settled, which includes consent judgments, voluntary dismissals, and dismissals stating settlement or "other dismissals"). Thus, an overwhelming majority of patent litigation is settled, a result our legal system generally encourages. See Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 660-62 (2004).
2. ***Settlements Resulting in Licensing Agreements.*** Some type of license arrangement usually forms the core of a patent settlement. The agreement can assume a straightforward license between the patentee and a

'reasonable' restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal)" and thus "place a huge damper on such settlements." Majority op. at 212 n.26. I doubt that this doomsday scenario would, in fact, take place. Courts would eventually develop rules for judging the reasonableness of a settlement, and as with other litigation, the majority of cases would be resolved in motion practice. Moreover, the majority again emphasizes the acknowledged interest in settlements without acknowledging the absent party in Hatch Waxman litigation settlements, the consumer of medicines. Those consumers have no ability to affect the settlement, which, in some cases, may benefit both parties beyond any expectation they could have from the litigation itself while harming the consumer. There is a panglossian aspect to the majority's tacit assumption that the settling parties will not act to injure the consumer or competition.

competitor—the erstwhile alleged infringer. Another form is a cross-license, typically associated with a blocking-patents scenario—when each party holds patent rights. There can also be complex patent pooling arrangements among various patent holders. All of these scenarios have much to admire from an efficiency and social welfare perspective. As the DOJ/FTC Antitrust Licensing Guidelines state, cross-licensing and pooling arrangements “may provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation. By promoting the dissemination of technology, cross-licensing and pooling arrangements are often procompetitive.” U.S. Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* § 5.5 (1995). Yet, the terms of these arrangements may also give rise to antitrust concerns if they involve price fixing, market division, or coordinated output restrictions. *Id.* See also *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963). For scholarly commentary, see Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002); George Priest, *Cartels and Patent License Arrangements*, 20 J.L. & ECON. 309 (1977).

3. **The Architecture of Hatch-Waxman.** To fully appreciate the antitrust issues relating to exclusion payments (sometimes called “reverse payments”), it would be helpful to have a basic outline of the Hatch-Waxman legislation, formally known as the Drug Price Competition and Patent Term Restoration Act. In 1984, Congress passed the Hatch-Waxman Act, which focused on the relationship between the incentives of pioneer pharmaceutical companies and the desire for prompt market access to bio-equivalent generic alternatives. Under the provisions of the legislation, the pioneer, when filing its New Drug Application (NDA) as part of the FDA approval process, must list—in what is commonly referred to as the “Orange Book”^{*}—any patents that would be infringed by a generic company. 21 U.S.C. § 355(b)(1)(F). An Orange Book listing is a particularly powerful tool for the pioneer because it allows him to potentially secure a 30-month delay of FDA approval for the generic drug.

A generic company, who seeks to introduce a generic drug into the market, can file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA). By filing an ANDA, the generic company does not have to undergo the rigorous and costly FDA clinical trials that the pioneer company endured.^{**} But the generic company must prove bio-equivalency between the generic drug and the pioneer drug,

^{*}The “Orange Book”—which lists all approved drugs—is formally known as the “Approved Drug Products and Therapeutic Equivalents” that is published by the FDA. It is called the Orange Book because prior to it being available on the FDA website, the agency published a hardcopy that had an orange cover. See www.fda.gov/cder/ob.

^{**}The FDA new drug approval process is typically associated with three clinical phases. Phase I relates to the safety of the drug, but is restricted to a small number of human volunteers. Phase II pertains to determining preliminary efficacy and establishing proper dosage. And Phase III involves a large number of human patients that actually have the disease the drug is designed to treat. This phase seeks to determine both safety and efficacy.

meaning that the generic drug has the same active ingredient (although not necessarily the same inactive ingredients), dosage, and strength. If a pioneer's patent is listed in the Orange Book, however, the generic company is required to file a certification that discusses how the pioneer's listed patents will affect the generic company's plan to market a generic version of the pioneer drug. Most relevantly, the generic company has the option of filing a Paragraph IV certification, which asserts that the pioneer's patent is either invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Importantly, the Hatch-Waxman Act provides the generic company who first files an ANDA and Paragraph IV certification with a 180-day period of exclusivity. This period of exclusivity bars other generic companies from marketing their generic version for 180 days after the first generic drug is commercialized or the pioneer patent is invalidated or held not to be infringed, whichever is earlier. The 180-day exclusivity is a powerful incentive for generics to challenge pioneer patents.

If the generic company opts for a Paragraph IV certification, it must also provide the pioneer with notice and details of its claim of invalidity or non-infringement within 20 days of the ANDA filing. 21 U.S.C. § 355(j)(2)(B)(i)-(ii). At this point, the pioneer can take advantage of the aforementioned 30-month stay provision for ANDA approval, but only if the pioneer files a patent infringement suit against the generic concern within 45 days from the generic's notice. The ANDA will be approved "immediately" if the pioneer does not file suit. (Another option, infrequently used, is for the pioneer not to file suit, allow the ANDA to be approved and the generic drug introduced. This strategy, while risky, gives the pioneer the option to sue for damages.) Once suit is filed, a federal court will decide if the patent is proved invalid or not infringed, or vice versa. If the result is the former, then the FDA can approve the ANDA, and the generic will hit the market, even if the district court's determination occurs within the 30-month period. If the latter, the court will issue an injunction to keep the generic from entering the market until the pioneer's patent expires. 21 U.S.C. § 355(j)(5)(B)(iii). And the FDA will not be permitted to approve the ANDA until the patent expires. For a discussion of the Hatch-Waxman procedures see *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998).

4. **Exclusion Payments and the Courts.** The combination of the pioneer's 30-month stay and the generic's 180-day exclusivity provide fertile ground for creative settlement agreements. The pioneer wants to keep the generic drug off the market, and is willing to pay millions to achieve this end; generics want to keep other generic producers from entering the market. How these preferences play out in settlement agreements and the antitrust implications have been the subject of numerous court cases, and a revision to the Hatch-Waxman Act (discussed below). The federal courts have overwhelmingly held these reverse payment settlement agreements do not violate the antitrust laws. So far, plaintiffs challenging exclusion payment settlements have succeeded in only one circuit court case, in which the Sixth Circuit held that the defendants' settlement was a *per se* antitrust violation. See *In re Cardizem CD Antitrust Litigation* (332 F.3d 896). As seen in *In re Tamoxifen*, however, courts have distinguished *Cardizem* from other cases involving exclusion payments, because the *Cardizem* settlement

prohibited the generic manufacturer from relinquishing its 180-day exclusivity for marketing a generic drug and also prevented it from developing any other related drugs, whether or not they infringed on the patent. *See also In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d at 526 (E.D.N.Y. 2005); *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d at 1306 (11th Cir. 2003).

Recent Congressional changes to the Hatch-Waxman Act have rendered obsolete settlements like those seen in *Cardizem*. In *Cardizem*, the pioneer and generic drug company agreed that the generic company would keep its 180-day exclusivity period indefinitely by not releasing its generic drug. This arrangement precluded any other generic company from entering the market, because no other generic drug could be marketed until 180 days after the settling generic company released its generic drug. The 2003 amendments to the Hatch-Waxman Act stopped these types of settlements by requiring the generic company to release its drug by the earliest of either 75 days after the FDA approves the ANDA or three months after the ANDA is submitted. If the generic company does not release its drug within this timeframe, it forfeits its 180-day exclusivity period. 21 U.S.C.A. § 355 (j)(5)(D). *See Erika King Lietzan, A Brief History of 180-Day Exclusivity Under The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 FOOD & DRUG L.J. 287 (2004).

Challengers of exclusion payments have argued that all settlements with exclusion payment should create a presumption that the patent holder exceeded the scope of its patent, because, unlike licensing agreements or negotiated entry dates for the generic drugs, exclusion payments allow the patent holder to maintain a monopoly power that is disproportionate with the probability that the patent would withstand a trial verdict. *See, e.g.,* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d at 528 (E.D.N.Y. 2005); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d at 1073 (11th Cir. 2005). Such a presumption would require the parties to the settlement to show that the settlement had pro-competitive effects by bringing more competition or efficiency to the market. The courts, however, have refused to treat exclusion payments as presumptively illegal. *See In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d at 531 (E.D.N.Y. 2005). Rather, courts have widely adopted an approach similar to the Second Circuit's, which puts the burden on the antitrust plaintiffs to show that the settlement extended the exclusionary power of the patent. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, (E.D.N.Y. 2005); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d at 1066 (11th Cir. 2005). The burden is significant, as some courts have adopted an "objectively baseless" standard that requires antitrust plaintiffs to show that the defendants entered into a sham settlement knowing that the patent would not survive the underlying litigation. *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d at 993 (N.D. Ill. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d at 535 (E.D.N.Y. 2005).

As the federal courts attempt to strike a balance between patent and antitrust laws, they have relied on the statutory presumption of patent validity and weighed in favor of the patent holders. *See* 35 U.S.C.A. § 282.

Unless antitrust plaintiffs can meet the “clear and convincing” standard to defeat the presumption of patent validity or show that the generic drug did not infringe upon the pioneer’s patent (and the parties were aware of that fact at the time of settlement), courts generally will not assume that a settlement including an exclusion payment exceeded the scope of the patent. The United States Supreme Court has had a few opportunities to review the issue, but has denied the petitions for certiorari in all cases. *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied sub nom. Walgreen Co. v. Abbott Labs.*, 543 U.S. 939 (2004); *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

There has also been a great deal of commentary on this issue. *See, e.g.*, Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Thomas F. Cotter, *Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789 (2003); Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 INNOVATION POLICY AND THE ECONOMY 145 (Adam B. Jaffe et al. eds., 2004); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004).

4. Refusal to Deal

A basic tenet of patent law is the patentee enjoys the right to exclude others from making, using and selling the claimed invention, which includes the right not to use, sell or license its patent rights. But the right to exclude is not boundless and must be exercised in a manner consistent with antitrust principles. *Independent Service Organizations* explores the limits of the patentee’s right to exclude in the context of a unilateral, unconditional refusal to sell its patented technology and the antitrust implications arising therefrom.

IN RE INDEPENDENT SERVICE ORGANIZATIONS ANTITRUST LITIGATION

203 F.3d 1322 (Fed. Cir. 2000)

MAYER, Chief Judge

CSU, L.L.C. appeals the judgment of the United States District Court for the District of Kansas, dismissing on summary judgment CSU’s claims that Xerox’s refusal to sell patented parts and copyrighted manuals and to license copyrighted software violate the antitrust laws. Because we agree with the district court that CSU has not raised a genuine issue as to any material fact and that Xerox is entitled to judgment as a matter of law, we affirm.

BACKGROUND

Xerox manufactures, sells, and services high-volume copiers. Beginning in 1984, it established a policy of not selling parts unique to its series 10 copiers to independent service organizations (“ISOs”), including CSU, unless they were also end-users of the copiers. In 1987, the policy was expanded to include all new products as well as existing series 9 copiers. Enforcement of this policy was tightened in 1989, and Xerox cut off CSU’s direct purchase of restricted parts. Xerox also implemented an “on-site end-user verification” procedure to confirm that the parts ordered by certain ISOs or their customers were actually for their end-user use. Initially this procedure applied to only the six most successful ISOs, which included CSU.

To maintain its existing business of servicing Xerox equipment, CSU used parts cannibalized from used Xerox equipment, parts obtained from other ISOs, and parts purchased through a limited number of its customers. For approximately one year, CSU also obtained parts from Rank Xerox, a majority-owned European affiliate of Xerox, until Xerox forced Rank Xerox to stop selling parts to CSU and other ISOs. In 1994, Xerox settled an antitrust lawsuit with a class of ISOs by which it agreed to suspend its restrictive parts policy for six and one-half years and to license its diagnostic software for four and one-half years. CSU opted out of that settlement and filed this suit alleging that Xerox violated the Sherman Act by setting the prices on its patented parts much higher for ISOs than for end-users to force ISOs to raise their prices. This would eliminate ISOs in general and CSU in particular as competitors in the relevant service markets for high speed copiers and printers.

Xerox counterclaimed for patent and copyright infringement and contested CSU’s antitrust claims as relying on injury solely caused by Xerox’s lawful refusal to sell or license patented parts and copyrighted software. Xerox also claimed that CSU could not assert a patent or copyright misuse defense to Xerox’s infringement counterclaims based on Xerox’s refusal to deal.

The district court granted summary judgment to Xerox dismissing CSU’s antitrust claims and holding that if a patent or copyright is lawfully acquired, the patent or copyright holder’s unilateral refusal to sell or license its patented invention or copyrighted expression is not unlawful exclusionary conduct under the antitrust laws, even if the refusal to deal impacts competition in more than one market. The court also held, in both the patent and copyright contexts, that the right holder’s intent in refusing to deal and any other alleged exclusionary acts committed by the right holder are irrelevant to antitrust law. This appeal followed.

DISCUSSION

The issue is whether the district court erred in granting Xerox’s motion for summary judgment on CSU’s antitrust claims. . . .

As a general proposition, when reviewing a district court’s judgment involving federal antitrust law, we are guided by the law of the regional circuit in which that district court sits, in this case the Tenth Circuit. We apply our own law, not regional circuit law, to resolve issues that clearly involve our exclusive jurisdiction. “Whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a

question of Federal Circuit law.” *Nobelpharma*, 141 F.3d at 1068; see *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1360 (Fed. Cir. 1999) (en banc in relevant part) (“*Pro-Mold* and *Nobelpharma* make clear that our responsibility as the tribunal having sole appellate responsibility for the development of patent law requires that we do more than simply apply our law to questions of substantive patent law. In order to fulfill our obligation of promoting uniformity in the field of patent law, it is equally important to apply our construction of patent law to the questions whether and to what extent patent law preempts or conflicts with other causes of action.”). The district court’s grant of summary judgment as to CSU’s antitrust claims arising from Xerox’s refusal to sell its patented parts is therefore reviewed as a matter of Federal Circuit law, while consideration of the antitrust claim based on Xerox’s refusal to sell or license its copyrighted manuals and software is under Tenth Circuit law.

A.

Intellectual property rights do not confer a privilege to violate the antitrust laws. See *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999). “But it is also correct that the antitrust laws do not negate the patentee’s right to exclude others from patent property.” *Id.* “The commercial advantage gained by new technology and its statutory protection by patent do not convert the possessor thereof into a prohibited monopolist.” *Abbott Lab. v. Brennan*, 952 F.2d 1346, 1354 (Fed. Cir. 1991). “The patent right must be ‘coupled with violations of § 2’, and the elements of violation of 15 U.S.C. § 2 must be met.”¹ *Id.* “Determination of whether the patentee meets the Sherman Act elements of monopolization or attempt to monopolize is governed by the rules of application of the antitrust laws to market participants, with due consideration to the exclusivity that inheres in the patent grant.” *Id.* at 1354-55.

A patent alone does not demonstrate market power. The United States Department of Justice and Federal Trade Commission have issued guidance that, even where it exists, such “market power does not ‘impose on the intellectual property owner an obligation to license the use of that property to others.’” *Intergraph*, 195 F.3d at 1362 (citing United States Department of Justice and Federal Trade Comm’n Antitrust Guidelines for the Licensing of Intellectual Property 4 (1995)). There is “no reported case in which a court ha[s] imposed antitrust liability for a unilateral refusal to sell or license a patent. . . .” *Id.* (citing *Image Technical Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1216 (9th Cir. 1997)). The patentee’s right to exclude is further supported by section 271(d) of the Patent Act which states, in pertinent part, that “[n]o patent owner otherwise entitled to relief . . . shall be denied relief or deemed guilty of misuse or *illegal extension of the patent right* by reason of his having . . . (4) refused to license or use any rights to the patent . . .” 35 U.S.C. § 271(d) (1999) (emphasis added).

The patentee’s right to exclude, however, is not without limit. As we recently observed in *Glass Equipment Development Inc. v. Besten, Inc.*, a patent

1. Section 2 of the Sherman Act, 15 U.S.C. § 2, prohibits monopolization or attempts to monopolize: “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony. . . .”

owner who brings suit to enforce the statutory right to exclude others from making, using, or selling the claimed invention is exempt from the antitrust laws, even though such a suit may have an anticompetitive effect, unless the infringement defendant proves one of two conditions. 174 F.3d 1337, 1343 (Fed. Cir. 1999). First, he may prove that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965). Or he may demonstrate that the infringement suit was a mere sham to cover what is actually no more than an attempt to interfere directly with the business relationships of a competitor. *See id.* (citing *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)). Here, CSU makes no claim that Xerox obtained its patents through fraud in the Patent and Trademark Office; the *Walker Process* analysis is not implicated.

“[I]rrespective of the patent applicant’s conduct before the [Patent and Trademark Office], an antitrust claim can also be based on [an] allegation that a suit is baseless; in order to prove that a suit was within *Noerr*’s ‘sham’ exception to immunity, [see *Noerr*, 365 U.S. at 144], an antitrust plaintiff must prove that the suit was both *objectively* baseless and *subjectively* motivated by a desire to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy.” *Nobelpharma*, 141 F.3d at 1071 (citing *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993)). “Accordingly, if a suit is not objectively baseless, an antitrust defendant’s subjective motivation is immaterial.” *Id.* at 1072. CSU has alleged that Xerox misused its patents but has not claimed that Xerox’s patent infringement counterclaims were shams.

To support its argument that Xerox illegally sought to leverage its presumably legitimate dominance in the equipment and parts market into dominance in the service market, CSU relies on a footnote in *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 480 n.29 (1992), that “[t]he Court has held many times that power gained through some natural and legal advantage such as a patent, . . . can give rise to liability if ‘a seller exploits his dominant position in one market to expand his empire into the next.’” Notably, *Kodak* was a tying case when it came before the Supreme Court, and no patents had been asserted in defense of the antitrust claims against Kodak. Conversely, there are no claims in this case of illegally tying the sale of Xerox’s patented parts to unpatented products. Therefore, the issue was not resolved by the *Kodak* language cited by CSU. Properly viewed within the framework of a tying case, the footnote can be interpreted as restating the undisputed premise that the patent holder cannot use his statutory right to refuse to sell patented parts to gain a monopoly in a market *beyond the scope of the patent*.

The cited language from *Kodak* does nothing to limit the right of the patentee to refuse to sell or license in markets within the scope of the statutory patent grant. In fact, we have expressly held that, absent exceptional circumstances, a patent may confer the right to exclude competition altogether in more than one antitrust market.

CSU further relies on the Ninth Circuit’s holding on remand in *Image Technical Services* that “‘while exclusionary conduct can include a monopolist’s unilateral refusal to license a [patent] or to sell its patented . . . work, a monopolist’s ‘desire to exclude others from its [protected] work is a presumptively valid business justification for any immediate harm to consumers.’”

125 F.3d at 1218. By that case, the Ninth Circuit adopted a rebuttable presumption that the exercise of the statutory right to exclude provides a valid business justification for consumer harm, but then excused as harmless the district court's error in failing to give any instruction on the effect of intellectual property rights on the application of the antitrust laws. *See id.* at 1219-20. It concluded that the jury must have rejected the presumptively valid business justification as pretextual. *See id.* This logic requires an evaluation of the patentee's subjective motivation for refusing to sell or license its patented products for pretext. We decline to follow *Image Technical Services*.

We have held that "if a [patent infringement] suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial." *Nobelpharma*, 141 F.3d at 1072. We see no more reason to inquire into the subjective motivation of Xerox in refusing to sell or license its patented works than we found in evaluating the subjective motivation of a patentee in bringing suit to enforce that same right. In the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws. We therefore will not inquire into his subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anti-competitive effect, so long as that anticompetitive effect is not illegally extended beyond the statutory patent grant. It is the infringement defendant and not the patentee that bears the burden to show that one of these exceptional situations exists and, in the absence of such proof, we will not inquire into the patentee's motivations for asserting his statutory right to exclude. Even in cases where the infringement defendant has met this burden, which CSU has not, he must then also prove the elements of the Sherman Act violation.

We answer the threshold question of whether Xerox's refusal to sell its patented parts exceeds the scope of the patent grant in the negative.² Therefore, our inquiry is at an end. Xerox was under no obligation to sell or license its patented parts and did not violate the antitrust laws by refusing to do so.

* * *

Comments

1. ***Unilateral and Unconditional Refusals to Deal.*** In the United States it has long been recognized that the patent owner has no duty to use, sell, or license his patented invention. *See Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 429 (1908) (stating "exclusion may be said to have been of the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not use it, without question of motive"); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940) (patentee has right to refuse to license or sell its patented product); *U.S. v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) (stating "Westinghouse has done no more than to license some of its patents and

2. Having concluded that Xerox's actions fell within the statutory patent grant, we need not separately consider CSU's allegations of patent misuse and they are rejected.

refuse to license others. ‘(T)he right to invoke the State’s power to prevent others from utilizing his discovery without his consent’ is the essence of the patentee’s statutory monopoly. The right to license that patent, exclusively or otherwise, or to refuse to license at all, is ‘the untrammelled right’ of the patentee.”). Moreover, a patentee may license some competitors, but not others; provide relatively favorable terms to some, but not to others.

With this tenet in mind, *ISO* can be viewed as holding a patentee who unilaterally and unconditionally refuses to deal with a third party is merely exercising his statutory rights under the patent code in a manner not inconsistent with antitrust laws. See Peter M. Boyle, Penelope M. Lister & J. Clayton Everett, Jr., *Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?*, 69 ANTITRUST L.J. 739, 747 (2002) (“We agree with others who have read *Xerox* [*i.e.*, *ISO*] as standing for the limited proposition that an intellectual property owner may unilaterally and unconditionally refuse to license or sell products covered by lawfully acquired and valid patents or copyrights free from any antitrust liability. Although marred by murky reasoning and thin support on critical points, this holding finds support in orthodox antitrust principles.”). In a speech, given shortly after the *ISO* case, then chairman of the FTC, Robert Pitofsky, stated “I have no quarrel with the fundamental rule that a patent holder has no obligation to license or sell in the first instance. A patent holder is not under any general obligation to create competition against itself within the scope of its patent.” Robert Pitofsky, *Challenges to the New Economy: Issues at the Intersection of Antitrust and Intellectual Property* (June 15, 2000—American Antitrust Institute Conference: An Agenda for Antitrust in the 21st Century, available at <http://www.ftc.gov/speeches/pitofsky/000615speech>); ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION 27-28 (U.S. Department of Justice and Federal Trade Commission, April 2007) (discussing why an unconditional refusal to deal is consistent with antitrust principles).

The *ISO* case can also be read as endorsing the proposition that when antitrust law and patent law are in conflict, patent law is favored. This notion finds support in *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) (stating “[t]he patent laws . . . are in pari materia with the antitrust laws and modify them pro tanto”). See also *Miller Insituform, Inc. v. Insituform of North America, Inc.*, 830 F.2d 606, 608 (6th Cir. 1987) (citing *Simpson*); *Data General Corp. v. Grumman Systems Support Corp.*, 36 F.3d 1146 (1st Cir. 1994) (stating “[t]he courts appear to have partly settled an analogous conflict between the patent laws and the antitrust laws, treating the former as creating an implied limited exception to the latter” (citing *Simpson*)); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) (stating a patentee’s unilateral refusal to license “expressly permitted by the patent laws”).

2. **Conditional Refusals and “Beyond the Scope of the Patent.”** While the right to exclude under 35 U.S.C. § 154 is strong, it does not provide an absolute right of exclusion. The *ISO* court identified three situations where the patentee would violate § 2 of the Sherman Act: (1) *Walker Process* fraud, (2) sham litigation, and (3) illegal tying. But the court also recognized the “undisputed premise that the patent holder cannot use his statutory right to refuse to sell patented parts to gain a monopoly in a market *beyond the scope of the patent*” (emphasis in original). Thus, it may be too narrow a

reading of *ISO* that violations of antitrust law are limited to the three instances expressly mentioned by the court. See ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS, *supra* at 18-19 (criticizing *ISO* dicta limiting antitrust liability to illegal tying, fraud on the PTO, and sham litigation); Boyle et al., *Antitrust Law at the Federal Circuit*, *supra*, at 758 (stating “[t]here is no reason to believe that the three ‘exceptions’ to a patentee’s ‘antitrust immunity’ enumerated in [*ISO*] exhaust the possibilities of anticompetitive acts involving the exercise of patent rights”).

An example of a patentee using his patent rights in this manner (*i.e.*, beyond the scope of his patent) is the *conditional* refusal to deal, as opposed to an unconditional and unilateral refusal. The *ISO* court did not address conditional refusals directly, but it is far from certain that the court would come out the same way as it did when presented with an unconditional refusal. In a conditional refusal context, the patentee is not simply saying “no, I refuse to deal, period,” as in a unilateral refusal; rather, he says, “no, I refuse to deal, unless. . . .” or “I will deal if. . . .” For example, “suppose a patent holder refuses to sell except on condition that the purchaser not buy from a potential competitor.” Pitofsky, *Challenges to the New Economy*. Or a patentee “seeks to compel certain types of conduct or obligations from its licensees rather than merely to distinguish between groups of buyers” or tries to obtain “promises by licensees to act or refrain from acting in certain ways in the future.” Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Unilateral Refusals to Deal in the U.S.*, 2 J. COMPETITION L. & ECON. 1, 38-39 (2006). See also David McGowan, *Innovation, Uncertainty, and Stability in Antitrust Law*, 16 BERKELEY TECH. L.J. 729, 781-82 (2001) (stating that “[a] unilateral refusal to license a work protected by a lawfully acquired intellectual property right is nothing more than the exercise of economic power that Congress has granted, and it should not be made the basis for a claim under the antitrust laws. Conditional refusals are different; they may extend a patentee’s economic power beyond the scope of an intellectual property right. Conditional refusals therefore pose a risk of welfare-reducing strategic behavior that goes beyond the scope of power granted by Congress and which therefore may require antitrust analysis”); ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS, *supra* at 6 (stating “[c]onditional refusals to license that cause competitive harm are subject to antitrust liability”).

C. INEQUITABLE CONDUCT AND THE DUTY OF CANDOR

A patent applicant and other individuals associated with filing and prosecuting patent applications (*e.g.*, the applicant’s attorney) owe a duty of candor in dealing with the PTO. This means that for each pending claim, information known to be “material” to patentability must be disclosed to the PTO. The duty of candor, grounded in 37 C.F.R. § 1.56, is based on the notion that the “public interest is best served when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to

patentability.” Rule 1.56(a). An individual who violates this duty of candor is guilty of *inequitable conduct*, which is the subject of the *Kingsdown* and *Agfa* cases.

KINGSDOWN MED. CONSULTANTS, LTD. v. HOLLISTER, INC.

863 F.2d 867 (Fed. Cir. 1988)

MARKEY, Chief Judge.

Kingsdown Medical Consultants, Ltd. and E.R. Squibb & Sons, Inc., (Kingsdown) appeal from a judgment of the United States District Court for the Northern District of Illinois, holding U.S. Patent No. 4,460,363 ('363) unenforceable because of inequitable conduct before the United States Patent and Trademark Office (PTO). We reverse and remand.

BACKGROUND

Kingsdown sued Hollister Incorporated (Hollister) for infringement of claims 2, 4, 5, 9, 10, 12, 13, 14, 16, 17, 18, 27, 28, and 29 of Kingsdown's '363 patent. The district court held the patent unenforceable because of Kingsdown's conduct in respect of claim 9 and reached no other issue.

The invention claimed in the '363 patent is a two-piece ostomy appliance for use by patients with openings in their abdominal walls for release of waste.

The two pieces of the appliance are a pad and a detachable pouch. The pad is secured to the patient's body encircling the abdominal wall opening. Matching coupling rings are attached to the pad and to the pouch. When engaged, the rings provide a water tight seal. Disengaging the rings allows for removal of the pouch.

A. The Prosecution History

Kingsdown filed its original patent application in February 1978. The '363 patent issued July 17, 1984. The intervening period of more than six-and-a-half years saw a complex prosecution, involving the submission, rejection, amendment, re-numbering, etc., of 118 claims, a continuation application, an appeal, a petition to make special, and citation and discussion of 44 references.

After a series of office actions and amendments, Kingsdown submitted claim 50. . . . The examiner found that claim 50 contained allowable subject matter, but rejected the claim for indefiniteness under 35 U.S.C. § 112, second paragraph, objecting to “encircled,” because the coupling ring could not, in the examiner's view, “encircle” the aperture in the pad, the ring and aperture not being “coplanar.” The examiner had not in earlier actions objected to “encircled” to describe similar relationships in other claims. Nor had the examiner found the identical “encircled” language indefinite in original claims 1 and 6 which were combined to form claim 50.

To render claim 50 definite, and thereby overcome the § 112 rejection, Kingsdown amended the claim. . . . In an advisory action, the examiner said the changes in claim language overcame the § 112 rejection and that amended claim 50 would be allowable.

While Kingsdown's appeal of other rejected claims was pending, Kingsdown's patent attorney saw a two-piece ostomy appliance manufactured by Hollister. Kingsdown engaged an outside counsel to file a continuation application and withdrew the appeal.

Thirty-four claims were filed with the continuation application. . . . In prosecuting the continuation, a total of 44 references, including 14 new references, were cited and 29 claims were substituted for the 34 earlier filed, making a total of 63 claims presented. Kingsdown submitted a two-column list, one column containing the claim numbers of 22 previously allowed claims, the other column containing the claim numbers of the 21 claims in the continuation application that corresponded to those previously allowed claims. That list indicated, incorrectly, that claim 43 in the continuation application corresponded to allowed claim 50 that had been rejected for indefiniteness under § 112. Claim 43 was renumbered as the present claim 9 in the '363 patent.

* * *

B. The District Court

The district court rendered its opinion and announced its decision orally from the bench.

Having examined the prosecution history, the district court found that the examiner could have relied on the representation that claim 43 corresponded to allowable claim 50 and rejected Kingsdown's suggestion that the examiner must have made an independent examination of claim 43, because: (1) in the Notice of Allowance, the examiner said the claims were allowed "in view of applicant's communication of 2 July 83." [The correct date was 2 July 1982.] (2) There was no evidence that the examiner had compared the language of amended claim 50 with that of claim 43; and (3) the examiner could justifiably rely on the representation because of an applicant's duty of candor.

The court found the deceitful intent element of inequitable conduct, because Kingsdown was grossly negligent in not noticing the error, or, in the alternative, because Kingsdown's acts indicated an intent to deceive the PTO.

The court found that Kingsdown's patent attorney was grossly negligent in not catching the misrepresentation because a mere ministerial review of the language of amended claim 50 in the parent application and of claim 43 in the continuing application would have uncovered the error, and because Kingsdown's patent attorney had had several opportunities to make that review.

* * *

ISSUE

Whether the district court's finding of intent to deceive was clearly erroneous, rendering its determination that inequitable conduct occurred an abuse of discretion.

OPINION

We confront a case of first impression, in which inequitable conduct has been held to reside in an incorrect inclusion in a continuation application of a claim that contained allowable subject matter, but had been rejected as indefinite in the parent application.

Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence. *J. P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984), *cert. denied*, 474 U.S. 822 (1985). The findings on materiality

and intent are subject to the clearly erroneous standard of Rule 52(a) Fed. R. Civ. P. and are not to be disturbed unless this court has a definite and firm conviction that a mistake has been committed. *J. P. Stevens*, 747 F.2d at 1562.

"To be guilty of inequitable conduct, one must have intended to act inequitably." *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987). Kingsdown's attorney testified that he was not aware of the error until Hollister mentioned it in March 1987, and the experts for both parties testified that they saw no evidence of deceptive intent. As above indicated, the district court's finding of Kingsdown's intent to mislead is based on the alternative grounds of: (a) gross negligence; and (b) acts indicating an intent to deceive. Neither ground, however, supports a finding of intent in this case.

a. Negligence

The district court inferred intent based on what it perceived to be Kingsdown's gross negligence. Whether the intent element of inequitable conduct is present cannot always be inferred from a pattern of conduct that may be described as gross negligence. That conduct must be sufficient to require a finding of deceitful intent in the light of all the circumstances. We are not convinced that deceitful intent was present in Kingsdown's negligent filing of its continuation application or, in fact, that its conduct even rises to a level that would warrant the description "gross negligence."

It is well to be reminded of what actually occurred in this case — a ministerial act involving two claims, which, because both claims contained allowable subject matter, did not result in the patenting of anything anticipated or rendered obvious by anything in the prior art and thus took nothing from the public domain. In preparing and filing the continuation application, a newly-hired counsel for Kingsdown had two versions of "claim 50" in the parent application, an unamended rejected version and an amended allowed version. As is common, counsel renumbered and transferred into the continuation all (here, 22) claims "previously allowed". In filing its claim 43, it copied the "wrong", *i.e.*, the rejected, version of claim 50. That error led to the incorrect listing of claim 43 as corresponding to allowed claim 50 and to incorporation of claim 43 as claim 9 in the patent. In approving the continuation for filing, Kingsdown's regular attorney did not, as the district court said, "catch" the mistake.

In view of the relative ease with which others also overlooked the differences in the claims, Kingsdown's failure to notice that claim 43 did not correspond to the amended and allowed version of claim 50 is insufficient to warrant a finding of an intent to deceive the PTO. Undisputed facts indicating that relative ease are: (1) the similarity in language of the two claims; (2) the use of the same claim number, 50, for the amended and unamended claims; (3) the multiplicity of claims involved in the prosecution of both applications; (4) the examiner's failure to reject claims using "encircled" in the parent application's first and second office actions, making its presence in claim 43 something less than a glaring error; [The word "encircled" was the basis of the examiner's § 112 rejection in claim 50. But the examiner did not object to an identical use of "encircled" in two other claims.] (5) the two-year interval between the rejection/amendment of claim 50 and the filing of the continuation; (6) failure of the examiner to reject claim 43 under § 112 or to notice the differences between claim 43 and amended claim 50 during what must be presumed, absent contrary evidence, to have been an examination of the

continuation; and (7) the failure of Hollister to notice the lack of correspondence between claim 43 and the amended version of claim 50 during three years of discovery and until after it had carefully and critically reviewed the file history 10 to 15 times with an eye toward litigation. That Kingsdown did not notice its mistake during more than one opportunity of doing so, does not in this case, and in view of Hollister's frequent and focused opportunities, establish that Kingsdown intended to deceive the PTO.

We do not, of course, condone inattention to the duty of care owed by one preparing and filing a continuation application. Kingsdown's counsel may have been careless, but it was clearly erroneous to base a finding of intent to deceive on that fact alone.

* * *

Thus the first basis for the district court's finding of deceitful intent (what it viewed as "gross negligence") cannot stand.

b. Acts

The district court also based its finding of deceitful intent on the separate and alternative inferences it drew from Kingsdown's acts in viewing the Hollister device, in desiring to obtain a patent that would "cover" that device, and in failing to disclaim or reissue after Hollister charged it with inequitable conduct. The district court limited its analysis here to claim 9 and amended claim 50.

It should be made clear at the outset of the present discussion that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant and cannot of itself evidence deceitful intent.

The district court appears to have dealt with claim 9 in isolation because of Hollister's correct statement that when inequitable conduct occurs in relation to one claim the entire patent is unenforceable. *J.P. Stevens*, 747 F.2d at 1561. But Hollister leapfrogs from that correct proposition to one that is incorrect, *i.e.*, that courts may not look outside the involved claim in determining, in the first place, whether inequitable conduct did in fact occur at all. Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings, to the prior art, to an attorney's remarks, to co-pending and continuing applications, and often, as here, to earlier or later versions of itself in light of amendments made to it. The district court accepted Hollister's argument that Kingsdown included claim 43 (unamended claim 50) in its continuing application because its chances of proving infringement of claim 43 were greater than would have been its chances of proving infringement of amended claim 50, in view of Hollister's "floating flange" argument against infringement of the latter. Neither the court nor Hollister tells us how Kingsdown could have known in July 1982 what Hollister's defense would be years later, when suit was filed.

Faced with Hollister's assertion that an experienced patent attorney would knowingly and intentionally transfer into a continuing application a

claim earlier rejected for indefiniteness, without rearguing that the claim was not indefinite, the district court stated that “how an experienced patent attorney could allow such conduct to take place” gave it “the greatest difficulty.” A knowing failure to disclose and knowingly false statements are always difficult to understand. However, a transfer of numerous claims *en masse* from a parent to a continuing application, as the district court stated, is a ministerial act. As such, it is more vulnerable to errors which by definition result from inattention, and is less likely to result from the scienter involved in the more egregious acts of omission and commission that have been seen as reflecting the deceitful intent element of inequitable conduct in our cases.

The district court, in finding intent, made a passing reference to Kingsdown’s continuation of its suit after Hollister charged inequitable conduct. Hollister vigorously argues before us that Kingsdown’s continuing its suit while failing to disclaim or reissue is proof of bad faith. A failure to disclaim or reissue in 1987, however, would not establish that Kingsdown acted in bad faith when it filed its continuation application in 1982. Moreover, a suggestion that patentees should abandon their suits, or disclaim or reissue, in response to every charge of inequitable conduct raised by an alleged infringer would be nothing short of ridiculous. The right of patentees to resist such charges must not be chilled to extinction by fear that a failure to disclaim or reissue will be used against them as evidence that their original intent was deceitful. Nor is there in the record any basis for expecting that any such disclaimer or reissue would cause Hollister to drop its inequitable conduct defense or refrain from reliance on such remedial action as support for that defense. Kingsdown’s belief in its innocence meant that a court test of the inequitable conduct charge was inevitable and appropriate. A requirement for disclaimer or reissue to avoid adverse inferences would merely encourage the present proliferation of inequitable conduct charges.

We are forced to the definite and firm conviction that a mistake has been committed, amounting to an abuse of discretion. The district court’s finding of deceitful intent was clearly erroneous.

RESOLUTION OF CONFLICTING PRECEDENT

“Gross Negligence” and the Intent Element of Inequitable Conduct

Some of our opinions have suggested that a finding of gross negligence compels a finding of an intent to deceive. Others have indicated that gross negligence alone does not mandate a finding of intent to deceive.

“Gross negligence” has been used as a label for various patterns of conduct. It is definable, however, only in terms of a particular act or acts viewed in light of all the circumstances. We adopt the view that a finding that particular conduct amounts to “gross negligence” does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.

Nature of Question

Some of our opinions have indicated that whether inequitable conduct occurred is a question of law. In *Gardco Mfg. Inc. v. Herst Lighting Co.*, 820 F.2d

1209, 1212 (Fed. Cir. 1987) (citing *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806 (1945)), the court indicated that the inequitable conduct question is equitable in nature. We adopt the latter view, *i.e.*, that the ultimate question of whether inequitable conduct occurred is equitable in nature.

Standard of Review

As an equitable issue, inequitable conduct is committed to the discretion of the trial court and is reviewed by this court under an abuse of discretion standard. We, accordingly, will not simply substitute our judgment for that of the trial court in relation to inequitable conduct.

Effect of Inequitable Conduct

When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable. We, *en banc*, reaffirm that rule as set forth in *J.P. Stevens*.

CONCLUSION

Having determined that the district court's finding of intent is clearly erroneous, the panel reverses the judgment based on a conclusion of inequitable conduct before the PTO and remands the case for such further proceedings as the district court may deem appropriate.

AGFA CORP. v. CREO PRODUCTS INC.

451 F.3d 1366 (Fed. Cir. 2006)

RADER, Circuit Judge.

After a bench trial, the United States District Court for the District of Massachusetts declared all of Agfa Corporation's asserted patents unenforceable for inequitable conduct. [T]his court affirms.

I.

Large scale printing typically uses presses with plates made of materials such as aluminum or polyester. Conventionally, those plates are formed with a two-step method. The first step places a desired image on polyester film. The next step transfers that image to the printing plate. A light-sensitive chemical emulsion on the plate often facilitates that transfer. Mounted on the printing press, the plate then reproduces images in a conventional manner.

Unlike that conventional technique, "computer-to-plate" (CTP) systems take a desired image, which can include both written and graphic content, and transfer that image directly from a computer onto the plate. These plates made with a CTP system then substitute for conventionally formed plates. CTP systems offer clear advantages over conventional methods of forming printing plates.

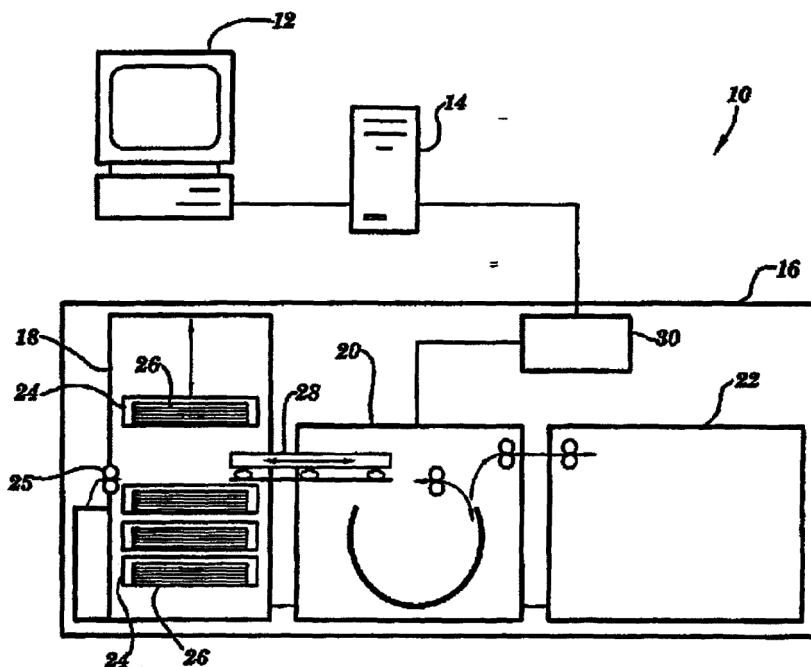
Agfa owns U.S. Patent Nos. 5,655,452 (the '452 patent); 5,738,014 (the '014 patent); 5,788,455 (the '455 patent); 5,791,250 (the '250 patent); 5,992,324 (the '324 patent); and 6,000,337 (the '337 patent). Those patents claim various features of Agfa's CTP system, *i.e.*, its "Galileo" system. As taught in the

asserted patents, Agfa's Galileo system further improves CTP automation by facilitating the creation of multiple plates of different sizes. Agfa's patents all feature the same specification and drawings. Figure 1 of the '452 patent, reproduced below, is representative of Agfa's patented system.

As shown in that figure, CTP system 10 includes a computer 12 and image processor 14 linked to a platesetter 16. The platesetter includes a plate handler 18 having a number of cassettes 24, which include stacks of plates 26. During operation, the handler 18 can move the cassettes up or down such that a "picker" 28 can access any particular individual plate. Each cassette can include up to 100 plates, each separated from the adjoining plates by a protective "slip sheet," which is automatically removed by a slip sheet removal mechanism 25. While each cassette contains plates of the same size, plate size can differ from cassette to cassette. Thus, during operation, the "picker" can change plate size by selecting a different cassette.

Because the plates are light sensitive, an operator loads the cassettes in a darkroom. After receiving the cassettes, the system operates without human intervention. The system selects a plate and transfers it to the imaging engine 22. The imaging engine prints an image directly onto the plate. The claim construction dispute in this case, however, concerns the plate handler 18. More specifically, as discussed below, the claim construction dispute concerns the meaning of the term "stack" that appears in every asserted claim.

Agfa and Creo compete in the CTP market. Agfa sued Creo alleging that Creo's CTP system infringed all of Agfa's Galileo patents. As a defense, as well as a counterclaim, Creo asserted that all of Agfa's Galileo patents are unenforceable due to Agfa's inequitable conduct before the United States Patent and Trademark Office (PTO). According to Creo, Agfa wrongfully declined to disclose material prior art to the PTO during prosecution of Agfa's asserted patents. Specifically, Creo contended that Agfa did not disclose at least three



prior art systems, the Creo Platesetter 3244, the Barco LithoSetter, and the Gerber Crescent/42. Creo further asserted that this prior art was more relevant to Agfa's applications than the single reference discussed in the specification common to all of Agfa's applications, a U.S. Patent on computer-to-film printing.

II.

* * *

B. Inequitable Conduct

1. Claim Construction

To reach inequitable conduct, the trial court necessarily construed the claims. According to Agfa, the trial court misconstrued the term "stack," common to all asserted claims. As a representative example of the asserted claims, claim 1 of the '452 patent recites:

1. A method for automatically selecting a plate for imaging in an automated plate handler, comprising the steps of:
 - a. automatically positioning a plurality of *stacks of plates* stored in the plate handler and placing *a stack* of the plate size required for an imaging job in an access position;
 - b. automatically separating and removing a single plate from the stack of plates in the access position and transferring the single plate out of the plate handler for imaging; and
 - c. automatically removing a slip sheet from on top of *the stack of plates* in the access position.

'452 patent, col. 11, l. 66-col. 12, l. 11 (emphasis added). Agfa argues that the term "stack" covers only a horizontal arrangement of plates, like those shown in figure 1 of the '452 patent, reproduced above. The trial court disagreed, construing stack as "encompassing a number of plates arranged together in an orderly fashion, regardless of the orientation (horizontal or vertical) of the collection as a whole." This court perceives that the trial court's construction, and its reasoning leading to that construction, is sound.

The trial court first consulted the ordinary meaning of "stack," for which it cited a dictionary definition. As this court explained in *Phillips v. AWH Corp.*, the ordinary meaning of some claim terms "may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of widely accepted meaning of commonly understood words." 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). "In such cases, general purpose dictionaries may be helpful." *Id.* This case falls squarely within those guidelines from *Phillips*. The customary meaning within this field of art does not limit the term "stack."

The meaning of the claim language does not limit "stack" to plates arranged one on top of another. Accordingly, when a stack is tilted more than 45 degrees, it remains a stack because the plates are still arranged in a top-to-bottom fashion. After all, the top of a plate remains its top even when that plate tilts beyond 45 degrees. In other words, the relationship of plates in a stack depends on the orientation of those plates relative to one another. The

orientation of the resulting stack from the vantage point of elements outside the stack is irrelevant.

Moreover, nothing in the disclosures of the asserted patents suggests that “stack” has any meaning in the art that would limit its scope to horizontal stacks. The trial court buttressed its construction with the observation that three of the asserted patents include dependent claims that further specify a horizontal (or other particular) arrangement of the claimed stacks. *See, e.g.*, ’250 patent, col. 12, ll. 16-18 (claim 2) (“The method according to claim 1, wherein the stacks of plates stored in the plate handler are positioned substantially horizontally.”). Properly applying the claim differentiation guideline in the context of dependent claims, the trial court correctly found support for the proposition that those dependent claims suggest that the “stack” standing alone is not limited to horizontally positioned stacks.

Similar to this court in *Phillips* itself, the trial court declined to limit these patent claims to their preferred embodiment. The asserted patents indeed depict a horizontal arrangement of stacks as the preferred embodiment. As noted, this court has repeatedly rejected the contention that depiction of a single embodiment in a patent necessarily limits the claims to that depicted scope. This case illustrates again the reason for this court’s refusal to limit broader claim language to a preferred embodiment in the patent specification. Of necessity, any depiction of any stack will necessarily show that stack arranged in a particular manner. Nothing beyond that depiction, however, limits the claim language—the defining portion of the patent document—to some particular orientation. Without any indication beyond the necessary depiction to suggest limiting the invention to this single embodiment, the broader language of the claims cannot carry that unexpressed and unintended (at the time of patent drafting) limitation.

2. Materiality

Unenforceability due to inequitable conduct requires proof of materiality and intent by clear and convincing evidence. Upon finding evidence that satisfies a threshold measure of materiality and intent, the trial court then weighs that evidence to determine that the equities warrant a conclusion of inequitable conduct. In evaluating materiality, the trial court followed the standard set forth in PTO Rule 56. That rule considers information material to patentability when:

[I]t is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2004). The trial court found that the information withheld by Agfa satisfied both parts (1) and (2) of that rule. With respect to prima facie unpatentability, part (1) of Rule 56, the trial court focused on prior art CTP systems, patents, and brochures. This prior art, taken alone or in combination, established a prima facie case of unpatentability for claims in each of Agfa’s

asserted patents. The primary challenge to the trial court's materiality finding was that an incorrect claim construction caused error in findings of materiality. Because, as discussed above, the trial court's claim construction was correct, these challenges of error fail.

The trial court also found that the undisclosed prior art was inconsistent with Agfa's position during examination, and so was also material under part (2) of Rule 56. During examination of two of Agfa's applications, the examiner requested clarification about the CTP technology described in the Background sections. In particular, the examiner wished to know what aspects of the CTP technology described in the Background were actually conventional. The trial court found that Agfa's responses to the examiner "were misleading in light of all the information [the patent agent's] had about the Undisclosed CTP References. . . . Indeed, [one of the patent agents] admitted that he could not have made the arguments he did make in response to the Examiner's request if he had disclosed the Creo Platesetter 3244 or the Barco LithoSetter. . . ." *Id.*

On appeal, Agfa responds that Rule 56 "does not provide that a 'misleading' statement is material." Appellant's Brief at 56. This contention belies the weakness of Agfa's position. The trial court did not find that the misleading statements were material. Instead, the trial court found that undisclosed prior art was material because it was inconsistent with Agfa's misleading statements to the examiner during prosecution.

3. Intent

Turning to intent, the trial court found abundant evidence from which to infer Agfa's culpable intent. For example, the evidence regarding Agfa's knowledge of the Creo Platesetter 3244 was overwhelming: senior Agfa employees, including an inventor named on all the asserted patents and the agents who prosecuted the applications, attended an exposition put on by Agfa at which Creo's product was displayed; Agfa and Creo entered into a reseller agreement under which Agfa agreed to sell Creo's platesetter outside the United States; and Agfa distributed brochures describing Creo's products. In the words of the trial court, "[i]t was widely known within Agfa, including among the engineering and patent departments, that Agfa was selling Creo's Platesetter 3244, and that Creo was a significant player in the field of CTP output devices." *Id.* In addition to Agfa's particular familiarity with Creo's platesetter, the trial court explained that Agfa was well aware of other CTP prior art. According to the trial court, during development of the Galileo project, Agfa kept a spreadsheet entitled "Overview of [CTP] Products." The inventors common to all Agfa's asserted patents possessed that spreadsheet, including its information on the Creo Platesetter 3244, the Barco LithoSetter, and the Gerber Crescent/42. Based on Agfa's extensive knowledge of the prior art, the trial court reasoned that "[Agfa's] failure to disclose information about [the various] CTP systems to the [PTO] supports an inference of intent to deceive because patentability arguments could not have been made had the withheld information been disclosed."

Both the evidence and the law support the trial court's intent determination. This court has held that a trial court may infer deceptive intent based on a showing that a patentee withheld references with which it was intimately familiar and which were inconsistent with its own patentability arguments to the PTO. *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001)

(citing *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992)). “[A] patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish subject good faith sufficient to prevent the drawing of an inference of intent to mislead.” *Id.*

On appeal, Agfa questions the trial court’s intent finding based on its claim construction argument. Specifically, Agfa argues that regardless of the proper meaning of “stack,” it understood that term as applying only to horizontal stacks. Accordingly, Agfa contends that it should not be charged with knowledge of materiality under a claim construction it did not anticipate. Without knowledge of materiality, Agfa argues, the trial court cannot properly infer intent.

To the contrary, the trial court found Agfa’s assertion that its patent agents did not appreciate the materiality of the undisclosed references, or that they unintentionally withheld those references, not credible. Specifically, the trial court relied on the substantial documentation and internal discussions of those references in the design and creation of the Galileo system. This court must defer heavily to the trial court’s credibility determinations. *JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1334 (Fed. Cir. 2005) (“[C]redibility determinations by the trial judge can virtually never be clear error.”).

In addition, Agfa’s claim construction argument seems to assume that it had no obligation to submit prior art that did not include horizontal stacks. In Agfa’s words: “[w]hen stack is given its ordinary meaning of objects placed one on top of another, the CTP references that disclose vertically-oriented plates clearly do not establish a *prima facie* case of *anticipation*.” Thus, Agfa seeks to confine the material references that support an intent finding to only those references that anticipate the claimed invention. Materiality is not synonymous with anticipation, but instead embraces the broader concept of patentability. Thus, even if Agfa’s assertions about its understanding of “stack” during prosecution were accepted, the undisclosed prior art would still have been material because some, but not all, of that art included horizontally arranged stacks.

With respect to the ’324 patent, that patent is a continuation of the ’014 patent, about which the district court made specific findings. Thus, *Fox Industries, Inc. v. Structural Preservation Systems, Inc.*, 922 F.2d 801 (Fed. Cir. 1990), supports the trial courts decision regarding the ’324 patent. *Fox Industries* explains that inequitable conduct “early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.” *Id.* at 804. Later applications are, of course, not always tainted by the inequitable conduct of earlier applications. See *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1332 (Fed. Cir. 1998) (“[W]here the claims are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application.”). The ’324 patent is a continuation, not a divisional, of the ’014 patent. Furthermore, Agfa has not suggested that the ’324 patent claims subject matter sufficiently distinct from its parent to preclude the trial court’s inequitable conduct determination. Thus, the trial court’s inequitable conduct analysis properly included the ’324 patent.

4. Balancing

Beyond the trial court's findings of materiality and intent, Agfa also challenges the trial court's inequitable conduct determination based on those findings. Agfa's argument is that, notwithstanding its detailed inequitable conduct analysis, the district court did not perform a balancing of materiality and intent. This court, however, has no doubt that the district court perceived this to be a case of intentional, large scale, inequitable conduct. "The inequitable conduct established by the evidence here was not incidental or sporadic, but thoroughgoing." The district court paints a picture of a group of engineers and patent agents who set out to design their own version of their competitors' products by attending trade shows and reviewing literature, all the while taking notes and holding meetings to decide which features from which printing presses would work well in Agfa's Galileo system. Those same agents then prepared and prosecuted the asserted patents, never sharing with the PTO any of the information they had compiled about the products upon which they modeled their system. The trial court thus found high levels of both materiality and intent, and did so with respect to numerous undisclosed pieces of prior art. In such a case, the trial court did not err by issuing its opinion without an express and detailed balancing analysis.

Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003), also supports this result. In *Hoffmann-La Roche*, this court explained the importance of determining "whether the material misrepresentations or omissions in question are sufficiently serious in the light of the evidence of intent to deceive, to warrant the severe sanction of holding the patent unenforceable." *Id.* at 1372. In *Hoffmann-La Roche*, this court remanded both because this court had not upheld all of the grounds for unenforceability and because the trial court had not addressed the weight of the various findings of materiality and intent. *Id.* In this case, however, this court has upheld the trial court's findings of high levels of both materiality and intent. With those findings firmly established in this case, the district court's less express balancing sufficed. In this setting, *Hoffmann-La Roche* does not require more.

Comments

1. **The Duty of Candor.** Rule 1.56 (commonly referred to as "rule 56") imposes a duty of candor and good faith on persons prosecuting patent applications before the PTO. This duty applies not only to applicants, but to "each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application." See *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 n.6 (Fed. Cir. 1995). One who violates this duty is guilty of inequitable conduct, which renders the entire patent unenforceable, irrespective of the validity of the claims. See *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (en banc). See also *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006) ("If inequitable conduct occurred with respect to one or more claims of an

application, the entire patent is unenforceable.”). And unlike misuse, a finding of inequitable conduct cannot be purged. Inequitable conduct embraces an express misrepresentation of a material fact, a failure to disclose material information, or disclosure of false material information, coupled with an intent to deceive. *Molins*, 48 F.3d at 1178.

2. **Materiality.** Rule 56, which defines “material,” was amended on March 16, 1992. Prior to this time, materiality was defined as information a reasonable examiner would have considered important in deciding whether to allow the application to issue as a patent. The 1992 amendment added specificity to the meaning of materiality, defining it as information that “is not cumulative to information already of record or being made of record,” and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

- (i) Opposing an argument of unpatentability relied on by the Office, or
- (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (1999). But the pre-1992 rule 56 remains relevant and continues to be applied by the Federal Circuit. See *Digital Control, Inc. v. The Charles Machine Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (holding that pre-1992 “reasonable examiner” standard remains sufficient ground for inequitable conduct materiality even after 1992 amendment of 37 C.F.R. § 1.56). Under either standard, a reference can be material even though the patent would have issued if the examiner knew about the reference. See *Li Second Family v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000) (stating “[i]nformation concealed from the PTO may be material even though it would not invalidate the patent.”); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997) (prior art found to be material even though patent would have issued had reference been disclosed). The lesson is that in “[c]lose cases, the question of materiality should be resolved by disclosure.” *LaBounty Mfg., Inc. v. United States Int’l Trade Comm’n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992). Materiality attaches not only to prior art references such as patents, but also to false affidavits and declarations. See *Digital Control*, 437 F.3d at 1318 (stating “the submission of a false affidavit may be determined to be ‘inherently material’”).

3. **Intent.** The intent prong of inequitable conduct focuses on intent to *deceive*, not intent to withhold. See *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003) (stating “[i]ntent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible”). Proving intent in any setting is difficult. In the context of inequitable conduct, there is rarely evidence of a “smoking gun.” But this type of explicit evidence is not necessary to satisfy the intent prong of inequitable conduct. Rather, intent is typically “inferred from the facts and circumstances surrounding the applicant’s overall conduct.” *Paragon Podiatry Lab., Inc. v. KLM Labs, Inc.*, 984 F.2d 1182, 1189 (Fed. Cir. 1993). While circumstantial evidence is permissible, the patentee’s conduct must rise to a level greater than gross negligence. *Kingsdown*, 863 F.2d at 876.

The omission of material information is particularly troubling. As the court in *Paragon* noted, the “concealment of sales information can be

particularly egregious because, unlike the applicant's failure to disclose, for example, a material patent reference, the examiner has no way of securing the information on his own." *Id.* at 1193. *See also Semiconductor Energy Laboratory Co., Ltd. v. Samsung Electronics Co., Ltd.*, 204 F.3d 1368 (Fed. Cir. 2000) (finding requisite intent when a single page, English-language translation of Japanese-language reference omitted a material portion of the reference); *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007) (stating "[w]hile [patentee] wholly neglected to disclose the Festival Market sales to the PTO, it enthusiastically touted sales made after the critical date as evidence of the commercial appeal of its process. That combination of action and omission permits an inference of the minimum, threshold level of intent required for inequitable conduct").

4. **Balancing Materiality and Intent.** A party challenging a patent on inequitable conduct grounds must establish threshold levels of both materiality and intent. Only then can a court weigh both to determine whether a finding of inequitable conduct is warranted. *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 744 (Fed. Cir. 2002) (stating "[i]nequitable conduct entails a two-step analysis: first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all of the circumstances to determine whether the applicant's conduct is so culpable that the patent should be unenforceable"). Importantly, the more material a particular reference, the less evidence of intent is required, and vice versa. In other words, there is an inverse relationship between materiality and intent. *See Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991).

D. EXPERIMENTAL USE

There are two forms of experimental use—statutory and common law. Regarding the former, under § 271(e) certain activities are exempted from infringement, namely activity that is “solely for uses reasonably related to the development and submission of information” under federal food and drug laws. This safe harbor is known as the Bolar Amendment or FDA exemption, and the breadth of its reach was at issue in *Merck v. Integra Lifesciences I*, the principal case below. The common law exemption, while it remains, is not robust and is explored in *Madey v. Duke*, the principal case in § D.2. Indeed, the Federal Circuit has never applied the doctrine in a manner that would absolve infringement liability.

1. Statutory Experimental Use Under § 271(e)(1)

MERCK v. INTEGRA LIFESCIENCES I

545 U.S. 193 (2005)

Justice SCALIA delivered the opinion of the Court.

This case presents the question whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U.S.C. § 271(e)(1).

I

It is generally an act of patent infringement to “mak[e], us[e], offe[r] to sell, or sel[l] any patented invention . . . during the term of the patent therefor.” § 271(a). In 1984, Congress enacted an exemption to this general rule, see Drug Price Competition and Patent Term Restoration Act of 1984 as amended, 35 U.S.C. § 271(e)(1), which provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) . . .) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. . . .

The Federal Food, Drug, and Cosmetic Act (FDCA), is “a Federal law which regulates the manufacture, use, or sale of drugs.” See 21 U.S.C. § 355(a). Under the FDCA, a drugmaker must submit research data to the FDA at two general stages of new-drug development.¹ First, a drugmaker must gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application (IND). See 21 U.S.C. § 355(i). The IND must describe “preclinical tests (including tests on animals) of [the] drug adequate to justify the proposed clinical testing.” 21 U.S.C. § 355(i)(1)(A); see 21 CFR §§ 312.23(a)(5) and (a)(8) (specifying necessary information from preclinical tests). Second, to obtain authorization to market a new drug, a drugmaker must submit a new drug application (NDA), containing “full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use.” 21 U.S.C. § 355(b)(1). Pursuant to FDA regulations, the NDA must include all clinical studies, as well as preclinical studies related to a drug’s efficacy, toxicity, and pharmacological properties.

II

A

Respondents Integra Lifesciences I, Ltd., and the Burnham Institute, own five patents related to the tripeptide sequence Arg-Gly-Asp, known in single-letter notation as the “RGD peptide.” U.S. Patent Nos. 4,988,621, 4,792,525, 5,695,997, 4,879,237, and 4,789,734. The RGD peptide promotes cell ad-

1. Drugmakers that desire to market a generic drug (a drug containing the same active ingredients as a drug already approved for the market) may file an abbreviated new drug application (ANDA) with the FDA. See 21 U.S.C. § 355(j). The sponsor of a generic drug does not have to make an independent showing that the drug is safe and effective, either in preclinical or clinical studies. See § 355(j)(2)(A). It need only show that the drug includes the same active ingredients as, and is bioequivalent to, the drug that it is mimicking. See §§ 355(j)(2)(A)(ii) and (iv); § 355(j)(8)(B).

hesion by attaching to $\alpha_v\beta_3$ integrins, receptors commonly located on the outer surface of certain endothelial cells.

Beginning in 1988, petitioner Merck KGaA provided funding for angiogenesis research conducted by Dr. David Cheresh at the Scripps Research Institute (Scripps). Angiogenesis is the process by which new blood vessels sprout from existing vessels; it plays a critical role in many diseases, including solid tumor cancers, diabetic retinopathy, and rheumatoid arthritis. In the course of his research, Dr. Cheresh discovered that it was possible to inhibit angiogenesis by blocking the $\alpha_v\beta_3$ integrins on proliferating endothelial cells. In 1994, Dr. Cheresh succeeded in reversing tumor growth in chicken embryos, first using a monoclonal antibody (LM609) he developed himself and later using a cyclic RGD peptide (EMD 66203) provided by petitioner. Dr. Cheresh's discoveries were announced in leading medical journals and received attention in the general media.

With petitioner's agreement to fund research at Scripps due to expire in July 1995, Dr. Cheresh submitted a detailed proposal for expanded collaboration between Scripps and petitioner on February 1, 1995. The proposal set forth a 3-year timetable in which to develop "integrin antagonists as angiogenesis inhibitors," beginning with *in vitro* and *in vivo* testing of RGD peptides at Scripps in year one and culminating with the submission of an IND to the FDA in year three. Petitioner agreed to the material terms of the proposal on February 20, 1995, and on April 13, 1995, pledged \$6 million over three years to fund research at Scripps. Petitioner's April 13 letter specified that Scripps would be responsible for testing RGD peptides produced by petitioner as potential drug candidates but that, once a primary candidate for clinical testing was in "the pipeline," petitioner would perform the toxicology tests necessary for FDA approval to proceed to clinical trials.

Pursuant to the agreement, Dr. Cheresh directed *in vitro* and *in vivo* experiments on RGD peptides provided by petitioner from 1995 to 1998. These experiments focused on EMD 66203 and two closely related derivatives, EMD 85189 and EMD 121974, and were designed to evaluate the suitability of each of the peptides as potential drug candidates. Accordingly, the tests measured the efficacy, specificity, and toxicity of the particular peptides as angiogenesis inhibitors, and evaluated their mechanism of action and pharmacokinetics in animals. Based on the test results, Scripps decided in 1997 that EMD 121974 was the most promising candidate for testing in humans. Over the same period, Scripps performed similar tests on LM609, a monoclonal antibody developed by Dr. Cheresh. Scripps also conducted more basic research on organic mimetics designed to block $\alpha_v\beta_3$ integrins in a manner similar to the RGD peptides; it appears that Scripps used the RGD peptides in these tests as "positive controls" against which to measure the efficacy of the mimetics.

In November 1996, petitioner initiated a formal project to guide one of its RGD peptides through the regulatory approval process in the United States and Europe. Petitioner originally directed its efforts at EMD 85189, but switched focus in April 1997 to EMD 121974. Petitioner subsequently discussed EMD 121974 with officials at the FDA. In October 1998, petitioner shared its research on RGD peptides with the National Cancer Institute (NCI), which agreed to sponsor clinical trials.

B

On July 18, 1996, respondents filed a patent-infringement suit against petitioner, Scripps, and Dr. Cheresch in the District Court for the Southern District of California. Respondents' complaint alleged that petitioner willfully infringed and induced others to infringe respondents' patents by supplying the RGD peptide to Scripps, and that Dr. Cheresch and Scripps infringed the same patents by using the RGD peptide in experiments related to angiogenesis. Respondents sought damages from petitioner and a declaratory judgment against Dr. Cheresch and Scripps. Petitioner answered that its actions involving the RGD peptides did not infringe respondents' patents, and that in any event they were protected by the common-law research exemption and 35 U.S.C. § 271(e)(1).

At the conclusion of trial, the District Court held that, with one exception, petitioner's pre-1995 actions related to the RGD peptides were protected by the common-law research exemption, but that a question of fact remained as to whether petitioner's use of the RGD peptides after 1995 fell within the § 271(e)(1) safe harbor. . . . The jury found that petitioner, Dr. Cheresch, and Scripps infringed respondents' patents and that petitioner had failed to show that its activities were protected by § 271(e)(1). It awarded damages of \$15 million.

A divided panel of the Court of Appeals for the Federal Circuit affirmed in part, and reversed in part. The panel majority affirmed the denial of judgment as a matter of law to petitioner, on the ground that § 271(e)(1)'s safe harbor did not apply because "the Scripps work sponsored by [petitioner] was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds."

III

As described earlier, 35 U.S.C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to . . . use . . . or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs." Though the contours of this provision are not exact in every respect, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.

As an initial matter, we think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA. This necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.

Respondents concede the breadth of § 271(e)(1) in this regard, but argue that the only preclinical data of interest to the FDA is that which pertains to the safety of the drug in humans. In respondents' view, preclinical studies related to a drug's efficacy, mechanism of action, pharmacokinetics, and pharmacology are not reasonably included in an IND or an NDA, and are

therefore outside the scope of the exemption. We do not understand the FDA's interest in information gathered in preclinical studies to be so constrained. To be sure, its regulations provide that the agency's "primary objectives in reviewing an IND are . . . to assure the safety and rights of subjects," 21 CFR 312.22(a) (2005), but it does not follow that the FDA is not interested in reviewing information related to other characteristics of a drug. To the contrary, the FDA requires that applicants include in an IND summaries of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals. *See* § 312.23(a)(5). The primary (and, in some cases, only) way in which a drugmaker may obtain such information is through preclinical *in vitro* and *in vivo* studies.

Moreover, the FDA does not evaluate the safety of proposed clinical experiments in a vacuum; rather, as the statute and regulations reflect, it asks whether the proposed clinical trial poses an "unreasonable risk." 21 U.S.C. § 355(i)(3)(B)(i). This assessment involves a comparison of the risks and the benefits associated with the proposed clinical trials. As the Government's brief, filed on behalf of the FDA, explains, the "FDA might allow clinical testing of a drug that posed significant safety concerns if the drug had a sufficiently positive potential to address a serious disease, although the agency would not accept similar risks for a drug that was less likely to succeed or that would treat a less serious medical condition." Brief for United States as *Amicus Curiae* 10. Accordingly, the FDA directs that an IND must provide sufficient information for the investigator to "make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial." Department of Health and Human Services, Guidance for Industry, Good Clinical Practice: Consolidated Guidance 43 (Apr. 1996). Such information necessarily includes preclinical studies of a drug's efficacy in achieving particular results.

Respondents contend that, even accepting that the FDA is interested in preclinical research concerning drug characteristics other than safety, the experiments in question here are necessarily disqualified because they were not conducted in conformity with the FDA's good laboratory practices regulations. This argument fails for at least two reasons. First, the FDA's requirement that preclinical studies be conducted under "good laboratory practices" applies only to experiments on drugs "to determine their safety," 21 CFR § 58.3(d). *See* 21 CFR § 58.1(a); § 312.23(a)(8)(iii) (2005) (only "non-clinical laboratory study subject to the good laboratory practice regulations under part 58" must certify compliance with good laboratory practice regulations). The good laboratory practice regulations do not apply to preclinical studies of a drug's efficacy, mechanism of action, pharmacology, or pharmacokinetics. Second, FDA regulations do not provide that even safety-related experiments not conducted in compliance with good laboratory practices regulations are not suitable for submission in an IND. Rather, such studies must include "a brief statement of the reason for the noncompliance." *Ibid.*

The Court of Appeals' conclusion that § 271(e)(1) did not protect petitioner's provision of the patented RGD peptides for research at Scripps appeared to rest on two somewhat related propositions. First, the court credited the fact that the "Scripps-Merck experiments did not supply information for submission to the [FDA], but instead identified the best drug

candidate to subject to future clinical testing under the FDA processes.” 331 F.3d, at 865. The court explained:

The FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval. For instance, the FDA does not require information about drugs other than the compound featured in an [IND] application. Thus, the Scripps work sponsored by [petitioner] was not ‘solely for uses reasonably related to’ clinical testing for FDA.

Second, the court concluded that the exemption “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.” *Id.*, at 867.⁷

We do not quibble with the latter statement. Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not “reasonably related to the development and submission of information” to the FDA. It does not follow from this, however, that § 271(e)(1)’s exemption from infringement categorically excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations.

As to the first proposition, it disregards the reality that, even at late stages in the development of a new drug, scientific testing is a process of trial and error. In the vast majority of cases, neither the drugmaker nor its scientists have any way of knowing whether an initially promising candidate will prove successful over a battery of experiments. That is the reason they conduct the experiments. Thus, to construe § 271(e)(1), as the Court of Appeals did, not to protect research conducted on patented compounds for which an IND is not ultimately filed is effectively to limit assurance of exemption to the activities necessary to seek approval of a generic drug: One can know at the outset that a particular compound will be the subject of an eventual application to the FDA only if the active ingredient in the drug being tested is identical to that in a drug that has already been approved.

The statutory text does not require such a result. Congress did not limit § 271(e)(1)’s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug. Rather, it exempted from infringement *all* uses of patented compounds “reasonably related” to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs. We decline to read the “reasonable relation” requirement so narrowly as to render

7. The Court of Appeals also suggested that a limited construction of § 271(e)(1) is necessary to avoid depriving so-called “research tools” of the complete value of their patents. Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record that they were not. See 331 F.3d, at 878 (Newman, J., dissenting) (“Use of an existing tool in one’s research is quite different from study of the tool itself”). We therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of “research tools” in the development of information for the regulatory process.

§ 271(e)(1)'s stated protection of activities leading to FDA approval for all drugs illusory. Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law." § 271(e)(1).

For similar reasons, the use of a patented compound in experiments that are not themselves included in a "submission of information" to the FDA does not, standing alone, render the use infringing. The relationship of the use of a patented compound in a particular experiment to the "development and submission of information" to the FDA does not become more attenuated (or less reasonable) simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA. Moreover, many of the uncertainties that exist with respect to the selection of a specific drug exist as well with respect to the decision of what research to include in an IND or NDA. As a District Court has observed, "[I]t will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency's approval." *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (C.A. Fed. 1993). This is especially true at the preclinical stage of drug approval. FDA regulations provide only that "[t]he amount of information on a particular drug that must be submitted in an IND . . . depends upon such factors as the novelty of the drug, the extent to which it has been studied previously, the known or suspected risks, and the developmental phase of the drug." 21 CFR § 312.22(b). We thus agree with the Government that the use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce "the types of information that are relevant to an IND or NDA." Brief of United States as *Amicus Curiae* 23.

Before the Court of Appeals, petitioner challenged the sufficiency of the evidence supporting the jury's finding that it failed to show that "all of the accused activities are covered by [§ 271(e)(1)]." That court rejected the challenge on the basis of a construction of § 271(e)(1) that was not consistent with the text of that provision or the relevant jury instruction.⁸ Thus, the evidence presented at trial has yet to be reviewed under the standards set forth in the jury instruction, which we believe to be consistent with, if less detailed than, the construction of § 271(e)(1) that we adopt today. We decline to undertake a review of the sufficiency of the evidence under a proper construction of § 271(e)(1) for the first time here. Accordingly, we vacate the judgment of the Court of Appeals and remand the case for proceedings consistent with this opinion.

8. The relevant jury instruction provided only that there must be a "decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question." App. 57a. It did not say that, to fall within § 271(e)(1)'s exemption from infringement, the patented compound used in experimentation must be the subject of an eventual application to the FDA. And it expressly rejected the notion that the exemption only included experiments that produced information included in an IND or NDA. *Ibid*.

Comments

1. **On Remand.** The Federal Circuit reversed the district court's infringement finding, stating the challenged experiments, all of which were conducted after discovery of the anti-angiogenesis property of the experimental RGD peptide provided by Merck, meet the criteria of being reasonably related to research that, if successful, would be appropriate to include in a submission to the FDA. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334 (Fed. Cir. 2007).
2. **Drug Development and the FDA Regulatory Process.** Drug development is expensive, reaching into the hundreds of millions of dollars. See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). Cf. Public Citizen, *Tufts Drug Study Sample is Skewed; True Figure of R&D Costs Likely Is 75 Percent Lower* (Dec. 4, 2001). And a majority of prospective molecules/drugs get weeded out before clinical trials or ultimately do not get approved by the FDA. The development spectrum typically begins with basic research, then moves to pre-clinical studies, and finally clinical studies that invoke the FDA approval process. Basic research focuses on general understanding of particular diseases and large screening studies of various biological compounds. The pre-clinical phase centers on fewer compounds and information gathering that can lead to clinical studies, which focus of safety and efficacy through testing on human subjects.
3. **Preclinical Testing, Research Tools and Supreme Court's Expansive Reading.** The Bolar Amendment was narrowly interpreted by the Federal Circuit, which held that the exemption applies to experimentation that "would contribute (relatively directly) to information the FDA considers in approving a drug" (e.g., New Drug Application (NDA) to the FDA, which contain the results of clinical trials and must be approved by the FDA before a drug is marketed). *Integra Lifesciences I v. Merck*, 331 F.3d 860, 867 (Fed. Cir. 2004). Thus, on the development spectrum ranging from basic upstream research to the downstream clinical/NDA stage, the Federal Circuit erred on the side of downstream application when interpreting the exemption. And the court, while not expressly holding that the exemption only applies to generic drug development, suggested as much in dicta.

According to the Federal Circuit:

The exemption viewed in this context does not endorse an interpretation of § 271(e)(1) that would encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market. It does not, for instance, expand the phrase "reasonably related" to embrace all stages of the development of new drugs merely because those new products will also need FDA approval. Thus, § 271(e)(1) simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process. The safe harbor does not reach any exploratory research that may rationally form only a predicate for future FDA clinical tests.

331 F.3d at 867. A broader reading of § 271(e), stated the court, "would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions." *Id.* One category the court was referring to

was upstream discoveries such as research tool patents. Research tools, such as peptides, enzymes, and non-diagnostic antibodies, are very important for screening drug candidates and for drug discovery. They are also important revenue generators for biotechnology companies.

The Supreme Court moved the exemption further upstream to include preclinical use of patented inventions, but footnote 7 expressly noted the Court need not decide whether the FDA exemption applies to research tools. Although the Court held the exemption applies when “a drugmaker has a reasonable basis for believing that a patented compound may work” even though the information gathered is not ultimately submitted to the FDA. Thus, unlike the Federal Circuit’s interpretation of § 271(e)(1), the Court’s view of the FDA research exemption includes pre-clinical activity, but not basic research.

2. Common Law Experimental Use

MADEY v. DUKE

307 F.3d 1351 (Fed. Cir. 2002)

GAJARSA, Circuit Judge.

Dr. John M.J. Madey (“Madey”) appeals from a judgment of the United States District Court for the Middle District of North Carolina. Madey sued Duke University (“Duke”), bringing claims of patent infringement and various other federal and state law claims. For a first set of alleged infringing acts, the court held that the experimental use defense applied to Duke’s use of Madey’s patented laser technology. The district court erred in applying the experimental use defense.

BACKGROUND

In the mid-1980s Madey was a tenured research professor at Stanford University. At Stanford, he had an innovative laser research program, which was highly regarded in the scientific community. An opportunity arose for Madey to consider leaving Stanford and take a tenured position at Duke. Duke recruited Madey, and in 1988 he left Stanford for a position in Duke’s physics department. In 1989 Madey moved his free electron laser (“FEL”) research lab from Stanford to Duke. The FEL lab contained substantial equipment, requiring Duke to build an addition to its physics building to house the lab. In addition, during his time at Stanford, Madey had obtained sole ownership of two patents practiced by some of the equipment in the FEL lab.

At Duke, Madey served for almost a decade as director of the FEL lab. During that time the lab continued to achieve success in both research funding and scientific breakthroughs. However, a dispute arose between Madey and Duke. Duke contends that, despite his scientific prowess, Madey ineffectively managed the lab. Madey contends that Duke sought to use the lab’s equipment for research areas outside the allocated scope of certain government funding, and that when he objected, Duke sought to remove him as lab director. Duke eventually did remove Madey as director of the lab in 1997. The removal is not at issue in this appeal, however, it is the genesis of this unique patent infringement case. As a result of the removal, Madey resigned from

Duke in 1998. Duke, however, continued to operate some of the equipment in the lab. Madey then sued Duke for patent infringement of his two patents, and brought a variety of other claims.

A. The Patents and Infringing Equipment

One of Madey's patents, U.S. Patent No. 4,641,103 ("the '103 patent"), covers a "Microwave Electron Gun" used in connection with free electron lasers. The other patent, U.S. Patent No. 5,130,994 ("the '994 patent"), is titled "Free-Electron Laser Oscillator For Simultaneous Narrow Spectral Resolution And Fast Time Resolution Spectroscopy." The details of these two patents are not material to the issues on appeal. Their use in the lab, however, as embodied in certain equipment, is central to this appeal.

The three alleged infringing devices are the Mark III FEL, the Storage Ring FEL, and the Microwave Gun Test Stand. Although it is not clear from the record, perhaps because Duke defended by asserting experimental use and government license defenses, Duke seems to concede that the alleged infringing devices and methods read on the claims of the patents.

The Patent Motion and the Experimental Use Defense

The district court acknowledged a common law "exception" for patent infringement liability for uses that, in the district court's words, are "solely for research, academic or experimental purposes." The district court recognized the debate over the scope of the experimental use defense, but cited this court's opinion in *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) to hold that the defense was viable for experimental, non-profit purposes, citing *Embrex*, 216 F.3d at 1349 (noting that courts should not "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes" (quoting *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984))).³

After having recognized the experimental use defense, the district court then fashioned the defense for application to Madey in the passage set forth below.

Given this standard [for experimental use], for [Madey] to overcome his burden of establishing actionable infringement in this case, he must establish that [Duke] has not used the equipment at issue "solely for an experimental or other non-profit purpose." 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000). More specifically, [Madey] must sufficiently establish that [Duke's] use of the patent had "definite, cognizable, and not insubstantial commercial purposes." *Roche Prods., Inc. v. Bolar Pharm. Co.*

On appeal, Madey attacks this passage as improperly shifting the burden to the plaintiff to allege and prove that the defendant's use was not experimental.

3. The accused infringer in *Roche* sought to assert the experimental use defense to allow early development of a generic drug. After the *Roche* decision, however, Congress changed the law, overruling *Roche* in part, but without impacting the experimental use doctrine. Congress provided limited ability for a company to practice a patent in furtherance of a drug approval application.

Before the district court, Madey argued that Duke's research in its FEL lab was commercial in character and intent. Madey relied on *Pitcairn v. United States*, 547 F.2d 1106 (1976), where the government used patented rotor structures and control systems for a helicopter to test the "lifting ability" and other attributes of the patented technology. The *Pitcairn* court held that the helicopters were not built solely for experimental purposes because they were also built to benefit the government in its legitimate business. Based on language in Duke's patent policy, Madey argues that Duke is in the business of "obtaining grants and developing possible commercial applications for the fruits of its 'academic research.'"

The district court rejected Madey's argument, relying on another statement in the preamble of the Duke patent policy which stated that Duke was "dedicated to teaching, research, and the expansion of knowledge . . . [and] does not undertake research or development work principally for the purpose of developing patents and commercial applications." The district court reasoned that these statements from the patent policy refute any contention that Duke is "in the business" of developing technology for commercial applications. According to the district court, Madey's "evidence" was mere speculation,⁴ and thus Madey did not meet his burden of proof to create a genuine issue of material fact. The court went on to state that "[w]ithout more concrete evidence to rebut [Duke's] stated purpose with respect to its research in the FEL lab, Plaintiff has failed to meet its burden of establishing patent infringement by a preponderance of the evidence."

II. DISCUSSION

C. The District Court's Application of Experimental Use

On appeal, Madey asserts three primary errors related to experimental use. First, Madey claims that the district court improperly shifted the burden to Madey to prove that Duke's use was not experimental. Second, Madey argues that the district court applied an overly broad version of the very narrow experimental use defense inconsistent with our precedent. Third, Madey attacks the supporting evidence relied on by the district court as overly general and not indicative of the specific propositions and findings required by the experimental use defense, and further argues that there is no support in the record before us to allow any court to apply the very narrow experimental use defense to Duke's ongoing FEL lab operation. We substantially agree with Madey on all three points. In addition, Madey makes a threshold argument concerning the continued existence of the experimental use doctrine in any form, which we turn to first. Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form.

4. Madey also argued that Duke's acceptance of funding from the government and private foundations was evidence of developing patented devices with commercial intent. The district court also rejected this proposition. *Summary Judgment Opinion* at 13 (citing *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935) (concluding that the experimental use defense applies when a university uses a patented device in furtherance of its educational purpose).

The Experimental Use Defense

Citing the concurring opinion in *Embrex*, Madey contends that the Supreme Court's opinion in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) eliminates the experimental use defense. The Supreme Court held in *Warner-Jenkinson* that intent plays no role in the application of the doctrine of equivalents. Madey implicitly argues that the experimental use defense necessarily incorporates an intent inquiry, and thus is inconsistent with *Warner-Jenkinson*. Like the majority in *Embrex*, we do not view such an inconsistency as inescapable, and conclude the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex*, 216 F.3d at 1349, and in *Roche*, 733 F.2d at 863.

The District Court Improperly Shifted the Burden to Madey

As a precursor to the burden-shifting issue, Madey argues that the experimental use defense is an affirmative defense that Duke must plead or lose. We disagree. Madey points to no source of authority for its assertion that experimental use is an affirmative defense. Indeed, we have referred to the defense in a variety of ways. See *Roche*, 733 F.2d at 862 (referring to experimental use as both an exception and a defense). Given this lack of precise treatment in the precedent, Madey has no basis to support its affirmative defense argument. The district court and the parties in the present case joined the issue during the summary judgment briefing. We see no mandate from our precedent, nor any compelling reason from other considerations, why the opportunity to raise the defense if not raised in the responsive pleading should not also be available at the later stages of a case, within the procedural discretion typically afforded the trial court judge.

The district court held that in order for Madey to overcome his burden to establish actionable infringement, he must establish that Duke did not use the patent-covered free electron laser equipment solely for experimental or other non-profit purposes. Madey argues that this improperly shifts the burden to the patentee and conflates the experimental use defense with the initial infringement inquiry.

We agree with Madey that the district court improperly shifted the burden to him. The district court folded the experimental use defense into the baseline assessment as to whether Duke infringed the patents. Duke characterizes the district court's holding as expressing the following sequence: first, the court recognized that Madey carried his burden of proof on infringement; second, the court held that Duke carried its burden of proof on the experimental use defense; and third, the court held that Madey was unable to marshal sufficient evidence to rebut Duke's shifting of the burden. We disagree with Duke's reading of the district court's opinion. The district court explicitly contradicts Duke's argument by stating that Madey failed to "meet its burden to establish patent infringement by a preponderance of the evidence." This statement is an assessment of whether Madey supported his initial infringement claim. It is not an assessment of which party carried or shifted the burden of evidence related to the experimental use defense. Thus, the district court did not conclude that Madey failed to rebut Duke's assertion of the experimental use defense. Instead, it erroneously required Madey to show as a part of his initial claim that Duke's use was not experimental. The defense, if available at all, must be established by Duke.

The District Court's Overly Broad Conception of Experimental Use

Madey argues, and we agree, that the district court had an overly broad conception of the very narrow and strictly limited experimental use defense. The district court stated that the experimental use defense inoculated uses that “were solely for research, academic, or experimental purposes,” and that the defense covered use that “is made for experimental, non-profit purposes only.” Both formulations are too broad and stand in sharp contrast to our admonitions in *Embrex* and *Roche* that the experimental use defense is very narrow and strictly limited. In *Embrex*, we followed the teachings of *Roche* and *Pitcairn* to hold that the defense was very narrow and limited to actions performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Embrex*, 216 F.3d at 1349. Further, use does not qualify for the experimental use defense when it is undertaken in the “guise of scientific inquiry” but has “definite, cognizable, and not insubstantial commercial purposes.” *Id.* (quoting *Roche*, 733 F.2d at 863). The concurring opinion in *Embrex* expresses a similar view: use is disqualified from the defense if it has the “slightest commercial implication.” *Id.* at 1353. Moreover, use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense. The district court supported its conclusion with a citation to *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935), a case that is not binding precedent for this court.

The *Ruth* case represents the conceptual dilemma that may have led the district court astray. Cases evaluating the experimental use defense are few, and those involving non-profit, educational alleged infringers are even fewer. In *Ruth*, the court concluded that a manufacturer of equipment covered by patents was not liable for contributory infringement because the end-user purchaser was the Colorado School of Mines, which used the equipment in furtherance of its educational purpose. *Id.* Thus, the combination of apparent lack of commerciality, with the non-profit status of an educational institution, prompted the court in *Ruth*, without any detailed analysis of the character, nature and effect of the use, to hold that the experimental use defense applied. *Id.* This is not consistent with the binding precedent of our case law postulated by *Embrex*, *Roche* and *Pitcairn*.

Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer’s legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.

In the present case, the district court attached too great a weight to the non-profit, educational status of Duke, effectively suppressing the fact that Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives.⁷ On remand, the district court will have to significantly narrow and limit its conception of the experimental use defense. The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

Comments

1. **Historical Development.** The common law experimental use doctrine finds its origin in an opinion by Justice Story in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813). Justice Story famously wrote that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Id.* at 1121. In that same year, Justice Story wrote in *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. 1813), that "the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification [citing *Whittemore*]."
2. **The Federal Circuit's Treatment of Experimental Use.** The Federal Circuit has taken a very narrow view of the common law experimental use exemption. For instance, in *Embrex Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000), the patent in suit concerned "methods for inoculating birds against disease by injecting vaccines into a specified region of the egg before hatching." *Id.* at 1346. The court held that an infringer's acts of having two scientists test a prototype machine cannot be deemed experimental use or de minimis. The tests were not for "scientific inquiry," but rather for commercial purpose, to wit, to demonstrate to potential customers the usefulness of the methods performed by the machines. That the infringer was unsuccessful in selling its machines conferred no immunity for the infringing acts of unauthorized testing. The court noted that it has "construed both the experimental use and de minimis exceptions very narrowly [citing *Roche*]." Notably, Judge Rader filed a concurrence wherein he stated that the "Patent Act leaves no room for any de minimis or experimental use excuses for infringement." *Id.* at 1352. For Judge Rader, experimental use cannot survive *Warner-Jenkinson* because that Court held intent is irrelevant to patent infringement. The *Madey* court rejected Judge Rader's reasoning, stating "we do not view such an inconsistency as inescapable, and conclude the experimental use

7. Duke's patent and licensing policy may support its primary function as an educational institution. See *Duke University Policy on Inventions, Patents, and Technology Transfer* (1996), available at <http://www.ors.duke.edu/policies/patpol.htm> (last visited Oct. 3, 2002). Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream. See *id.*

defense persists albeit in the very narrow form articulated by this court in *Embrex*.”

3. **Criticism of Federal Circuit’s Experimental Use Doctrine.** A number of commentators have criticized the Federal Circuit’s treatment of the experimental use exemption and called for a more vigorous experimental use exemption. *See, e.g.,* Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004); Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

E. INVENTORSHIP

United States patent law requires that the correct inventors be named in the patent application. This requirement stems from the patent and copyright clause of the Constitution, namely that Congress has the power “[t]o promote the progress of . . . useful arts, by securing for limited times to . . . *inventors* the exclusive right to their . . . discoveries” (emphasis added). The *Hess* and *Acromed* cases explore the issue of inventorship, and the type of contribution one has to make before he legally qualifies as an “inventor.”

HESS v. ADVANCED CARDIOVASCULAR SYSTEMS, INC.

106 F.3d 976 (Fed. Cir. 1997)

FRIEDMAN, Senior Circuit Judge.

This appeal challenges the decision of the United States District Court for the Northern District of California that the materials and suggestions the appellant Robert L. Hess provided to the listed inventors of a patent did not make him a co-inventor of the patented device. We affirm.

I.

A.

United States Patent No. 4,323,071 (the ‘071 patent), which listed Drs. John B. Simpson and Edward W. Robert as the inventors, covers a balloon angioplasty catheter that is inserted into a patient’s artery which has a partial blockage, or stenosis. The balloon, fitted to the catheter, is inflated by forcing a radiographic fluid into it under pressure; the resulting expansion of the balloon eliminates or reduces the blockage of the artery.

While developing the catheter, Drs. Simpson and Robert were postdoctoral Cardiology Fellows at Stanford University Medical Center. A Swiss physician, Dr. Gruntzig, had pioneered the development of balloon angioplasty. After hearing Dr. Gruntzig speak at a cardiology conference at Stanford in March

1977 and later meeting him, Dr. Simpson spent time with Dr. Gruntzig in Europe, observing him perform balloon angioplasty procedures.

Upon returning to the United States Dr. Simpson discovered that Gruntzig catheters, made only in Switzerland, were in short supply. Drs. Simpson and Robert then decided to construct their own catheter. They had not examined the Gruntzig catheter in detail, but knew it had a balloon mounted on a shaft.

In attempting to find a material from which a balloon could be made, the doctors first experimented with a plastic called polyvinylchloride, which was ineffective, and next tried Teflon tubing, which produced unsatisfactory balloons. One of their Stanford colleagues (Bill Sanders) then referred them to the appellant Mr. Hess, an engineer at Raychem Corporation. At that time Mr. Hess was a technical liaison between Raychem's domestic and foreign operations; prior to that he had headed a business development group. Sanders made the suggestion because Raychem was one of the largest manufacturers of heat shrinkable materials and "might have some material" with which they could work.

The doctors told Mr. Hess, who had no previous experience with angioplasty, about the Gruntzig catheter. They stated they "wanted to . . . build a catheter . . . that incorporated a balloon on the end of a shaft." They explained what they were attempting to do, the problems they had encountered in finding a suitable material for the balloon, and that they were looking for a new material. They stated that the materials they had tried did not enable them properly to control balloon expansion.

Mr. Hess suggested that the doctors try Raychem's heat shrinkable irradiated modified polyolefin tubing and demonstrated how such a material could be used to form a balloon by heating the tubing above its crystalline melting point, applying pressure, and then cooling the material. Mr. Hess also suggested the use of an adhesive-free seal to attach the balloon to the catheter. He described how one end of the tubing could be shrunk fit onto the central shaft of the catheter without the use of any potentially-toxic adhesive chemicals. Mr. Hess stated that "the basic principles which I taught them" — involving heating the tubing "above its crystalline melting point, expanding it while it remains heated using internal pressure and then cooling it in its expanded state while your [sic] maintaining the pressure" — were "in various published textbooks and the like" and "was a generally known process to a number of companies."

Mr. Hess provided "multiple samples of . . . tubing," with which the doctors "experimented." At that meeting and in further discussions with the doctors, Mr. Hess also suggested "approaches to construction of the catheter" using the Raychem tubing.

Using that tubing, Drs. Simpson and Robert then developed and built their catheter. They had "difficulty . . . developing the . . . catheter" and spent "hours and days trying to configure this system to make it work," including "experimentation . . . with the tubing" Mr. Hess "gave" them. The two doctors worked on the catheter "virtually every day [for] four or five hours or more." The doctors finally developed the balloon using a technique called free-blowing, a technique which Mr. Hess admittedly did not suggest. Pursuant to Mr. Hess's suggestion, the doctors attempted to avoid the use of adhesives and shrink fit the balloon to the catheter shaft, but they encountered leakage problems. Without Mr. Hess's assistance and after further experimentation,

the doctors ultimately developed an acceptable adhesive-free seal. Mr. Hess did not participate in the day-to-day experimentation.

The doctors applied for a patent on their catheter in April, 1978 and the '071 patent issued with twenty-one claims (the "original claims") in April, 1982. The two inventors organized the appellee company Advanced Cardiovascular Systems, Inc. (ACS), to which they assigned the '071 patent, and began manufacturing and selling the catheter. An ACS officer stated that the "catheter gained widespread success in the marketplace, and sales of the product grew rapidly," and that the Simpson-Robert catheter "was profitable" to ACS. Raychem supplied ACS with tubing for manufacturing the catheters.

B.

In 1987, ACS sued SciMed Life Systems, Inc. (SciMed) in the United States District Court for the District of Minnesota for infringement of the '071 patent. The district court granted SciMed's motion for summary judgment of non-infringement, based on its interpretation of the claims. This court, however, vacated and remanded, rejecting the district court's claim interpretation.

The question of Mr. Hess's alleged co-inventorship apparently first arose when in its answer SciMed asserted, as one ground for challenging the validity of the patent, that there was a "failure of the patentees to join Hess as a co-patentee." In a declaration Mr. Hess executed in 1988, which SciMed filed in the patent infringement case, he described the aid he had given to Drs. Simpson and Robert in connection with the development of their catheter. In a 1990 affidavit, he repeated those statements and asserted that he "made substantive contributions to the subject matter disclosed" in the '071 patent and "should be named as a co-inventor thereof."

In September, 1987, ACS requested reexamination of certain claims in the '071 patent. In May 1990, the Patent and Trademark Office issued a reexamination certificate, which upheld the original claims and added claims 22-52 (the "reexamination claims").

In the summer of 1990, Mr. Hess intervened in the ACS-SciMed suit to file a cross-complaint against ACS seeking a declaration that he was a joint inventor of the catheter the '071 patent covered and seeking correction of the patent to reflect his status. The district court dismissed Mr. Hess's cross-complaint for failing to state a claim on which relief could be granted because the complaint was barred by laches. This court vacated the dismissal and remanded, holding that there were disputed issues of material fact with respect to laches that precluded dismissal.

While that appeal was pending, Mr. Hess filed suit in United States District Court for the Northern District of California against ACS, alleging that he was a co-inventor of the catheter the reexamination claims covered.

On the eve of trial ACS and SciMed settled their infringement suit. The Minnesota District Court then transferred to the Northern District of California Court the remaining portion of the case, which was Mr. Hess's cross-complaint asserting his co-inventorship of the catheter the '071 patent covers. The California District Court consolidated the two cases.

The California District Court granted summary judgment that Mr. Hess's claim of co-inventorship of the catheter the original claims covered was barred by laches, and set for trial the co-ownership issue with respect to the reexamination claims.

After a bench trial, the district court held that the evidence did not establish Mr. Hess's claim of co-inventorship of the catheter the reexamination claims covered. Ruling from the bench, the court determined that Mr. Hess was required to prove co-inventorship by clear and convincing evidence. The court stated:

[A]ll that Mr. Hess needs to establish is that he conceived some important element or some important claim that is claimed in the patent. . . . I don't think it's necessary for Mr. Hess to conceive of every feature of the catheter, but that he have some conceptual role in at least an important or a necessary element, or important and necessary claim.

The court noted:

[I]nventors can obtain the services and ideas and product of others without losing their exclusive right to ownership. . . . So merely that Mr. Hess was consulted, Mr. Hess made some contribution, doesn't in and of itself rise to the level of conception particularly if he's doing nothing more than explaining to the inventors what the then state of the art was and supplying a product to them for use in their invention.

The court found that

the information provided by Mr. Hess really didn't rise to the level of conception; that most, if not all, of his discussion with them were [sic] telling them what was available in the marketplace by way of product, and telling them how the product worked, and they, that is, Simpson and Robert, were the ones who used the product or used the-yes, used the product provided in their work. . . . [W]hen they were meeting with Mr. Hess, I think what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used. . . . Raychem became a supplier of product to Simpson and Robert, really all of which really leaves [sic] me to the conclusion that Mr. Hess' role was really as a representative of Raychem who is making available to a customer or potential customer the product that Raychem has, and its property uses and adaptation to what the inventors here wanted to do. . . . [I]t's [sic] also clear from the record that Mr. Hess didn't know anything about angioplasty or medical catheters until discussion with Dr. Robert and Dr. Simpson.

Finally, the court stated:

I do wish to state for the record that on a factual basis after having heard the evidence in the case, I'm also concluding that the evidence did not establish coinventorship of the original claims in the '071 patent and not just the reissue claims for that patent.

II.

The patent laws provide that whoever "invents" patentable subject matter is entitled to a patent thereon, 35 U.S.C. § 101 (1994), and that when an "invention" is "made by two or more persons jointly, they shall apply for [a] patent jointly." 35 U.S.C. § 116 (1994). The statute also deals with the situation where an inventor is not named in the application or the issued patent. 35 U.S.C. §§ 116, 256 (1994). Section 256 provides that if "through [inadvertent] error an inventor is not named in an issued patent . . . the Commissioner [of Patents] may . . . issue a certificate correcting such error," and that "[t]he

court . . . may order correction of the patent . . . and the Commissioner shall issue a certificate accordingly.”

The district court held that Mr. Hess had to prove his claim of co-inventorship by clear and convincing evidence, and that Mr. Hess had not done so. Mr. Hess challenges both of these rulings.

A.

As the Court of Claims stated in *Garrett Corp. v. United States*, 422 F.2d 874, 880 (1970), “[t]he burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence.” Although the case involved section 116, which governs patent applications, and the present case involves section 256, which covers issued patents, the pertinent statutory language is virtually identical, and the burden of proof on this issue is the same under both sections.

The rule rests on important policy considerations. “The inventors as named in an issued patent are presumed to be correct.” *Amax Fly Ash Corp. v. United States*, 206 Ct. Cl. 756, 514 F.2d 1041, 1047 (1975). As the court there stated, in holding that one claiming that the inventor listed in the patent derived the invention from the claimant’s work must show derivation by clear and convincing evidence, “the temptation for even honest witnesses to reconstruct, in a manner favorable to their own position, what their state of mind may have been years earlier, is simply too great to permit a lower standard.” *Id.* at 1047. This language is similarly applicable to claims of co-inventorship made after a patent has been issued—particularly where, as here, the patent has been outstanding for a considerable time and the patented device has been successful. In that situation, too, there is an equally strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention. In these circumstances, it would be inappropriate to permit a lower standard than clear and convincing evidence.

Mr. Hess apparently suggests that because of the particular circumstances of his participation in the activities of Drs. Simpson and Robert, the proper evidentiary standard for determining his co-inventorship claim should be preponderance rather than clear and convincing. Once the standard of proof has been determined, however—and we have held that it is clear and convincing evidence for determining co-inventorship—it applies without regard to the circumstances of a particular case. Permitting the exception Mr. Hess urges could significantly undermine the designated standard of proof, since litigants always can assert, and sometimes effectively, that their cases involve special circumstances.

B.

Mr. Hess concedes that the district court “articulat[ed] the appropriate test for inventorship.” The district court’s standard was whether Mr. Hess “conceived some important element or some important claim that is claimed in the patent,” and whether he had “some conceptual role in at least an important or a necessary element, or important and necessary claim.” Mr. Hess argues, however, that the court “completely misapplied” that standard “in finding that Hess’s contributions were not inventive.” This argument, however, is in reality only a reformulation of the contention that the district court’s findings upon

which the court based its conclusion that Mr. Hess had not established co-inventorship, are clearly erroneous.

We have carefully reviewed the evidence in the record. Although there is some conflict on the question of co-inventorship, the district court's findings that Mr. Hess was not a co-inventor of the catheter claimed in the '071 patent are not clearly erroneous.

When Drs. Simpson and Robert first met with Mr. Hess, he was totally unfamiliar with angioplasty catheterization and the problems it involved. They explained to him what they were trying to do, and what difficulties they encountered. He recommended a Raychem product that he believed would be suitable for making a balloon, showed them how a balloon could be formed by heating both ends of the tube (a procedure they did not use in making their patented catheter), and made other suggestions for making the catheter, using the Raychem tubing. Although the doctors followed and utilized some of Mr. Hess's suggestions in their extensive further research, testing and construction of their catheter, the district court justifiably concluded on this record that it was they, and not Mr. Hess, who actually conceived and made the patented invention and that Mr. Hess's contributions to the inventions did not constitute the conception necessary to establish co-inventorship.

More than 140 years ago the Supreme Court, in holding that Samuel Morse's discussions with scientists in connection with his invention of the telegraph did not alter his status of the sole inventor of that device, stated:

No invention can possibly be made, consisting of a combination of different elements . . . without a thorough knowledge of the properties of each of them, and the mode in which they operate on each other. And it can make no difference, in this respect, whether [the inventor] derives his information from books, or from conversation with men skilled in the science. If it were otherwise, no patent, in which a combination of different elements is used, could ever be obtained.

O'Reilly v. Morse, 56 U.S. (15 How.) 62, 111 (1853).

Similarly, in *Shatterproof Glass*, this court stated that

[a]n inventor "may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent."

Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624 (Fed. Cir. 1985).

Mr. Hess relies on the following statement in the 1914 district court opinion in *DeLaski & Thropp Circular Woven Tire Co. v. William R. Thropp & Sons Co.*, 218 F. 458, 464 (D.N.J. 1914), *aff'd*, 226 F. 941 (3d Cir. 1915), which he describes as "the controlling legal standard."

The conception of the entire device may be due to one, but if the other makes suggestions of practical value, which assisted in working out the main idea and making it operative, or contributes an independent part of the entire invention, which is united with the parts produced by the other and creates the whole, he is a joint inventor, even though his contribution be of comparatively minor importance and merely the application of an old idea.

That language, of course, is not binding precedent in this court, and its focus appears inconsistent with the approach the Supreme Court took in *Morse* and this court took in *Shatterproof Glass*. In any event, whether particular

suggestions and contributions of third persons amount to co-inventorship turns on the facts of the particular case.

Here the district court found that in his consultations with Drs. Simpson and Robert, Mr. Hess was “doing nothing more than explaining to the inventors what the then state of the art was and supplying a product to them for use in their invention”; that “most, if not all, of his discussion with them were [sic] telling them what was available in the marketplace by way of product, and telling them how the product worked”; and that “what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used.” The principles Mr. Hess explained to them were well known and found in textbooks. Mr. Hess did no more than a skilled salesman would do in explaining how his employer’s product could be used to meet a customer’s requirements. The extensive research and development work that produced the catheter was done by Drs. Simpson and Robert. Our review of the record satisfies us that those findings are not clearly erroneous, and that they support the district court’s conclusion that whatever contribution Mr. Hess made to Drs. Simpson and Robert did not constitute conception and therefore did not make Mr. Hess a co-inventor of the catheter claimed in the ’071 patent.

Mr. Hess relies on snippets of the doctors’ testimony in which, he asserts, the doctors conceded that Mr. Hess was responsible for significant portions of the invention the ’071 patent disclosed. Those statements, however, cannot bear the weight Mr. Hess gives them. In the context of the entire record, they do not refute the factual sufficiency of the evidence supporting the district court’s decision.

III.

Mr. Hess also argues that the district court erroneously dismissed on summary judgment, as barred by laches, that portion of his case that claimed co-inventorship of the invention disclosed in the original claims. That issue, however, is moot in view of the district court’s ruling that “on a factual basis after having heard the evidence in the case, I’m also concluding that the evidence did not establish coinventorship of the original claims in the ’071 patent and not just the reissue claims for that patent.” Accordingly, we do not consider it.

CONCLUSION

The judgment of the district court that Mr. Hess has not established his claim to co-inventorship of the catheter disclosed in the ’071 patent is affirmed.

ACROMED CORP. v. SOFAMOR DANEK GROUP, INC.

253 F.3d 1371 (Fed. Cir. 2001)

RADER, Circuit Judge.

At the close of evidence, the United States District Court for the Northern District of Ohio granted judgment as a matter of law (JMOL) that AcroMed Corporation’s (AcroMed’s) U.S. Patent No. 4,696,290 (’290 patent) is not invalid for improper inventorship. The jury’s verdict found that Sofamor Danek Group, Inc., and Danek Medical, Inc., (collectively Danek) literally infringed the claims of the ’290 patent and AcroMed’s U.S. Patent No.

4,854,311 ('311 patent). The jury further found the claims of the '311 patent not invalid. Because the district court correctly found insufficient evidence to invalidate the '290 patent and correctly upheld the jury verdict that the claims of the '311 patent were infringed and not invalid, this court affirms.

I

AcroMed is assignee of the '290 patent which names Dr. Arthur D. Steffee as its sole inventor. The '290 patent discloses a plate for surgical implantation onto a patient's spinal column. The spine plate straightens a spine misshapen by disc degeneration or fracture. This invention can thus alleviate pain and restore a patient's mobility.

In his first spine straightening operations, Dr. Steffee hooked and wired rods to patients' spines. This early method straightened spines somewhat, but the rods would later slip, thereby undercutting the effectiveness of the operation. To prevent slippage, Dr. Steffee began to use a plate-and-screw system similar to that described in the '290 patent.

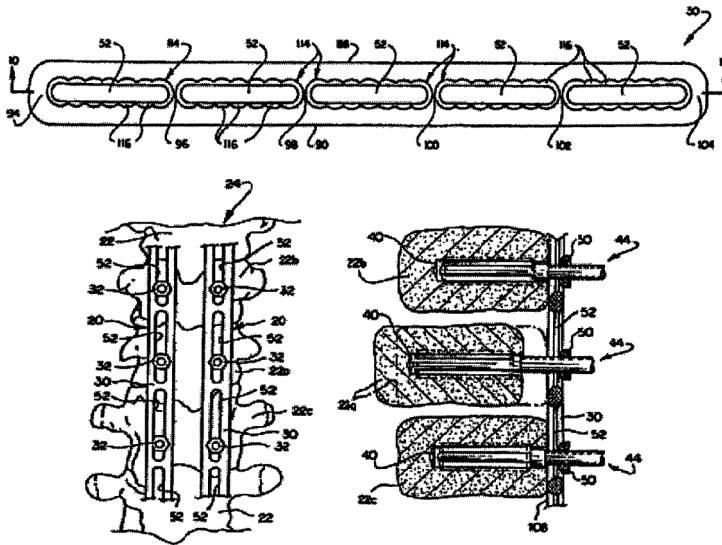
Dr. Steffee's first plate-and-screw system used a long plate with fixed location screw holes. Dr. Steffee implanted this type of plate-and-screw system by drilling or tapping holes into a patient's vertebrae, aligning the vertebral holes with holes in the plate, and then attaching the plate with bone screws. Dr. Steffee typically installed two such plates, one on each side of the spine. These systems fixed the vertebrae more rigidly than wire and rod systems. The plates with holes in fixed locations, however, were difficult to install and adapt to different patients because the holes were rarely spaced identically to pedicle distances between a patient's vertebrae.

Dr. Steffee thus improved his plate-and-screw system in 1982 while working at a hospital in Cleveland. He conceived of headless screws that would permit him to first optimally locate such screws in each vertebral pedicle, and then attach the spine plate to the installed screws. Dr. Steffee took his regular bone screws to the Cleveland Research Institute (CRI) hospital machine shop, and asked Frank Janson, a machinist, to cut the heads off of the screws. Without screw heads, Dr. Steffee needed to find another means to attach the plate to the screws in the spine. He conceived of using a tapered, conical nut from a Hagie pin, a pin commonly used by orthopedists to fix broken hips in children.

Next, Dr. Steffee recognized that he would need to modify the fixed location screw holes in the plate to facilitate attachment at different pedical distances between vertebrae. Dr. Steffee looked to another well-known device—a small, slotted Egger's plate which orthopedic surgeons use to fix long bone fractures. Dr. Steffee asked Mr. Janson to make a bigger Egger's plate to accommodate a spine.

Dr. Steffee's final problem was that the slots in the plate could slide along the screws and defeat proper fixation of the plate to the spine. To solve this problem, Dr. Steffee told Mr. Janson that he needed a plate designed so that the Hagie pin nut "sinks in and stays right there." Mr. Janson responded to this instruction by putting nests in the slots. The '290 patent claims the resulting combination.

The disclosed spine plate (30) has a series of elongated slots (52) configured with a series of nests, or arcuate recesses (116). Claim 1 of the '290 patent recites:



An apparatus for use with fasteners for maintaining vertebrae in a desired relationship, said apparatus comprising:

an elongated plate for connecting at least two vertebrae . . .

said elongated plate also having at least one elongated slot extending there through . . .

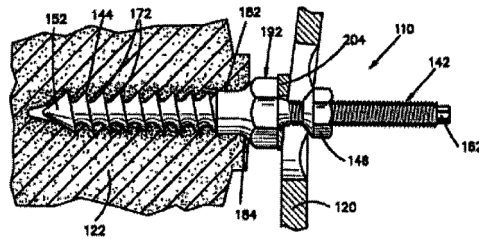
said slot being capable of receiving a fastener therein . . . and

said slot being defined by opposed slot surfaces extending longitudinally of said elongated plate and *arcuate recesses* in said opposed slot surfaces and spaced there along, the recesses in one of said opposed slot surfaces being aligned with the recesses in the other of said opposed slot surfaces to define said plurality of locations, *said recesses comprising means for blocking sliding movement* of [s]aid elongated plate relative to the fastener and of said elongated plate relative to the vertebrae when the fastener is located in a pair of aligned recesses

(emphasis added).

Dr. Steffee also improved the headless bone screw. The '311 patent discloses a bone screw with an elongated shank to, *e.g.*, fasten the plate of the '290 patent to a spine, connect broken bones, or connect prostheses to bones in any part of the body. The '311 patent describes the bone screw as having three identifiable segments: (1) a first externally threaded portion (142) for receiving a connecting member, such as a nut; (2) a cylindrical body portion for projecting into and engaging the bone opening surface (182); and (3) a second threaded portion for attaching the screw to the bone (144).

Bones have a hard outer shell (called cortical bone) and a spongy center (called cancellous bone). Cancellous bone contains blood vessels. Thus, once a hole is drilled or tapped into a bone, effluence (blood and other bodily fluids) may leak into the hole. This effluence can corrode and weaken the screw. According to the '311 patent, the claimed bone screw has a cylindrical body portion and a shoulder portion (184) that act as a sort of stopper, blocking effluence from leaking out of the bone. Claim 5 of the '311 patent recites:



A bone screw for connecting a bone portion with a bone connecting member, said bone screw comprising:

an elongated shank having a longitudinal central axis, a first externally threaded portion for receiving an internally threaded nut and a second externally threaded portion for threaded engagement with a surface defining an opening in the bone portion to attach the bone screw to the bone portion; and

means integral with said shank and having a transverse cross-section at least equal to the transverse cross-section of the opening in the bone portion for projecting into the opening and *for engaging a portion of the surface defining the opening in the bone portion* to restrict movement of said bone screw relative to the bone portion in a direction transverse to the longitudinal central axis of said shank and *to block effluence from the opening in the bone portion*, said means being located intermediate said first externally threaded portion and said second externally threaded portion

(emphasis added).

Dr. Steffee and another colleague founded AcroMed in 1983. Dr. Steffee assigned all of his rights in the '290 and '311 patents to AcroMed. In 1988, CRI disbanded and Mr. Janson went to work at AcroMed. When Mr. Janson began working for AcroMed, he completed an Employment Agreement requiring him to disclose any pre-existing invention in which he had an interest. Mr. Janson checked the box marked "Employee has no such property," and signed that agreement.

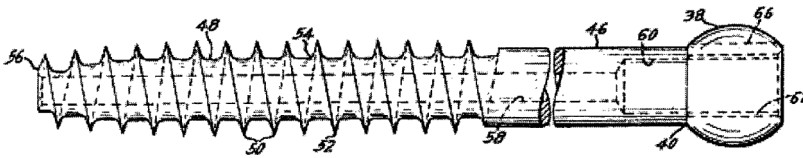
Mr. Janson worked as a machinist at AcroMed until 1992, and then continued as a consultant for AcroMed until June 1994. In June 1994, Mr. Janson met with Danek's counsel on two occasions. Later that year AcroMed requested Mr. Janson to sign a declaration and power of attorney to add him as a co-inventor of the '290 patent. AcroMed also requested Mr. Janson to assign his rights in the '290 patent if he signed the declaration. Mr. Janson declined to sign either the declaration or the assignment. Instead, on January 25, 1995, Mr. Janson signed an agreement with Danek to assign his "patent rights" to Danek for \$150,000.

AcroMed first sued Danek for infringement of the '290 patent by Danek's "Luque" system in 1988. The Luque was a semi-constrained plate-and-screw system without a way to hold the screws completely rigid to the plate. In March 1989, the parties entered a settlement agreement whereby AcroMed granted Danek a limited license under the '290 patent. In return, Danek paid AcroMed a license fee until 1996.

In 1992, Danek changed its technology into a constrained system. Danek developed several constrained systems, including the "DYNA-LOK" and "Z-PLATE" systems. In June 1993, AcroMed again filed suit claiming that Danek's DYNA-LOK, Z-PLATE, and various other spine plate systems in-

fringe the '311 and 290 patents. Danek counterclaimed that AcroMed's '290 patent is invalid for failure to name Mr. Janson as an inventor. Danek further counterclaimed that AcroMed's '311 patent is invalid due to anticipation by United States Patent No. 3,554,193 to Ilias Konstantinou (Konstantinou patent).

As depicted below, the Konstantinou patent discloses a hip-pinning device for repair of hip fractures. The device uses a lag screw to attach a bone plate to the upper region of a femur. The lag screw has a rounded head portion (38) that permits the screw to be angularly displaced within a hole in a bone plate. A surgeon can, thus, vary the angle at which he attaches the screw to the bone while maintaining the plate in a desired location.



After a ten-day jury trial, the district court judge granted AcroMed's motion for JMOL that the '290 patent was not invalid for improper inventorship. The jury returned a verdict that Danek's DYNA-LOK and Z-PLATE spine plates infringed the asserted claims of the '290 patent. The jury further found that Danek's DYNA-LOK and Z-PLATE 5.5 mm bone bolts infringed claims 5, 10, 14, and 16 of the 311 patent and that Danek's DYNA-LOK and Z-PLATE larger diameter bone bolts infringed claims 5, 10, 12, 13, 14, and 16. The jury additionally found all asserted claims of both the '290 and '311 patent to be neither anticipated nor obvious over prior art. The jury awarded AcroMed \$32,913,444 in damages and found that Danek had willfully infringed the '290 patent.

After the jury verdict, Danek renewed its motions for JMOL that the '290 patent is invalid for omitting an inventor, that its spine plates and screws do not infringe the '311 patent, and that the Konstantinou patent anticipates the '311 patent. The district court denied all of these motions. The district court then increased the damages to \$47,806,701 to account for post-verdict damages and prejudgment interest. Danek appealed.

II.

Inventorship is a question of law that this court reviews without deference.

Inventorship

The Patent Act accords each patent a presumption of validity. 35 U.S.C. § 282. Under this doctrine, each patent also receives the presumption that its named inventors are the true and only inventors. *Hess v. Advanced Cardiovascular Sys., Inc.* In order to rebut this presumption, a party challenging patent validity for omission of an inventor must present clear and convincing evidence that the omitted individual actually invented the claimed invention.

When an invention is the work of several inventors, they must jointly apply for the patent. 35 U.S.C. § 116; 35 U.S.C. § 111. Omission of an inventor can invalidate a patent unless the omission was an error "without any deceptive

intention.” 35 U.S.C. § 256; 35 U.S.C. § 102(f). Danek argues that Mr. Janson was an inventor of the '290 patent. Because Mr. Janson was not named as an inventor of the '290 patent, Danek asserts that a reasonable jury would have found the '290 patent invalid.

“Inventorship is a question of who actually invented the subject matter claimed in a patent.” *Sewall v. Walters*, 21 F.3d 411, 417 (Fed. Cir. 1994). “Conception is the touchstone of inventorship.” *Burroughs Wellcome*, 40 F.3d at 1227. Accordingly, each person claiming to be a joint inventor must have contributed to the conception of the invention. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997). To prove that contribution, the purported inventor must “provide corroborating evidence of any asserted contributions to the conception.” *Id.* at 1474; see *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993) (“[T]he case law is unequivocal that an inventor’s testimony respecting the facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof.”). Beyond conception, a purported inventor must show that he made “a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and [did] more than merely explain to the real inventors well-known concepts and/or the current state of the art.” *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351, 47 USPQ2d 1657, 1663 (Fed. Cir. 1998).

Danek asserts that Mr. Janson conceived the arcuate recesses recited in claim 1 of the '290 patent. Danek argues that Mr. Janson’s testimony that he invented the arcuate recesses and the conical nut is sufficient evidence of conception and contribution. The record, however, contains no evidence to corroborate this assertion.

Mr. Janson testified that he conceived of a conical nut and arcuate recesses to prevent sliding movement of a spine plate before Dr. Steffee ever mentioned problems with plate sliding. Mr. Janson further testified that he was the first to conceive of a spine plate with slots and the first to conceive of transforming regular bone screws into machine-threaded screws to accept a slotted plate. In other words, according to Mr. Janson, he conceived of the entire plate-and-screw combination. Danek, however, was not able to put forth other witnesses, dated drawings, or any other evidence to verify Mr. Janson’s assertions. In fact, Mr. Janson himself admitted that he did not communicate his conceptions to anyone.

On appeal, Danek argues that Dr. Steffee’s own testimony corroborates Mr. Janson’s claims of conceiving the arcuate recesses. In particular, Danek quotes the following deposition testimony made by Dr. Steffee:

I have always said Frank Jansen [sic] was the one who put the nests in the slots, that’s the only thing that Frank Jansen [sic] did. And I was right there when he asked me if he could do it. . . . He and I were standing there together, he asked me if he could put the drill press down and put those nest in, and I said, fine, it sounds like a good idea, let’s do it.

AcroMed concedes that Mr. Janson cut the arcuate recesses into the spine plate. Countersinking the slots in the spine plate, however, was not an inventive conception. The record in context supports the district court’s conclusion that Dr. Steffee alone conceived the invention. Specifically, Dr. Steffee testified that when he brought the slotted plate and conical nut to Mr. Janson, he explained: “When I drive the nut down, I have to have it so it sinks in and

stays right there.” Dr. Steffee thus instructed Mr. Janson to design the plate according to his conception. Mr. Janson’s work of putting arcuate recesses in the slots “was simply the exercise of the normal skill expected of an ordinary” machinist. *Sewall*, 21 F.3d at 416. Danek, having had the burden of proof at trial, did not present adequate evidence to suggest otherwise. As explained by the district court: “Danek could have countered this by producing testimony at trial concerning what would or would not be obvious to one ordinarily skilled in the art of making plates. Danek never did.”

Danek argues that the prosecution history of the ’290 patent provides clear and convincing evidence that the arcuate recesses were an inventive conception. During prosecution of the ’290 patent at the United States Patent and Trademark Office, the patent examiner rejected claim 1 as obvious over prior art. In its response, AcroMed explained that the prior art did not “disclose or suggest an *elongated plate with an elongated slot therein having arcuate recesses in the slot.*” AcroMed further explained that the prior art plates actually permitted sliding movement instead of the “blocking” it as recited in claim 1. Contrary to Danek’s contentions, AcroMed did not assert that the arcuate recesses alone rendered claim 1 patentable. Rather, AcroMed observed that the combination of an elongated plate with slots having arcuate recesses blocked sliding movements.

Danek further argues that the arcuate recesses are the sole feature that makes claim 1 patentable over prior art cited during trial to invalidate the ’290 patent for obviousness. These prior art references, however, do not provide substantial evidence that Mr. Janson’s countersinking of the elongated slots was more than the work of an ordinarily skilled machinist following instructions.

Claim 1 of the ’290 patent is a combination claim. This court has long established that “[c]ombination claims can consist of new combinations of old elements . . . for it may be that the combination of the old elements is novel and patentable.” *Clearstream Wastewater Sys. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1444 (Fed. Cir. 2000). In fact, all of the elements in claim 1 appear in the prior art. For example, the 290 spine plate was modeled after the Egger’s plate, a plate with elongated slots. A patent cited by Danek, Great Britain Patent No. 780,652, discloses plates for spinal fixation that are designed to prevent relative movement between fastening bolts and the plates. In fact, United States Patent No. 3,596,656 cited by the examiner during prosecution shows that arcuate recesses, or countersinking around a hole in a plate, appeared in prior art as early as the 1960s. Claim 1, however, combined these various old features to produce a new and nonobvious invention. The entire combination, not the arcuate recesses alone, renders claim 1 patentable.

Without corroborating evidence, Danek did not present clear and convincing evidence at trial that Mr. Janson’s countersinking of the elongated slots was an inventive conception. Thus, the record contains sufficient evidence to support the judgment that the ’290 patent withstood challenges to its validity based on excluding Mr. Janson as an inventor.

* * *

Comments

1. ***Naming the True and Original Inventor.*** In a recent biography of Robert Noyce, considered to be the founding father of the microchip (along with

Jack Kilby), Leslie Berlin writes, “If nearly any invention is examined closely enough, it almost immediately becomes apparent that the innovation was not the product of a single mind, even if it is attributed to one.” Rather, “[i]nvention is best understood as a team effort.” LESLIE BERLIN, *THE MAN BEHIND THE MICROCHIP: ROBERT NOYCE AND THE INVENTION OF SILICON VALLEY* 141 (2005). Indeed, ascertaining the identity of joint inventors is particularly difficult. As the Court of Claims said in *Jamesbury Corp. v. U.S.*, 518 F.2d 1384, 1396 (Ct. Cl. 1975), determining the “exact parameters of what constitutes joint inventorship . . . is one of the muddiest concepts in the muddy metaphysics of the patent law.”

Nonetheless, as unrealistic or difficult as it may be, a patent application must identify the true and original inventor, that is, the person who is responsible for inventing what is set forth in the claims. (Inventorship is different from ownership.) Not correctly naming the true and original inventor can result in invalidation of the patent.

2. ***Joint Inventors.*** In a joint or multi-inventor context, one can be an inventor without making a contribution equal to the other inventors; nor does being an inventor require an inventive contribution to every claim. Section 116 of the patent code reflects this view:

When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, . . . Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

The Federal Circuit elaborated on § 116 in *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998):

All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

Federal law explicitly provides that patents have the attributes of personal property, and that both patents and applications for patents are assignable. And, importantly, there is a recording statute for patents; so the chain of title should be searched before any assignment is executed. *See* 35 U.S.C. § 261.

3. ***Correcting Inventorship and “Deceptive Intention.”*** Patent law provides for the correction of nondeceptive misjoinder and nonjoinder of inventors. There are two specific statutory sections: 116 and 256. The former pertains to pending applications and allows a patentee to correct inventorship that “arose without any deceptive intention.” Section 256, which relates to issued patents, permits correction of inventorship that was done without “deceptive intention.”
4. ***Ownership vs. Inventorship.*** Absent a contractual obligation, patent rights vest in the inventor, even if he conceived or reduced to practice in the course of his employment. *See Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d

403, 407 (Fed. Cir. 1996). Under § 262, joint inventors are also joint owners; that is, tenants-in-common, who—in the absence of any agreement to the contrary—can practice the claimed invention or license others without the consent of and without an accounting to the other cotenants. Thus, anyone interested in owning a patent must be very careful to get an assignment from each and every individual who contributed to the conception of any claim in that patent. It is the norm, however, for employees, as part of their employment contract, to assign ownership rights in inventions to the employer. And even if there is not a contract, an employer may obtain a “shop right” in the employee’s invention. A “shop right,” based on the fact that the employer assisted the employee’s inventive efforts in some manner, is a common law doctrine that allows an employer to use an invention patented by one or more of its employees without liability for infringement. For a discussion of the “shop right,” see *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1580 (Fed. Cir. 1993).

F. PRE-EMPTION

Article VI of the Constitution—commonly known as the “Supremacy Clause”—states that the “Laws of the United States” (*i.e.*, federal law) . . . “shall be the supreme Law of the land.” This means that when there is a conflict between state law and federal law, the latter will pre-empt the former. Broadly conceived, patent law reflects a balance of competing considerations, and states cannot enact laws that conflict with this balance. The following principal cases unpack the pre-emption doctrine and explore under what circumstances federal law pre-empts state legislation.

1. The Framework of Pre-Emption Analysis

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA v. DISTRICT OF COLUMBIA

406 F. Supp. 2d 56 (D.D.C. 2005)*

LEON, District Judge.

On October 12, 2005, Plaintiff, Pharmaceutical Research and Manufacturers of America (“PhRMA”), filed a motion for a temporary restraining order and a preliminary injunction against the District of Columbia, Anthony A. Williams, in his official capacity as Mayor of the District of Columbia, the Office of the Attorney General of the District of Columbia, Robert J. Spagnoletti, in his official capacity as the Attorney General of the District of Columbia, the Office of Documents and Administrative Issuances of the District of Columbia, and Arnold R. Finlayson, in his official capacity as Administrator

*This decision was affirmed by the Federal Circuit on August 1, 2007. See 496 F.3d 1362 (Fed. Cir. 2007).

of the Office of Documents and Administrative Issuances (collectively the “District”), contending that D.C. Act 16-171, the Prescription Drug Excessive Pricing Act of 2005 (the “D.C. Act” or the “Act”), violates the Supremacy, Commerce, and Foreign Commerce Clauses of the United States Constitution. The motion for a temporary restraining order was denied the next day and a briefing schedule was set on October 21, 2005 for the motion for a preliminary injunction.

The same day, PhRMA filed a motion for an order consolidating the merits of the plaintiff’s action for a declaratory judgment with its application for a preliminary injunction pursuant to Federal Rules of Civil Procedure 57 and 65(a)(2).

The next day Biotechnology Industry Organization (“BIO”) filed its complaint seeking the same declaratory relief as PhRMA against the District. In the interests of judicial efficiency, the actions by PhRMA and BIO were consolidated on November 8, 2005, and the ruling on the merits and prayer for injunctive relief under Rule 65(a)(2) were eventually consolidated.

Based on the pleadings, oral arguments, and record, the Court finds the D.C. Act unconstitutional and GRANTS the plaintiffs’ claims for declaratory and injunctive relief.

BACKGROUND FACTS

I. Legislative History

The Prescription Drug Excessive Pricing Act of 2005 was initially introduced as legislation to the District of Columbia’s City Council (the “Council”) on February 1, 2005. The legislation was an effort by the Council “to restrain the excessive prices of prescription drugs,” D.C. Act § 28-4551(3), which it found to be threatening the “health, safety, and welfare of [the District’s] residents.” *Id.* at § 28-4551(2).³ Ultimately, the D.C. Act was passed by the Council on September 20, 2005, and signed on October 4, 2005 by Mayor Williams.

II. The D.C. Act

The D.C. Act specifically makes it “unlawful for any drug manufacturer or licensee thereof, *excluding a point of sale retail seller*, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug *that results in* the prescription drug being sold in the District for an excessive price,” D.C. Act § 28-4553 (emphasis added), and empowers any “affected party” to bring a suit in

3. The purpose and reasoning behind the D.C. Act is specifically set forth within three “Findings” pronounced in Section 4551 of the act:

- (1) The excessive prices of prescription drugs in the District of Columbia is threatening the health and welfare of the residents of the District as well as the District government’s ability to ensure that all residents receive the health care they need, and these excessive prices directly and indirectly cause economic harm to the District and damage the health and safety of its residents;
- (2) The traditional police powers of the District of Columbia include protecting and promoting the health, safety, and welfare of its residents, regulating monopoly pricing of goods and services, and regulating to assure consumer protection and to prevent and sanction unfair trade practices; and
- (3) To promote the health, safety, and welfare of its residents, it is incumbent on the government of the District of Columbia to take action to restrain the excessive prices of prescription drugs through mechanisms that are consistent with District and federal law, including the Constitution.

52 D.C. Reg. at 9061; D.C. Act § 28-4551(1)-(3).

the Superior Court of the District of Columbia for damages and injunctive relief against the manufacturers or licensees. *Id.* at § 28-4555. By prohibiting excessive retail sales prices, while excluding retail sellers from enforcement, the Act necessarily directs “affected” parties to target the manufacturers’ wholesale prices, and the casual relation, if any, between those wholesale prices and the allegedly “excessive” prices set by retailers that result therefrom.

Although it does not specifically define what makes a price “excessive,” the Council did include in the statute a formulaic mechanism as an optional way for a plaintiff to establish a *prima facie* case of excessiveness. *See* D.C. Act § 28-4554(a). Specifically, a *prima facie* case of excessive pricing “shall be established where the wholesale price of a patented prescription drug” sold in the District of Columbia is “30% higher than the comparable price” in either the United Kingdom, Germany, Canada, or Australia, if the drug is protected in those countries “by patents or other exclusive marketing rights.” *Id.* Upon doing so, the burden shifts from the affected party to the manufacturer of the patented prescription drug to prove, by a preponderance of the evidence, that the price of the drug, presumably at the retail level, is not excessive. *Id.* at § 28-4554(b). The D.C. Act does not state whether this formulaic approach is the only way to establish a *prima facie* case that a patented prescription drug is excessive. *Id.* It does specifically provide, however, that once a *prima facie* case is established the manufacturer of the drug can prove that the price of the drug is not excessive given the cost of inventing, developing, and producing the drug, the global sales and profits from the drug to date, the amount of “government funded research that supported the development of the drug, and the impact of price” of the drug to access to the drug by the District of Columbia government and its residents. D.C. Act § 28-4554(b).

If the manufacturer fails to meet its burden, and a Superior Court judge finds that “excessive pricing” was the “result” of the manufacturers’ wholesale price, the judge can issue civil penalties and exercise any of the following additional options: “(1) Temporary, preliminary, or permanent injunctions to enjoin the sales of prescription drugs in the District at excessive prices; (2) Appropriate fines for each violation; (3) Damages, including treble damages; (4) Reasonable attorney’s fees; (5) The cost of litigation; or (6) Any other relief the Court deems proper.” D.C. Act § 28-4555(b)(1)-(6).

III. The Plaintiffs

PhRMA is a non-profit organization whose members consist of leading research based pharmaceutical and biotechnology companies who account for “close to 70% of the sales of prescription drugs in the United States. PhRMA serves as a “policy advocate” for its members and the pharmaceutical industry before federal and state government entities. BIO is a large biotechnology organization that consists of more than 1,100 members from around the world, BIO provides “advocacy, business development, and communications services” for its members and also represents other organizations which are related to the biotechnology field or provide services to the industry.

PhRMA’s members manufacture and sell patented prescription drugs within the United States from facilities outside of the District of Columbia to wholesalers who are also located, for the most part, outside the District of Columbia. In most circumstances, patented prescription drugs that are

manufactured by PhRMA's members are subsequently resold in the District of Columbia by retailers who are exempt from enforcement under the D.C. Act. BIO's members manufacture and sell patented prescription drugs and products which are mainly sold to entities outside of the District of Columbia. BIO represents companies that maintain patents and create patentable inventions.

While most of the wholesale sales by plaintiffs occur outside the District of Columbia, members of PhRMA and BIO both occasionally sell a small number of products, drugs, and therapies directly to doctors, hospitals, and pharmacies within the District of Columbia. *See* Powell Decl. ¶ 7 ("Although PhRMA members supply very limited quantities of patented prescription drugs directly to doctors and healthcare institutions in the District of Columbia, the vast majority of patented prescription drugs that are eventually provided to patients in the United States are initially sold by pharmaceutical manufacturers either to drug wholesalers . . . or to large retail pharmacy chains that warehouse their own drugs . . ."); *see* Sachdev Aff. ¶ 8 ("The overwhelming majority of therapies produced by BIO members are supplied to customers outside the District of Columbia, Such therapies are rarely supplied directly from BIO members to doctors and healthcare institutions in the District.")

ANALYSIS

* * *

II. The Supremacy Clause Challenge

PhRMA and BIO each facially challenge the D.C. Act as violative of the Supremacy Clause of the United States Constitution. In essence, they contend that the law is preempted by the Supremacy Clause because it is a direct obstacle to the purposes and execution of the federal patent laws relative to manufactured drugs. The District disagrees, contending that the D.C. Act is not preempted by the Supremacy Clause since it neither excludes federal patent law, nor serves as an obstacle to the intended purpose of those laws as applied to the manufacturers of prescription drugs.

For the following reasons, the Court finds the D.C. Act, as drafted, is a clear obstacle to the accomplishment and execution of the purpose and objectives set by Congress in passing federal patent laws relating to prescription drugs and, therefore, finds it violates the Supremacy Clause of the United States Constitution.

A. Conflict Preemption

The Supremacy Clause of the United States Constitution states that "the Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, § 1, cl. 2. Thus, where Congress legislates within the scope of its constitutionally granted powers, that legislation may displace state law. *Wardair Canada Inc. v. Fla. Dep't of Revenue*, 477 U.S. 1, 6 (1986) (holding that a state tax on aviation fuel did not violate the Commerce Clause of the Constitution and was not preempted by Congress); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) (finding that a state's unfair competition law cannot prohibit the copying of a product that is not protected by a patent or copyright because the law "clashed" with the objectives of the federal patent laws).

Where federal legislation contains no specific preemption language, however, it is the duty of the federal courts to inquire whether an implied preemption exists in a given situation. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992) (holding that a state's licensing laws were preempted to the extent that they conflicted with the Occupational Safety and Health Act of 1970). In that regard, two types of implied preemption have been recognized by the courts: field and conflict preemption. *Id.* Field preemption applies to those situations, unlike here, where the scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). *Hines* is a classic example of field preemption. 312 U.S. 52. In *Hines*, the Supreme Court found that the immigration system that Congress had enacted in regard to the registration of aliens was enacted in order to create "one uniform national registration system," and that the federal regulation was such that a state law could not be enforced when it interfered with the congressional regulation. 312 U.S. at 73-74.

Conflict preemption, on the other hand, applies to those situations where compliance with both state and federal regulations is either a "physical impossibility,"⁸ or, as alleged here, "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 67. Plaintiffs contend that the D.C. Act is preempted by the Supremacy Clause because it poses such a conflict to the accomplishment and execution of the very purpose and objectives Congress had in mind when it passed the Patent Term Restoration Act and related non-patent market exclusivity statutes. How so?

Plaintiffs' argument is premised on its assertion that the federal patent laws and related pharmaceutical market exclusivity laws reflect Congress' considered judgment of the economic incentives and protections necessary to best promote the development of new medications. Indeed, plaintiffs contend that Congress gave pharmaceutical innovation even greater statutory protection than other types of innovation when it passed the Patent Term Restoration Act of 1984, which allowed pharmaceutical manufacturers to extend the terms of their patents and provided certain market exclusivity provisions that insulate manufacturers from generic competition *after* its original patent expires. *Id.* at 17; Patent Term Restoration Act of 1984, 35 U.S.C. § 156 (2005); 21 U.S.C. §§ 355 *et seq.* Unfortunately for the District, even a casual review of the congressional history attendant to these considerable legislative achievements bears out the truth of the plaintiffs' unmistakable assertion.

Congress' regulation of our nation's pharmaceutical industry is grounded in large part in a complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation, research, and development of new drugs. Indeed, Congressman Henry Waxman, one of the principal sponsors of the Patent Term Restoration Act, articulated Congress'

8. One such example of conflict preemption in which compliance with both federal law and state law was impossible occurred in *McDermott v. Wisconsin*, 228 U.S. 115 (1913). In *McDermott*, a state law made it criminal to offer for sale syrup that was not labeled in compliance with the state law, even though the syrup offered for sale did meet federal labeling requirements. *Id.* at 124-27. Here, the Supreme Court held that the state law was preempted by the federal regulation. *See id.* at 136-37.

very purpose behind allowing pharmaceutical patent holders to set a price in their discretion:

Because there is no one else in competition, and as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product. But at some point public policy calls for the free market system competition which will bring about the result of a lower price for the consumer. That is the purpose of the legislation.

130 Cong. Rec. 24,427 (1984) (statement of Rep. Waxman).⁹ Not surprisingly, some of the federal courts have also acknowledged the same.

In *Pfizer Inc v. Dr. Reddy's Laboratories, Ltd.*, the Federal Circuit specifically commented on the empirical balance within the Patent Term Restoration Act as follows:

By restoring a portion of the patent term that is consumed during the approval phase, the incentive to develop and market products that require lengthy pre-marketing approval is intended to be preserved: The purpose of [the Patent Term Restoration Act] is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval.

359 F.3d 1361, 1364 (Fed. Cir. 2004) (quoting H.R. Rep. No. 98-857, at 15 (1984). And on a more general note, the Supreme Court itself has also recognized that the federal patent laws reflect a “carefully crafted bargain” among the various interests at stake. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) (stating that the patent system “embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years”).

How then does the D.C. Act's thinly veiled effort to force manufacturers to limit the wholesale price of those drugs to less than 30% more than the wholesale price of the same patented drugs sold in four designated “high income” countries square with the congressional purpose and objectives inherent in the Patent Term Restoration Act? It doesn't!

B. The D.C. Act Is an Unmistakable Obstacle to Congress' Objectives

Although well motivated, the D.C. Act was unequivocally designed to force drug manufacturers who sell their products both in the District and in certain foreign countries to either limit the price of their product, or face the consequences of expensive litigation over an undefined standard of “excessiveness” which is likely to vary widely across the spectrum of judges on the

9. Congressman Carlos Moorhead, when discussing the Patent Term Restoration Act, stated: We have struggled for a long time with this legislation, and most of the things that are in this bill . . . are the result of much effort and work over a long period of time and which resulted in compromises between various industries that are involved, the people that will be affected, the senior citizens of our country, the people who manufacture generics, and the people whose patents need to be protected to guarantee that they can get a recovery on the investment that they have made.

130 Cong. Rec. 24,428 (1984) (statement of Rep. Moorhead).

Superior Court. Considering the relative ease of the *prima facie* case litigation option provided for in the statute, and the severity of the penalties at the judges' disposal, manufacturers will be hard pressed to choose to roll the dice on the expensive option of convincing a given Court that an application of the factors set forth in Section 4554(b) of the D.C. Act yields a non-excessive assessment or a lack of casual connection between the domestic wholesale price and the retailers' "excessive" price. Such choices give new meaning to that old expression: caught between a rock and a hard place. Most manufacturers who want to continue selling their products in the District will undoubtedly do exactly what the City Council wants: adjust their wholesale price to an amount no greater than 30% more than the wholesale price of the same product in the four designated foreign countries. And one need not speculate too long as to the likely collateral consequences throughout the pharmaceutical industry nationwide that such capitulations would cause. Punishing the holders of pharmaceutical patents in this manner flies directly in the face of a system of rewards calculated by Congress to insure the continued strength of an industry vital to our national interests. Ironically, the factors Congress weighed in calculating their system of rewards are the very same factors the Act requires manufacturers to litigate in Superior Court in response to a *prima facie* case. See D.C. Act § 28-4554(b).

In short, using the litigation process to determine on a drug to drug basis the application of a given drug's pricing vis-à-vis that in a foreign country directly interferes with, and second guesses, the balance set by Congress in the current system of patents and market exclusivity for pharmaceutical products. Moreover, by allowing foreign drug prices to serve as the benchmark by which excessiveness may be determined in this country, the City Council is effectively substituting Congress' regulatory scheme for this industry with the regulatory system that has been formulated by these enumerated foreign countries. Because Congress' judgment in this area is supreme, the D.C. Act is preempted and therefore facially unconstitutional.

2. Pre-Emption of State Law

KEWANEE OIL CO. v. BICRON

416 U.S. 470 (1974)

Chief Justice BURGER delivered the opinion of the Court.

We granted certiorari to resolve a question on which there is a conflict in the courts of appeals: whether state trade secret protection is pre-empted by operation of the federal patent law.

I

Harshaw Chemical Co., an unincorporated division of petitioner, is a leading manufacturer of a type of synthetic crystal which is useful in the detection of ionizing radiation. In 1949 Harshaw commenced research into the growth of this type crystal and was able to produce one less than two inches in diameter. By 1966, as the result of expenditures in excess of \$1 million,

Harshaw was able to grow a 17-inch crystal, something no one else had done previously. Harshaw had developed many processes, procedures, and manufacturing techniques in the purification of raw materials and the growth and encapsulation of the crystals which enabled it to accomplish this feat. Some of these processes Harshaw considers to be trade secrets.

The individual respondents are former employees of Harshaw who formed or later joined respondent Bicron. While at Harshaw the individual respondents executed, as a condition of employment, at least one agreement each, requiring them not to disclose confidential information or trade secrets obtained as employees of Harshaw. Bicron was formed in August 1969 to compete with Harshaw in the production of the crystals, and by April 1970, had grown a 17-inch crystal.

Petitioner brought this diversity action in United States District Court for the Northern District of Ohio seeking injunctive relief and damages for the misappropriation of trade secrets. The District Court, applying Ohio trade secret law, granted a permanent injunction against the disclosure or use by respondents of 20 of the 40 claimed trade secrets until such time as the trade secrets had been released to the public, had otherwise generally become available to the public, or had been obtained by respondents from sources having the legal right to convey the information.

The Court of Appeals for the Sixth Circuit held that the findings of fact by the District Court were not clearly erroneous, and that it was evident from the record that the individual Respondents appropriated to the benefit of Bicron secret information on processes obtained while they were employees at Harshaw. Further, the Court of Appeals held that the District Court properly applied Ohio law relating to trade secrets. Nevertheless, the Court of Appeals reversed the District Court, finding Ohio's trade secret law to be in conflict with the patent laws of the United States. The Court of Appeals reasoned that Ohio could not grant monopoly protection to processes and manufacturing techniques that were appropriate subjects for consideration under 35 U.S.C. § 101 for a federal patent but which had been in commercial use for over one year and so were no longer eligible for patent protection under 35 U.S.C. § 102(b).

We hold that Ohio's law of trade secrets is not preempted by the patent laws of the United States, and, accordingly, we reverse.

II

Ohio has adopted the widely relied-upon definition of a trade secret found at Restatement of Torts § 757, comment b (1939). According to the Restatement,

(a) trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

The subject of a trade secret must be secret, and must not be of public knowledge or of a general knowledge in the trade or business. This necessary

element of secrecy is not lost, however, if the holder of the trade secret reveals the trade secret to another “in confidence, and under an implied obligation not to use or disclose it.” These others may include those of the holder’s “employees to whom it is necessary to confide it, in order to apply it to the uses for which it is intended.” Often the recipient of confidential knowledge of the subject of a trade secret is a licensee of its holder. *See Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

The protection accorded the trade secret holder is against the disclosure or unauthorized use of the trade secret by those to whom the secret has been confided under the express or implied restriction of nondisclosure or nonuse. The law also protects the holder of a trade secret against disclosure or use when the knowledge is gained, not by the owner’s volition, but by some “improper means,” Restatement of Torts § 757(a), which may include theft, wiretapping, or even aerial reconnaissance. A trade secret law, however, does not offer protection against discovery by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering, that is by starting with the known product and working backward to divine the process which aided in its development or manufacture.

No person, having obtained possession of an article representing a trade secret or access thereto with the owner’s consent, shall convert such article to his own use or that of another person, or thereafter without the owner’s consent make or cause to be made a copy of such article, or exhibit such article to another.

Whoever violates section 1333.51 of the Revised Code shall be fined not more than five thousand dollars, imprisoned not less than one nor more than ten years, or both.

Novelty, in the patent law sense, is not required for a trade secret. “Quite clearly discovery is something less than invention.” *A. O. Smith Corp. v. Petroleum Iron Works Co.*, 73 F.2d 531, 538 (C.A.6 1934). However, some novelty will be required if merely because that which does not possess novelty is usually known; secrecy, in the context of trade secrets, thus implies at least minimal novelty.

The subject matter of a patent is limited to a “process, machine, manufacture, or composition of matter, or . . . improvement thereof,” 35 U.S.C. § 101, which fulfills the three conditions of novelty and utility as articulated and defined in 35 U.S.C. §§ 101 and 102, and nonobviousness, as set out in 35 U.S.C. § 103. If an invention meets the rigorous statutory tests for the issuance of a patent, the patent is granted, for a period of 17 years, giving what has been described as the “right of exclusion.” This protection goes not only to copying the subject matter, which is forbidden under the Copyright Act, 17 U.S.C. §§ 1 et seq., but also to independent creation.

III

The first issue we deal with is whether the States are forbidden to act at all in the area of protection of the kinds of intellectual property which may make up the subject matter of trade secrets.

Article I, § 8, cl. 8, of the Constitution grants to the Congress the power

[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . .

In the 1972 Term, in *Goldstein v. California*, 412 U.S. 546 (1973), we held that the cl. 8 grant of power to Congress was not exclusive and that, at least in the case of writings, the States were not prohibited from encouraging and protecting the efforts of those within their borders by appropriate legislation. The States could, therefore, protect against the unauthorized re-recording for sale of performances fixed on records or tapes, even though those performances qualified as “writings” in the constitutional sense and Congress was empowered to legislate regarding such performances and could pre-empt the area if it chose to do so. This determination was premised on the great diversity of interests in our Nation—the essentially non-uniform character of the appreciation of intellectual achievements in the various States. Evidence for this came from patents granted by the States in the 18th century. 412 U.S., at 557.

Just as the States may exercise regulatory power over writings so may the States regulate with respect to discoveries. States may hold diverse viewpoints in protecting intellectual property to invention as they do in protecting the intellectual property relating to the subject matter of copyright. The only limitation on the States is that in regulating the area of patents and copyrights they do not conflict with the operation of the laws in this area passed by Congress, and it is to that more difficult question we now turn.

IV

The question of whether the trade secret law of Ohio is void under the Supremacy Clause involves a consideration of whether that law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” We stated in *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964), that when state law touches upon the area of federal statutes enacted pursuant to constitutional authority, “it is ‘familiar doctrine’ that the federal policy ‘may not be set at naught, or its benefits denied’ by the state law. This is true, of course, even if the state law is enacted in the exercise of otherwise undoubted state power.”

The laws which the Court of Appeals in this case held to be in conflict with the Ohio law of trade secrets were the patent laws passed by the Congress in the unchallenged exercise of its clear power under Art. I, § 8, cl. 8, of the Constitution. The patent law does not explicitly endorse or forbid the operation of trade secret law. However, as we have noted, if the scheme of protection developed by Ohio respecting trade secrets “clashes with the objectives of the federal patent laws,” *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S., at 231, then the state law must fall. To determine whether the Ohio law “clashes” with the federal law it is helpful to examine the objectives of both the patent and trade secret laws.

The stated objective of the Constitution in granting the power to Congress to legislate in the area of intellectual property is to “promote the Progress of Science and useful Arts.” The patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development. The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens. In return for the right of exclusion, this “reward for inventions,” the

patent laws impose upon the inventor a requirement of disclosure. To insure adequate and full disclosure so that upon the expiration of the 17-year period “the knowledge of the invention enures to the people, who are thus enabled without restriction to practice it and profit by its use,” the patent laws require that the patent application shall include a full and clear description of the invention and “of the manner and process of making and using it” so that any person skilled in the art may make and use the invention. 35 U.S.C. § 112. When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art. The Court has also articulated another policy of the patent law: that which is in the public domain cannot be removed therefrom by action of the States.

The maintenance of standards of commercial ethics and the encouragement of invention are the broadly stated policies behind trade secret law. “The necessity of good faith and honest, fair dealing, is the very life and spirit of the commercial world.” *National Tube Co. v. Eastern Tube Co.*, 3 Ohio Cir. Cr. R., N.S. at 462. In *A. O. Smith Corp. v. Petroleum Iron Works Co.*, 73 F.2d, at 539, the Court emphasized that even though a discovery may not be patentable, that does not

destroy the value of the discovery to one who makes it, or advantage the competitor who by unfair means, or as the beneficiary of a broken faith, obtains the desired knowledge without himself paying the price in labor, money, or machines expended by the discover.

Having now in mind the objectives of both the patent and trade secret law, we turn to an examination of the interaction of these systems of protection of intellectual property established by the Congress and the other by a State to determine whether and under what circumstances the latter might constitute “too great an encroachment on the federal patent system to be tolerated.” *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S., at 232.

As we noted earlier, trade secret law protects items which would not be proper subjects for consideration for patent protection under 35 U.S.C. § 101. As in the case of the recordings in *Goldstein v. California*, Congress, with respect to nonpatentable subject matter, “has drawn no balance; rather, it has left the area unattended, and no reason exists why the State should not be free to act.” *Goldstein v. California*, *supra*, 412 U.S., at 570.

Since no patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter of 35 U.S.C. § 101, the holder of such a discovery would have no reason to apply for a patent whether trade secret protection existed or not. Abolition of trade secret protection would, therefore, not result in increased disclosure to the public of discoveries in the area of nonpatentable subject matter. Also, it is hard to see how the public would be benefited by disclosure of customer lists or advertising campaigns; in fact, keeping such items secret encourages businesses to initiate new and individualized plans of operation, and constructive competition results. This, in turn, leads to a greater variety of business methods than would otherwise be the case if privately developed

marketing and other data were passed illicitly among firms involved in the same enterprise.

Congress has spoken in the area of those discoveries which fall within one of the categories of patentable subject matter of 35 U.S.C. § 101 and which are, therefore, of a nature that would be subject to consideration for a patent. Processes, machines, manufactures, compositions of matter and improvements thereof, which meet the tests of utility, novelty, and nonobviousness are entitled to be patented, but those which do not, are not. The question remains whether those items which are proper subjects for consideration for a patent may also have available the alternative protection accorded by trade secret law.

Certainly the patent policy of encouraging invention is not disturbed by the existence of another form of incentive to invention. In this respect the two systems are not and never would be in conflict. Similarly, the policy that matter once in the public domain must remain in the public domain is not incompatible with the existence of trade secret protection. By definition a trade secret has not been placed in the public domain.

The more difficult objective of the patent law to reconcile with trade secret law is that of disclosure, the quid pro quo of the right to exclude. We are helped in this stage of the analysis by Judge Henry Friendly's opinion in *Painton & Co. v. Bourns, Inc.*, 442 F.2d 216 (C.A.2 1971). There the Court of Appeals thought it useful, in determining whether inventors will refrain because of the existence of trade secret law from applying for patents, thereby depriving the public from learning of the invention, to distinguish between three categories of trade secrets:

- (1) the trade secret believed by its owner to constitute a validly patentable invention; (2) the trade secret known to its owner not to be so patentable; and (3) the trade secret whose valid patentability is considered dubious. *Id.*, at 224.

Trade secret protection in each of these categories would run against breaches of confidence—the employee and licensee situations—and theft and other forms of industrial espionage.

As to the trade secret known not to meet the standards of patentability, very little in the way of disclosure would be accomplished by abolishing trade secret protection. With trade secrets of nonpatentable subject matter, the patent alternative would not reasonably be available to the inventor. "There can be no public interest in stimulating developers of such (unpatentable) knowhow to flood an overburdened Patent Office with applications (for) what they do not consider patentable." *Ibid.* The mere filing of applications doomed to be turned down by the Patent Office will bring forth no new public knowledge or enlightenment, since under federal statute and regulation patent applications and abandoned patent applications are held by the Patent Office in confidence and are not open to public inspection.

Even as the extension of trade secret protection to patentable subject matter that the owner knows will not meet the standards of patentability will not conflict with the patent policy of disclosure, it will have a decidedly beneficial effect on society. Trade secret law will encourage invention in areas where patent law does not reach, and will prompt the independent innovator to proceed with the discovery and exploitation of his invention. Competition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention.

Even if trade secret protection against the faithless employee were abolished, inventive and exploitive effort in the area of patentable subject matter that did not meet the standards of patentability would continue, although at a reduced level. Alternatively with the effort that remained, however, would come an increase in the amount of self-help that innovative companies would employ. Knowledge would be widely dispersed among the employees of those still active in research. Security precautions necessarily would be increased, and salaries and fringe benefits of those few officers or employees who had to know the whole of the secret invention would be fixed in an amount thought sufficient to assure their loyalty. Smaller companies would be placed at a distinct economic disadvantage, since the costs of this kind of self-help could be great, and the cost to the public of the use of this invention would be increased. The innovative entrepreneur with limited resources would tend to confine his research efforts to himself and those few he felt he could trust without the ultimate assurance of legal protection against breaches of confidence. As a result, organized scientific and technological research could become fragmented, and society, as a whole, would suffer.

Another problem that would arise if state trade secret protection were precluded is in the area of licensing others to exploit secret processes. The holder of a trade secret would not likely share his secret with a manufacturer who cannot be placed under binding legal obligation to pay a license fee or to protect the secret. The result would be to hoard rather than disseminate knowledge. Instead, then, of licensing others to use his invention and making the most efficient use of existing manufacturing and marketing structures within the industry, the trade secret holder would tend either to limit his utilization of the invention, thereby depriving the public of the maximum benefit of its use, or engage in the time-consuming and economically wasteful enterprise of constructing duplicative manufacturing and marketing mechanisms for the exploitation of the invention. The detrimental misallocation of resources and economic waste that would thus take place if trade secret protection were abolished with respect to employees or licensees cannot be justified by reference to any policy that the federal patent law seeks to advance.

Nothing in the patent law requires that States refrain from action to prevent industrial espionage. In addition to the increased costs for protection from burglary, wire-tapping, bribery, and the other means used to misappropriate trade secrets, there is the inevitable cost to the basic decency of society when one firm steals from another. A most fundamental human right, that of privacy, is threatened when industrial espionage is condoned or is made profitable; the state interest in denying profit to such illegal ventures is unchallengeable.

The next category of patentable subject matter to deal with is the invention whose holder has a legitimate doubt as to its patentability. The risk of eventual patent invalidity by the courts and the costs associated with that risk may well impel some with a good-faith doubt as to patentability not to take the trouble to seek to obtain and defend patent protection for their discoveries, regardless of the existence of trade secret protection. Trade secret protection would assist those inventors in the more efficient exploitation of their discoveries and not conflict with the patent law. In most cases of genuine doubt as to patent validity the potential rewards of patent protection are so far superior to those

accruing to holders of trade secrets, that the holders of such inventions will seek patent protection, ignoring the trade secret route. For those inventors “on the line” as to whether to seek patent protection, the abolition of trade secret protection might encourage some to apply for a patent who otherwise would not have done so. For some of those so encouraged, no patent will be granted and the result

will have been an unnecessary postponement in the divulging of the trade secret to persons willing to pay for it. If (the patent does issue), it may well be invalid, yet many will prefer to pay a modest royalty than to contest it, even though Lear allows them to accept a license and pursue the contest without paying royalties while the fight goes on. The result in such a case would be unjustified royalty payments from many who would prefer not to pay them rather than agreed fees from one or a few who are entirely willing to do so. *Painton & Co. v. Bourns, Inc.*, 442 F.2d, at 225.

The point is that those who might be encouraged to file for patents by the absence of trade secret law will include inventors possessing the chaff as well as the wheat. Some of the chaff—the nonpatentable discoveries—will be thrown out by the Patent Office, but in the meantime society will have been deprived of use of those discoveries through trade secret-protected licensing. Some of the chaff may not be thrown out. This Court has noted the difference between the standards used by the Patent Office and the courts to determine patentability. *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966). In *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), the Court thought that an invalid patent was so serious a threat to the free use of ideas already in the public domain that the Court permitted licensees of the patent holder to challenge the validity of the patent. Better had the invalid patent never issued. More of those patents would likely issue if trade secret law were abolished. Eliminating trade secret law for the doubtfully patentable invention is thus likely to have deleterious effects on society and patent policy which we cannot say are balanced out by the speculative gain which might result from the encouragement of some inventors with doubtfully patentable inventions which deserve patent protection to come forward and apply for patents. There is no conflict, then, between trade secret law and the patent law policy of disclosure, at least insofar as the first two categories of patentable subject matter are concerned.

The final category of patentable subject matter to deal with is the clearly patentable invention, i.e., that invention which the owner believes to meet the standards of patentability. It is here that the federal interest in disclosure is at its peak; these inventions, novel, useful and nonobvious, are “the things which are worth to the public the embarrassment of an exclusive patent.” *Graham v. John Deere Co.*, 383 U.S. at 9, (quoting Thomas Jefferson). The interest of the public is that the bargain of 17 years of exclusive use in return for disclosure be accepted. If a State, through a system of protection, were to cause a substantial risk that holders of patentable inventions would not seek patents, but rather would rely on the state protection, we would be compelled to hold that such a system could not constitutionally continue to exist. In the case of trade secret law no reasonable risk of deterrence from patent application by those who can reasonably expect to be granted patents exists.

Trade secret law provides far weaker protection in many respects than the patent law. While trade secret law does not forbid the discovery of the trade

secret by fair and honest means, e.g., independent creation or reverse engineering, patent law operates “against the world,” forbidding any use of the invention for whatever purpose for a significant length of time. The holder of a trade secret also takes a substantial risk that the secret will be passed on to his competitors, by theft or by breach of a confidential relationship, in a manner not easily susceptible of discovery or proof. Where patent law acts as a barrier, trade secret law functions relatively as a sieve. The possibility that an inventor who believes his invention meets the standards of patentability will sit back, rely on trade secret law, and after one year of use forfeit any right to patent protection, 35 U.S.C. § 102(b), is remote indeed.

Nor does society face much risk that scientific or technological progress will be impeded by the rare inventor with a patentable invention who chooses trade secret protection over patent protection. The ripeness-of-time concept of invention, developed from the study of the many independent multiple discoveries in history, predicts that if a particular individual had not made a particular discovery others would have, and in probably a relatively short period of time. If something is to be discovered at all very likely it will be discovered by more than one person. Even were an inventor to keep his discovery completely to himself, something that neither the patent nor trade secret laws forbid, there is a high probability that it will be soon independently developed. If the invention, though still a trade secret, is put into public use, the competition is alerted to the existence of the inventor’s solution to the problem and may be encouraged to make an extra effort to independently find the solution thus known to be possible. The inventor faces pressures not only from private industry, but from the skilled scientists who work in our universities and our other great publicly supported centers of learning and research.

We conclude that the extension of trade secret protection to clearly patentable inventions does not conflict with the patent policy of disclosure. Perhaps because trade secret law does not produce any positive effects in the area of clearly patentable inventions, as opposed to the beneficial effects resulting from trade secret protection in the areas of the doubtfully patentable and the clearly unpatentable inventions, it has been suggested that partial pre-emption may be appropriate, and that courts should refuse to apply trade secret protection to inventions which the holder should have patented, and which would have been, thereby, disclosed. However, since there is no real possibility that trade secret law will conflict with the federal policy favoring disclosure of clearly patentable inventions partial pre-emption is inappropriate. Partial pre-emption, furthermore, could well create serious problems for state courts in the administration of trade secret law. As a preliminary matter in trade secret actions, state courts would be obliged to distinguish between what a reasonable inventor would and would not correctly consider to be clearly patentable, with the holder of the trade secret arguing that the invention was not patentable and the misappropriator of the trade secret arguing its undoubted novelty, utility, and nonobviousness. Federal courts have a difficult enough time trying to determine whether an invention, narrowed by the patent application procedure and fixed in the specifications which describe the invention for which the patent has been granted, is patentable. Although state courts in some circumstances must join federal courts in judging whether an issued patent is valid, *Lear, Inc. v. Adkins*, *supra*, it would

be undesirable to impose the almost impossible burden on state courts to determine the patentability—in fact and in the mind of a reasonable inventor—of a discovery which has not been patented and remains entirely uncircumscribed by expert analysis in the administrative process. Neither complete nor partial pre-emption of state trade secret law is justified.

Trade secret law and patent law have co-existed in this country for over one hundred years. Each has its particular role to play, and the operation of one does not take away from the need for the other. Trade secret law encourages the development and exploitation of those items of lesser or different invention than might be accorded protection under the patent laws, but which items still have an important part to play in the technological and scientific advancement of the Nation. Trade secret law promotes the sharing of knowledge, and the efficient operation of industry; it permits the individual inventor to reap the rewards of his labor by contracting with a company large enough to develop and exploit it. Congress, by its silence over these many years, has seen the wisdom of allowing the States to enforce trade secret protection. Until Congress takes affirmative action to the contrary, States should be free to grant protection to trade secrets.

Justice DOUGLAS, with whom Justice BRENNAN concurs, dissenting.

Today's decision is at war with the philosophy of *Sears, Roebuck & Co. v. Stiffel Co.*, *supra* and *Compco Corp. v. Day-Brite Lighting, Inc.* Those cases involved patents—one of a pole lamp and one of fluorescent lighting fixtures each of which was declared invalid. The lower courts held, however, that though the patents were invalid the sale of identical or confusingly similar products to the products of the patentees violated state unfair competition laws. We held that when an article is unprotected by a patent, state law may not forbid others to copy it, because every article not covered by a valid patent is in the public domain. Congress in the patent laws decided that where no patent existed, free competition should prevail; that where a patent is rightfully issued, the right to exclude others should obtain for no longer than 17 years, and that the States may not “under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws,” 376 U.S., at 231.

The product involved in this suit, sodium iodide synthetic crystals, was a product that could be patented but was not. Harshaw the inventor apparently contributed greatly to the technology in that field by developing processes, procedures, and techniques that produced much larger crystals than any competitor. These processes, procedures, and techniques were also patentable; but no patent was sought. Rather Harshaw sought to protect its trade secrets by contracts with its employees. And the District Court found that, as a result of those secrecy precautions, “not sufficient disclosure occurred so as to place the claimed trade secrets in the public domain”; and those findings were sustained by the Court of Appeals.

The District Court issued a permanent injunction against respondents, ex-employees, restraining them from using the processes used by Harshaw. By a patent which would require full disclosure Harshaw could have obtained a 17-year monopoly against the world. By the District Court's injunction, which the Court approves and reinstates, Harshaw gets a permanent injunction running into perpetuity against respondents. In *Sears*, as in the present case,

an injunction against the unfair competitor issued. We said: "To allow a State by use of its law of unfair competition to prevent the copying of an article which represents too slight an advance to be patented would be to permit the State to block off from the public something which federal law has said belongs to the public. The result would be that while federal law grants only 14 or 17 years' protection to genuine inventions, see 35 U.S.C. §§ 154, 173, States could allow perpetual protection to articles too lacking in novelty to merit any patent at all under federal constitutional standards. This would be too great an encroachment on the federal patent system to be tolerated." 376 U.S., at 231-232.

The conflict with the patent laws is obvious. The decision of Congress to adopt a patent system was based on the idea that there will be much more innovation if discoveries are disclosed and patented than there will be when everyone works in secret. Society thus fosters a free exchange of technological information at the cost of a limited 17-year monopoly.

A trade secret, unlike a patent, has no property dimension. That was the view of the Court of Appeals, 478 F.2d 1074, 1081; and its decision is supported by what Mr. Justice Holmes said in *DuPont de Nemours Powder Co. v. Masland*, 244 U.S. 100, 102:

The word property as applied to trade-marks and trade secrets is an unanalyzed expression of certain makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence that he accepted. The property may be denied but the confidence cannot be. Therefore the starting point for the present matter is not property or due process of law, but that the defendant stood in confidential relations with the plaintiffs, or one of them. These have given place to hostility, and the first thing to be made sure of is that the defendant shall not fraudulently abuse the trust reposed in him. It is the usual incident of confidential relations. If there is any disadvantage in the fact that he knew the plaintiffs' secrets he must take the burden with the good.

The difference between the two things, letters-patent and copyright, may be illustrated by reference to the subjects just enumerated. Take the case of medicines. Certain mixtures are found to be of great value in the healing art. If the discoverer writes and publishes a book on the subject (as regular physicians generally do), he gains no exclusive right to the manufacture and sale of the medicine; he gives that to the public. If he desires to acquire such exclusive right, he must obtain a patent for the mixture as a new art, manufacture, or composition of matter. He may copyright his book, if he pleases; but that only secures to him the exclusive right of printing and publishing his book. So of all other inventions or discoveries.

Baker v. Selden, 101 U.S. 99, 102-103.

A suit to redress theft of a trade secret is grounded in tort damages for breach of a contract a historic remedy, *Cataphote Corp. v. Hudson*, 5 Cir., 422 F.2d 1290. Damages for breach of a confidential relation are not pre-empted by this patent law, but an injunction against use is pre-empted because the patent law states the only monopoly over trade secrets that is enforceable by specific performance; and that monopoly exacts as a price full disclosure. A trade secret can be protected only by being kept secret. Damages for breach of a contract are one thing; an injunction barring disclosure does service for the protection accorded valid patents and is therefore pre-empted.

From the findings of fact of the lower courts, the process involved in this litigation was unique, such a great discovery as to make its patentability a virtual certainty. Yet the Court's opinion reflects a vigorous activist anti-patent philosophy. My objection is not because it is activist. This is a problem that involves no neutral principle. The Constitution in Art. I, § 8, cl. 8, expresses the activist policy which Congress has enforced by statutes. It is that constitutional policy which we should enforce, not our individual notions of the public good.

BONITO BOATS, INC. v. THUNDER CRAFT BOATS, INC.

489 U.S. 141 (1989)

Justice O'CONNOR delivered the opinion of the Court.

We must decide today what limits the operation of the federal patent system places on the States' ability to offer substantial protection to utilitarian and design ideas which the patent laws leave otherwise unprotected. In *Interpart Corp. v. Italia*, 777 F.2d 678 (1985), the Court of Appeals for the Federal Circuit concluded that a California law prohibiting the use of the "direct molding process" to duplicate unpatented articles posed no threat to the policies behind the federal patent laws. In this case, the Florida Supreme Court came to a contrary conclusion. It struck down a Florida statute which prohibits the use of the direct molding process to duplicate unpatented boat hulls, finding that the protection offered by the Florida law conflicted with the balance struck by Congress in the federal patent statute between the encouragement of invention and free competition in unpatented ideas. We granted certiorari to resolve the conflict, and we now affirm the judgment of the Florida Supreme Court.

I

In September 1976, petitioner Bonito Boats, Inc. (Bonito), a Florida corporation, developed a hull design for a fiberglass recreational boat which it marketed under the trade name Bonito Boat Model 5VBR. Designing the boat hull required substantial effort on the part of Bonito. A set of engineering drawings was prepared, from which a hardwood model was created. The hardwood model was then sprayed with fiberglass to create a mold, which then served to produce the finished fiberglass boats for sale. The 5VBR was placed on the market sometime in September 1976. There is no indication in the record that a patent application was ever filed for protection of the utilitarian or design aspects of the hull, or for the process by which the hull was manufactured. The 5VBR was favorably received by the boating public, and "a broad interstate market" developed for its sale.

In May 1983, after the Bonito 5VBR had been available to the public for over six years, the Florida Legislature enacted Fla.Stat. § 559.94 (1987). The statute makes "[i]t . . . unlawful for any person to use the direct molding process to duplicate for the purpose of sale any manufactured vessel hull or component part of a vessel made by another without the written permission of that other person." § 559.94(2). The statute also makes it unlawful for a person to "knowingly sell a vessel hull or component part of a vessel duplicated in violation of subsection (2)." § 559.94(3). Damages, injunctive relief, and

attorney's fees are made available to "[a]ny person who suffers injury or damage as the result of a violation" of the statute. § 559.94(4). The statute was made applicable to vessel hulls or component parts duplicated through the use of direct molding after July 1, 1983. § 559.94(5).

On December 21, 1984, Bonito filed this action in the Circuit Court of Orange County, Florida. The complaint alleged that respondent here, Thunder Craft Boats, Inc. (Thunder Craft), a Tennessee corporation, had violated the Florida statute by using the direct molding process to duplicate the Bonito 5VBR fiberglass hull, and had knowingly sold such duplicates in violation of the Florida statute. Bonito sought "a temporary and permanent injunction prohibiting [Thunder Craft] from continuing to unlawfully duplicate and sell Bonito Boat hulls or components," as well as an accounting of profits, treble damages, punitive damages, and attorney's fees. Respondent filed a motion to dismiss the complaint, arguing that under this Court's decisions in *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), the Florida statute conflicted with federal patent law and was therefore invalid under the Supremacy Clause of the Federal Constitution.

On appeal, a sharply divided Florida Supreme Court agreed with the lower courts' conclusion that the Florida law impermissibly interfered with the scheme established by the federal patent laws. The majority read our decisions in *Sears* and *Compco* for the proposition that "when an article is introduced into the public domain, only a patent can eliminate the inherent risk of competition and then but for a limited time." 515 So. 2d, at 222. Relying on the Federal Circuit's decision in the *Interpart* case, the three dissenting judges argued that the Florida antirect molding provision "does not prohibit the copying of an unpatented item. It prohibits one method of copying; the item remains in the public domain." 515 So. 2d, at 223.

II

Article I, § 8, cl. 8, of the Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the "Progress of Science and useful Arts." As we have noted in the past, the Clause contains both a grant of power and certain limitations upon the exercise of that power. Congress may not create patent monopolies of unlimited duration, nor may it "authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966).

From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy. . . . Protection is offered to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. . . . The novelty requirement of patentability is presently expressed in 35 U.S.C. §§ 102(a) and (b). Sections 102(a) and (b)

operate in tandem to exclude from consideration for patent protection knowledge that is already available to the public. They express a congressional determination that the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use. From the Patent Act of 1790 to the present day, the public sale of an unpatented article has acted as a complete bar to federal protection of the idea embodied in the article thus placed in public commerce. . . . In addition to the requirements of novelty and utility, the federal patent law has long required that an innovation not be anticipated by the prior art in the field. Even if a particular combination of elements is “novel” in the literal sense of the term, it will not qualify for federal patent protection if its contours are so traced by the existing technology in the field that the “improvement is the work of the skillful mechanic, not that of the inventor.” *Hotchkiss v. Greenwood*, 11 How. 248, 267 (1851). In 1952, Congress codified this judicially developed requirement in 35 U.S.C. § 103. . . .

The attractiveness of such a bargain, and its effectiveness in inducing creative effort and disclosure of the results of that effort, depend almost entirely on a backdrop of free competition in the exploitation of unpatented designs and innovations. The novelty and nonobviousness requirements of patentability embody a congressional understanding, implicit in the Patent Clause itself, that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception. Moreover, the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure. State law protection for techniques and designs whose disclosure has already been induced by market rewards may conflict with the very purpose of the patent laws by decreasing the range of ideas available as the building blocks of further innovation. The offer of federal protection from competitive exploitation of intellectual property would be rendered meaningless in a world where substantially similar state law protections were readily available. To a limited extent, the federal patent laws must determine not only what is protected, but also what is free for all to use.

Thus our past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws. The tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources is constant. Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess. We have long held that after the expiration of a federal patent, the subject matter of the patent passes to the free use of the public as a matter of federal law. Where the public has paid the congressionally mandated price for disclosure, the States may not render the exchange fruitless by offering patent-like protection to the subject matter of the expired patent. “It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property.” *Singer*, 16 S. Ct., at 1008.

In our decisions in *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), we found that publicly known design and utilitarian ideas which were unprotected by patent occupied much the same position as the subject matter of an expired patent. The *Sears* case involved a pole lamp originally designed by the plaintiff Stiffel,

who had secured both design and mechanical patents on the lamp. Sears purchased unauthorized copies of the lamps, and was able to sell them at a retail price practically equivalent to the wholesale price of the original manufacturer. Stiffel brought an action against Sears in Federal District Court, alleging infringement of the two federal patents and unfair competition under Illinois law. The District Court found that Stiffel's patents were invalid due to anticipation in the prior art, but nonetheless enjoined Sears from further sales of the duplicate lamps based on a finding of consumer confusion under the Illinois law of unfair competition. The Court of Appeals affirmed, coming to the conclusion that the Illinois law of unfair competition prohibited product simulation even in the absence of evidence that the defendant took some further action to induce confusion as to source.

This Court reversed, finding that the unlimited protection against copying which the Illinois law accorded an unpatentable item whose design had been fully disclosed through public sales conflicted with the federal policy embodied in the patent laws. The Court stated:

In the present case the "pole lamp" sold by Stiffel has been held not to be entitled to the protection of either a mechanical or a design patent. An unpatentable article, like an article on which the patent has expired, is in the public domain and may be made and sold by whoever chooses to do so. What Sears did was to copy Stiffel's design and sell lamps almost identical to those sold by Stiffel. This it had every right to do under the federal patent laws.

376 U.S., at 231.

A similar conclusion was reached in *Compco*, where the District Court had extended the protection of Illinois' unfair competition law to the functional aspects of an unpatented fluorescent lighting system. The injunction against copying of an unpatented article, freely available to the public, impermissibly "interfere[d] with the federal policy, found in Art. I, § 8, cl. 8, of the Constitution and in the implementing federal statutes, of allowing free access to copy whatever the federal patent and copyright laws leave in the public domain." *Compco*, 376 U.S., at 237.

The pre-emptive sweep of our decisions in *Sears* and *Compco* has been the subject of heated scholarly and judicial debate. Read at their highest level of generality, the two decisions could be taken to stand for the proposition that the States are completely disabled from offering any form of protection to articles or processes which fall within the broad scope of patentable subject matter. Since the potentially patentable includes "anything under the sun that is made by man," *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), the broadest reading of *Sears* would prohibit the States from regulating the deceptive simulation of trade dress or the tortious appropriation of private information.

That the extrapolation of such a broad pre-emptive principle from *Sears* is inappropriate is clear from the balance struck in *Sears* itself. The *Sears* Court made it plain that the States "may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods." *Sears, supra*, 376 U.S., at 232. Trade dress is, of course, potentially the subject matter of design patents. Yet our decision in *Sears* clearly indicates that the States may place limited regulations on the cir-

cumstances in which such designs are used in order to prevent consumer confusion as to source. Thus, while *Sears* speaks in absolutist terms, its conclusion that the States may place some conditions on the use of trade dress indicates an implicit recognition that all state regulation of potentially patentable but unpatented subject matter is not *ipso facto* pre-empted by the federal patent laws.

What was implicit in our decision in *Sears*, we have made explicit in our subsequent decisions concerning the scope of federal pre-emption of state regulation of the subject matter of patent. Thus, in *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974), we held that state protection of trade secrets did not operate to frustrate the achievement of the congressional objectives served by the patent laws. Despite the fact that state law protection was available for ideas which clearly fell within the subject matter of patent, the Court concluded that the nature and degree of state protection did not conflict with the federal policies of encouragement of patentable invention and the prompt disclosure of such innovations. . . .

At the heart of *Sears* and *Compco* is the conclusion that the efficient operation of the federal patent system depends upon substantially free trade in publicly known, unpatented design and utilitarian conceptions. In *Sears*, the state law offered “the equivalent of a patent monopoly,” 376 U.S., at 233, in the functional aspects of a product which had been placed in public commerce absent the protection of a valid patent. While, as noted above, our decisions since *Sears* have taken a decidedly less rigid view of the scope of federal pre-emption under the patent laws, *e.g.*, *Kewanee*, *supra*, 416 U.S., at 479-480, we believe that the *Sears* Court correctly concluded that the States may not offer patent-like protection to intellectual creations which would otherwise remain unprotected as a matter of federal law. Both the novelty and the non-obviousness requirements of federal patent law are grounded in the notion that concepts within the public grasp, or those so obvious that they readily could be, are the tools of creation available to all. They provide the baseline of free competition upon which the patent system’s incentive to creative effort depends. A state law that substantially interferes with the enjoyment of an unpatented utilitarian or design conception which has been freely disclosed by its author to the public at large impermissibly contravenes the ultimate goal of public disclosure and use which is the centerpiece of federal patent policy. Moreover, through the creation of patent-like rights, the States could essentially redirect inventive efforts away from the careful criteria of patentability developed by Congress over the last 200 years. We understand this to be the reasoning at the core of our decisions in *Sears* and *Compco*, and we reaffirm that reasoning today.

III

We believe that the Florida statute at issue in this case so substantially impedes the public use of the otherwise unprotected design and utilitarian ideas embodied in unpatented boat hulls as to run afoul of the teaching of our decisions in *Sears* and *Compco*. It is readily apparent that the Florida statute does not operate to prohibit “unfair competition” in the usual sense that the term is understood. The law of unfair competition has its roots in the common-law tort of deceit: its general concern is with protecting *consumers* from confusion as to source. While that concern may result in the creation of “quasi-

property rights” in communicative symbols, the focus is on the protection of consumers, not the protection of producers as an incentive to product innovation. . . .

In contrast to the operation of unfair competition law, the Florida statute is aimed directly at preventing the exploitation of the design and utilitarian conceptions embodied in the product itself. The sparse legislative history surrounding its enactment indicates that it was intended to create an inducement for the improvement of boat hull designs. To accomplish this goal, the Florida statute endows the original boat hull manufacturer with rights against the world, similar in scope and operation to the rights accorded a federal patentee. Like the patentee, the beneficiary of the Florida statute may prevent a competitor from “making” the product in what is evidently the most efficient manner available and from “selling” the product when it is produced in that fashion. The Florida scheme offers this protection for an unlimited number of years to all boat hulls and their component parts, without regard to their ornamental or technological merit. Protection is available for subject matter for which patent protection has been denied or has expired, as well as for designs which have been freely revealed to the consuming public by their creators.

In this case, the Bonito 5VBR fiberglass hull has been freely exposed to the public for a period in excess of six years. For purposes of federal law, it stands in the same stead as an item for which a patent has expired or been denied: it is unpatented and unpatentable. See 35 U.S.C. § 102(b). Whether because of a determination of unpatentability or other commercial concerns, petitioner chose to expose its hull design to the public in the marketplace, eschewing the bargain held out by the federal patent system of disclosure in exchange for exclusive use. Yet, the Florida statute allows petitioner to reassert a substantial property right in the idea, thereby constricting the spectrum of useful public knowledge. Moreover, it does so without the careful protections of high standards of innovation and limited monopoly contained in the federal scheme. We think it clear that such protection conflicts with the federal policy “that all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent.” *Lear, Inc. v. Adkins*, 395 U.S., at 668.

That the Florida statute does not remove all means of reproduction and sale does not eliminate the conflict with the federal scheme. In essence, the Florida law prohibits the entire public from engaging in a form of reverse engineering of a product in the public domain. This is clearly one of the rights vested in the federal patent holder, but has never been a part of state protection under the law of unfair competition or trade secrets. See *Kewanee*, 416 U.S., at 476 (“A trade secret law, however, does not offer protection against discovery by . . . so-called reverse engineering, that is by starting with the known product and working backward to divine the process which aided in its development or manufacture”). The duplication of boat hulls and their component parts may be an essential part of innovation in the field of hydrodynamic design. Variations as to size and combination of various elements may lead to significant advances in the field. Reverse engineering of chemical and mechanical articles in the public domain often leads to significant advances in technology. If Florida may prohibit this particular method of study and recomposition of an unpatented article, we fail to see the principle that would prohibit a State from banning the use of chromatography in the

reconstitution of unpatented chemical compounds, or the use of robotics in the duplication of machinery in the public domain.

Moreover, as we noted in *Kewanee*, the competitive reality of reverse engineering may act as a spur to the inventor, creating an incentive to develop inventions that meet the rigorous requirements of patentability. The Florida statute substantially reduces this competitive incentive, thus eroding the general rule of free competition upon which the attractiveness of the federal patent bargain depends. The protections of state trade secret law are most effective at the developmental stage, before a product has been marketed and the threat of reverse engineering becomes real. During this period, patentability will often be an uncertain prospect, and to a certain extent, the protection offered by trade secret law may “dovetail” with the incentives created by the federal patent monopoly. In contrast, under the Florida scheme, the would-be inventor is aware from the outset of his efforts that rights against the public are available regardless of his ability to satisfy the rigorous standards of patentability. Indeed, it appears that even the most mundane and obvious changes in the design of a boat hull will trigger the protections of the statute. See Fla. Stat. § 559.94(2) (1987) (protecting “any manufactured vessel hull or component part”). Given the substantial protection offered by the Florida scheme, we cannot dismiss as hypothetical the possibility that it will become a significant competitor to the federal patent laws, offering investors similar protection without the *quid pro quo* of substantial creative effort required by the federal statute. The prospect of all 50 States establishing similar protections for preferred industries without the rigorous requirements of patentability prescribed by Congress could pose a substantial threat to the patent system’s ability to accomplish its mission of promoting progress in the useful arts. . . .

Petitioner and its supporting *amici* place great weight on the contrary decision of the Court of Appeals for the Federal Circuit in *Interpart Corp. v. Italia*. In upholding the application of the California “antidirect molding” statute to the duplication of unpatented automobile mirrors, the Federal Circuit stated: “The statute prevents unscrupulous competitors from obtaining a product and using it as the ‘plug’ for making a mold. The statute does not prohibit copying the design of the product in any other way; the latter if in the public domain, is free for anyone to make, use or sell.” 777 F.2d, at 685. The court went on to indicate that “the patent laws ‘say nothing about the right to copy or the right to use, they speak only in terms of the right to exclude.’” *Ibid*.

We find this reasoning defective in several respects. The Federal Circuit apparently viewed the direct molding statute at issue in *Interpart* as a mere regulation of the use of chattels. Yet, the very purpose of antidirect molding statutes is to “reward” the “inventor” by offering substantial protection against public exploitation of his or her idea embodied in the product. Such statutes would be an exercise in futility if they did not have precisely the effect of substantially limiting the ability of the public to exploit an otherwise unprotected idea. As *amicus* points out, the direct molding process itself has been in use since the early 1950’s. Indeed, U.S. Patent No. 3,419,646, issued to Robert L. Smith in 1968, explicitly discloses and claims a method for the direct molding of boat hulls. The specifications of the Smith Patent indicate that “[i]t is a major object of the present invention to provide a method for making large molded boat hull molds at very low cost, once a prototype hull has been provided.” In fact, it appears that Bonito employed a similar process in the

creation of its own production mold. It is difficult to conceive of a more effective method of creating substantial property rights in an intellectual creation than to eliminate the most efficient method for its exploitation. *Sears* and *Compco* protect more than the right of the public to contemplate the abstract beauty of an otherwise unprotected intellectual creation—they assure its efficient reduction to practice and sale in the marketplace. . . .

Our decisions since *Sears* and *Compco* have made it clear that the Patent and Copyright Clauses do not, by their own force or by negative implication, deprive the States of the power to adopt rules for the promotion of intellectual creation within their own jurisdictions. Thus, where “Congress determines that neither federal protection nor freedom from restraint is required by the national interest,” *Goldstein, supra*, 412 U.S., at 559, the States remain free to promote originality and creativity in their own domains.

Nor does the fact that a particular item lies within the subject matter of the federal patent laws necessarily preclude the States from offering limited protection which does not impermissibly interfere with the federal patent scheme. As *Sears* itself makes clear, States may place limited regulations on the use of unpatented designs in order to prevent consumer confusion as to source. In *Kewanee*, we found that state protection of trade secrets, as applied to both patentable and unpatentable subject matter, did not conflict with the federal patent laws. In both situations, state protection was not aimed exclusively at the promotion of invention itself, and the state restrictions on the use of unpatented ideas were limited to those necessary to promote goals outside the contemplation of the federal patent scheme. Both the law of unfair competition and state trade secret law have coexisted harmoniously with federal patent protection for almost 200 years, and Congress has given no indication that their operation is inconsistent with the operation of the federal patent laws.

Indeed, there are affirmative indications from Congress that both the law of unfair competition and trade secret protection are consistent with the balance struck by the patent laws. Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), creates a federal remedy for making “a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same. . . .” Congress has thus given federal recognition to many of the concerns that underlie the state tort of unfair competition, and the application of *Sears* and *Compco* to nonfunctional aspects of a product which have been shown to identify source must take account of competing federal policies in this regard. Similarly, as Justice Marshall noted in his concurring opinion in *Kewanee*: “State trade secret laws and the federal patent laws have co-existed for many, many, years. During this time, Congress has repeatedly demonstrated its full awareness of the existence of the trade secret system, without any indication of disapproval. Indeed, Congress has in a number of instances given explicit federal protection to trade secret information provided to federal agencies.” *Kewanee*, 416 U.S., at 494. The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to “stand by both concepts and to tolerate whatever tension there [is] between them.” *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984). The same cannot be said of the Florida statute at issue here, which offers protection beyond that available under the law of unfair competition or trade secret, without any showing of consumer confusion, or breach of trust or secrecy.

The Florida statute is aimed directly at the promotion of intellectual creation by substantially restricting the public's ability to exploit ideas that the patent system mandates shall be free for all to use. Like the interpretation of Illinois unfair competition law in *Sears and Roebuck*, the Florida statute represents a break with the tradition of peaceful co-existence between state market regulation and federal patent policy. The Florida law substantially restricts the public's ability to exploit an unpatented design in general circulation, raising the specter of state-created monopolies in a host of useful shapes and processes for which patent protection has been denied or is otherwise unobtainable. It thus enters a field of regulation which the patent laws have reserved to Congress. The patent statute's careful balance between public right and private monopoly to promote certain creative activity is a "scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

. . . . It is for Congress to determine if the present system of design and utility patents is ineffectual in promoting the useful arts in the context of industrial design. By offering patent-like protection for ideas deemed unprotected under the present federal scheme, the Florida statute conflicts with the "strong federal policy favoring free competition in ideas which do not merit patent protection." *Lear, Inc.*, 395 U.S., at 656. We therefore agree with the majority of the Florida Supreme Court that the Florida statute is preempted by the Supremacy Clause, and the judgment of that court is hereby affirmed.

Comments

1. **Three Grounds for Pre-Emption.** The Supreme Court has established three grounds for pre-emption. First, explicit pre-emption based on Congress expressly providing for pre-emption of a state law; second, field pre-emption, where "the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 98 (1992); and third, conflict pre-emption, "where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 98.
2. **The Choice Between Patent and Trade Secret Protection.** The *Kewanee* Court stated that given a choice between patent and trade secret protection, the rational inventor would opt for patent protection because a trade secret provides weaker protection. In fact, the Court later wrote this "point was central to the Court's conclusion that trade secret protection did not conflict with either the encouragement or disclosure policies of the federal patent law." *Bonito Boats*, 489 U.S. at 155. But survey evidence suggests trade secret protection is the appropriability mechanism of choice for in many industries, even though patent protection is available. See, e.g., Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 24 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000). There are often times

good reasons to choose trade secrets. First, trade secret law does not require public disclosure of the invention. Thus, an innovator may choose trade secret protection because the value of the invention is derived from it not being disclosed, as would be required by patent law. Second, even if disclosure would not destroy the invention's value, opting for patent protection may induce design around activity or signal to competitors there is a market for follow-on research. And third, trade secret protection can last in perpetuity as long as the information remains secret and maintains its value whereas a patent expires 20 years from its filing date. As a result, an innovator with a patentable invention may opt for a trade secret if he believes that competitors will have difficulty reverse engineering or independently developing the invention.

The *Kewanee* Court also focused on economic efficiency concerns to support its conclusion there was no conflict between trade secret protection and patent law. Recall the Court's statement, "[t]he holder of a trade secret would not likely share his secret with a manufacturer who cannot be placed under binding legal obligation to pay a license fee or to protect the secret. The result would be to hoard rather than disseminate knowledge." As such, trade secret protection and patent protection have consistent goals, namely the efficient use and production of information that can enhance social welfare. In short, "[t]he detrimental misallocation of resources and economic waste that would thus take place if trade secret protection were abolished with respect to employees or licensees cannot be justified by reference to any policy that the federal patent law seeks to advance." See WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 360 (2003) (stating the "patent route, because of its cost and required disclosures, often just is not attractive to an inventor of a patentable invention, so that to abolish or curtail trade secret would undermine incentives to innovate").

While *Sears/Compco* left room for the states to maneuver in the IP realm, the boat hull legislation of *Bonito* strayed too far into patent law's domain. Unlike the Ohio trade secret law (or trade secret law in general), the Florida statute in *Bonito Boats* was not seen by the Court has public-welfare enhancing. See Paul J. Heald, *Federal Intellectual Property Law and the Economics of Preemption*, 76 IOWA L. REV. 959, 987-88 (1991) (stating "the decision in *Bonito Boats* strongly suggests that, at a minimum, a state statute must attempt to offset monopoly costs by requiring an advance which benefits the public. . . . Rather than demanding the creation of value, the Florida law actually diminishes the availability of creations already in the public domain by making them the property of an individual").

CHAPTER 9

Remedies

INTRODUCTION

This chapter explores the types of remedies available to a patentee. A patent owner is entitled to both money damages and equitable relief. Damages must be “adequate to compensate for the infringement,” 35 U.S.C. § 284, and are measured based on either lost profits or a reasonable royalty. And damages may be trebled if willful infringement is found. A court may also “grant injunctions . . . to prevent the violation of any” of the rights conferred by a patent. *See* 35 U.S.C. § 283. The injunction is a remedy typically associated with a property right; and injunctive relief for patent infringement is conceptually similar to a real property owner enjoining a third party from trespassing on his land. A court has the power to issue preliminary and permanent injunctions. The patent code does not provide for criminal sanctions.

STATUTE: Injunction

35 U.S.C. § 283

STATUTE: Damages

35 U.S.C. § 284

STATUTE: Attorney fees

35 U.S.C. § 285

STATUTE: Time limitation on damages

35 U.S.C. § 286

STATUTE: Limitation on damages and other remedies; marking and notice

35 U.S.C. § 287

A. MONEY DAMAGES

Money damages are usually measured by calculating the patent owner’s *lost profits* or, if lost profits cannot be proved, by using a *reasonable royalty* method, which may be based on either an established or hypothetical royalty. The

Rite-Hite and *Grain Processing* cases explore a lost profit analysis, and the *Trio Process* case discusses the framework for constructing a reasonable royalty.

1. Lost Profits

Lost profits are based on profits lost by the patentee, not the profits made by the infringer. The modern legal framework for determining lost profits can be found in *Panduit Corp. v. Stahl Bros. Fibre Works*. In *Panduit*, the court stated:

To obtain as damages the profits on sales he would have made absent the infringement, i.e., the sales made by the infringer, a patent owner must prove: (1) demand for the patented product, (2) the absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made.

575 F.2d 1152, 1156 (6th Cir. 1978). The parameters of *Panduit* are explored in *Rite-Hite* and *Grain Processing*.

RITE-HITE CORP. v. KELLEY CO., INC.

56 F.3d 1538 (Fed. Cir. 1995)

LOURIE, Circuit Judge.

Kelley Company appeals from a decision of the United States District Court for the Eastern District of Wisconsin, awarding damages for the infringement of U.S. Patent 4,373,847, owned by Rite-Hite Corporation. The district court determined that Rite-Hite was entitled to lost profits for lost sales of its devices that were in direct competition with the infringing devices, but which themselves were not covered by the patent in suit. The appeal has been taken *en banc* to determine whether such damages are legally compensable under 35 U.S.C. § 284.

BACKGROUND

On March 22, 1983, Rite-Hite sued Kelley, alleging that Kelley's "Truk Stop" vehicle restraint infringed Rite-Hite's U.S. Patent 4,373,847 ("the '847 patent"). The '847 patent, issued February 15, 1983, is directed to a device for securing a vehicle to a loading dock to prevent the vehicle from separating from the dock during loading or unloading. Any such separation would create a gap between the vehicle and dock and create a danger for a forklift operator.

* * *

Rite-Hite sought damages calculated as lost profits for two types of vehicle restraints that it made and sold: the "Manual Dok-Lok" model 55 (MDL-55), which incorporated the invention covered by the '847 patent, and the "Automatic Dok-Lok" model 100 (ADL-100), which was not covered by the patent in suit. The ADL-100 was the first vehicle restraint Rite-Hite put on the market and it was covered by one or more patents other than the patent in suit. The Kelley Truk Stop restraint was designed to compete primarily with Rite-Hite's ADL-100. Both employed an electric motor and functioned

automatically, and each sold for \$1,000-\$1,500 at the wholesale level, in contrast to the MDL-55, which sold for one-third to one-half the price of the motorized devices. Rite-Hite does not assert that Kelley's Truk Stop restraint infringed the patents covering the ADL-100.

Of the 3,825 infringing Truk Stop devices sold by Kelley, the district court found that, "but for" Kelley's infringement, Rite-Hite would have made 80 more sales of its MDL-55; 3,243 more sales of its ADL-100; and 1,692 more sales of dock levelers, a bridging platform sold with the restraints and used to bridge the edges of a vehicle and dock. The court awarded Rite-Hite as a manufacturer the wholesale profits that it lost on lost sales of the ADL-100 restraints, MDL-55 restraints, and restraint-leveler packages. . . .

On appeal, Kelley contends that the district court erred as a matter of law in its determination of damages. Kelley does not contest the award of damages for lost sales of the MDL-55 restraints; however, Kelley argues that the patent statute does not provide for damages based on Rite-Hite's lost profits on ADL-100 restraints because the ADL-100s are not covered by the patent in suit. . . .

We affirm the damage award with respect to Rite-Hite's lost profits as a manufacturer on its ADL-100 restraint sales. . . .

DISCUSSION

A. Kelley's Appeal

I. Lost Profits on the ADL-100 Restraints

The district court's decision to award lost profits damages pursuant to 35 U.S.C. § 284 turned primarily upon the quality of Rite-Hite's proof of actual lost profits. The court found that, "but for" Kelley's infringing Truk Stop competition, Rite-Hite would have sold 3,243 additional ADL-100 restraints and 80 additional MDL-55 restraints. The court reasoned that awarding lost profits fulfilled the patent statute's goal of affording complete compensation for infringement and compensated Rite-Hite for the ADL-100 sales that Kelley "anticipated taking from Rite-Hite when it marketed the Truk Stop against the ADL-100." *Rite-Hite*, 774 F. Supp. at 1540, 21 USPQ2d at 1821. The court stated, "[t]he rule applied here therefore does not extend Rite-Hite's patent rights excessively, because Kelley could reasonably have foreseen that its infringement of the '847 patent would make it liable for lost ADL-100 sales in addition to lost MDL-55 sales." *Id.* . . .

Kelley maintains that Rite-Hite's lost sales of the ADL-100 restraints do not constitute an injury that is legally compensable by means of lost profits. It has uniformly been the law, Kelley argues, that to recover damages in the form of lost profits a patentee must prove that, "but for" the infringement, it would have sold a product covered by the patent in suit to the customers who bought from the infringer. Under the circumstances of this case, in Kelley's view, the patent statute provides only for damages calculated as a reasonable royalty. Rite-Hite, on the other hand, argues that the only restriction on an award of actual lost profits damages for patent infringement is proof of causation-in-fact. A patentee, in its view, is entitled to all the profits it would have made on any of its products "but for" the infringement. Each party argues that a judgment in favor of the other would frustrate the purposes of the patent statute. Whether the lost profits at issue are legally compensable is a question of law, which we review *de novo*.

Our analysis of this question necessarily begins with the patent statute. Implementing the constitutional power under Article I, section 8, to secure to inventors the exclusive right to their discoveries, Congress has provided in 35 U.S.C. § 284. The statute mandates that a claimant receive damages “adequate” to compensate for infringement. Section 284 further instructs that a damage award shall be “in no event less than a reasonable royalty”; the purpose of this alternative is not to direct the form of compensation, but to set a floor below which damage awards may not fall. Thus, the language of the statute is expansive rather than limiting. It affirmatively states that damages must be adequate, while providing only a lower limit and no other limitation.

The Supreme Court spoke to the question of patent damages in *General Motors*, stating that, in enacting § 284, Congress sought to “ensure that the patent owner would in fact receive full compensation for ‘any damages’ [the patentee] suffered as a result of the infringement.” *General Motors*, 461 U.S. at 654; *see also* H.R. Rep. No. 1587, 79th Cong., 2d Sess., 1 (1946) (the Bill was intended to allow recovery of “any damages the complainant can prove”); S. Rep. No. 1503, 79th Cong., 2d Sess., 2 (1946), (same). Thus, while the statutory text states tersely that the patentee receive “adequate” damages, the Supreme Court has interpreted this to mean that “adequate” damages should approximate those damages that will *fully compensate* the patentee for infringement. Further, the Court has cautioned against imposing limitations on patent infringement damages, stating: “When Congress wished to limit an element of recovery in a patent infringement action, it said so explicitly.” *General Motors*, 461 U.S. at 653 (refusing to impose limitation on court’s authority to award interest).

In *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476 (1964), the Court discussed the statutory standard for measuring patent infringement damages, explaining:

The question to be asked in determining damages is “how much had the Patent Holder and Licensee suffered by the infringement. And that question [is] primarily: had the Infringer not infringed, what would the Patentee Holder-Licensee have made?”

377 U.S. at 507. This surely states a “but for” test. In accordance with the Court’s guidance, we have held that the general rule for determining actual damages to a patentee that is itself producing the patented item is to determine the sales and profits lost to the patentee because of the infringement. To recover lost profits damages, the patentee must show a reasonable probability that, “but for” the infringement, it would have made the sales that were made by the infringer. *Id.*; *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 863 (Fed. Cir. 1985).

Panduit Corp. v. Stahl Bros. Fibre Works, Inc., 575 F.2d 1152 (6th Cir. 1978), articulated a four-factor test that has since been accepted as a useful, but non-exclusive, way for a patentee to prove entitlement to lost profits damages. The *Panduit* test requires that a patentee establish: (1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of the profit it would have made. *Panduit*, 575 F.2d at 1156. A showing under *Panduit* permits a court to reasonably infer that the lost profits claimed were in fact caused by the infringing sales, thus establishing a patentee’s *prima*

facie case with respect to “but for” causation. A patentee need not negate every possibility that the purchaser might not have purchased a product other than its own, absent the infringement. The patentee need only show that there was a reasonable probability that the sales would have been made “but for” the infringement. When the patentee establishes the reasonableness of this inference, *e.g.*, by satisfying the *Panduit* test, it has sustained the burden of proving entitlement to lost profits due to the infringing sales. The burden then shifts to the infringer to show that the inference is unreasonable for some or all of the lost sales.

Applying *Panduit*, the district court found that Rite-Hite had established “but for” causation. In the court’s view, this was sufficient to prove entitlement to lost profits damages on the ADL-100. Kelley does not challenge that Rite-Hite meets the *Panduit* test and therefore has proven “but for” causation; rather, Kelley argues that damages for the ADL-100, even if in fact caused by the infringement, are not legally compensable because the ADL-100 is not covered by the patent in suit.

Preliminarily, we wish to affirm that the “test” for compensability of damages under § 284 is not solely a “but for” test in the sense that an infringer must compensate a patentee for any and all damages that proceed from the act of patent infringement. Notwithstanding the broad language of § 284, judicial relief cannot redress every conceivable harm that can be traced to an alleged wrongdoing. For example, remote consequences, such as a heart attack of the inventor or loss in value of shares of common stock of a patentee corporation caused indirectly by infringement are not compensable. Thus, along with establishing that a particular injury suffered by a patentee is a “but for” consequence of infringement, there may also be a background question whether the asserted injury is of the type for which the patentee may be compensated.

Judicial limitations on damages, either for certain classes of plaintiffs or for certain types of injuries have been imposed in terms of “proximate cause” or “foreseeability.” Such labels have been judicial tools used to limit legal responsibility for the consequences of one’s conduct that are too remote to justify compensation. The general principles expressed in the common law tell us that the question of legal compensability is one “to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent.” See 1 Street, *Foundations of Legal Liability* 110 (1906) (quoted in W. Page Keeton et al., *Prosser & Keeton on the Law of Torts* § 42, at 279 (5th ed. 1984)).

We believe that under § 284 of the patent statute, the balance between full compensation, which is the meaning that the Supreme Court has attributed to the statute, and the reasonable limits of liability encompassed by general principles of law can best be viewed in terms of reasonable, objective foreseeability. If a particular injury was or should have been reasonably foreseeable by an infringing competitor in the relevant market, broadly defined, that injury is generally compensable absent a persuasive reason to the contrary. Here, the court determined that Rite-Hite’s lost sales of the ADL-100, a product that directly competed with the infringing product, were reasonably foreseeable. We agree with that conclusion. Being responsible for lost sales of a competitive product is surely foreseeable; such losses constitute the full compensation set forth by Congress, as interpreted by the Supreme Court,

while staying well within the traditional meaning of proximate cause. Such lost sales should therefore clearly be compensable.

Recovery for lost sales of a device not covered by the patent in suit is not of course expressly provided for by the patent statute. Express language is not required, however. Statutes speak in general terms rather than specifically expressing every detail. Under the patent statute, damages should be awarded “where necessary to afford the plaintiff full compensation for the infringement.” *General Motors*, 461 U.S. at 654. Thus, to refuse to award reasonably foreseeable damages necessary to make Rite-Hite whole would be inconsistent with the meaning of § 284.

Kelley asserts that to allow recovery for the ADL-100 would contravene the policy reason for which patents are granted: “[T]o promote the progress of . . . the useful arts.” U.S. Const., art. I, § 8, cl. 8. Because an inventor is only entitled to exclusivity to the extent he or she has invented and disclosed a novel, nonobvious, and useful device, Kelley argues, a patent may never be used to restrict competition in the sale of products not covered by the patent in suit. In support, Kelley cites antitrust case law condemning the use of a patent as a means to obtain a “monopoly” on unpatented material.

These cases are inapposite to the issue raised here. The present case does not involve expanding the limits of the patent grant in violation of the antitrust laws; it simply asks, once infringement of a valid patent is found, what compensable injuries result from that infringement, *i.e.*, how may the patentee be made whole. Rite-Hite is not attempting to exclude its competitors from making, using, or selling a product not within the scope of its patent. The Truk Stop restraint was found to infringe the ’847 patent, and Rite-Hite is simply seeking adequate compensation for that infringement; this is not an antitrust issue. Allowing compensation for such damage will “promote the Progress of . . . the useful Arts” by providing a stimulus to the development of new products and industries.

Kelley further asserts that, as a policy matter, inventors should be encouraged by the law to practice their inventions. This is not a meaningful or persuasive argument, at least in this context. A patent is granted in exchange for a patentee’s disclosure of an invention, not for the patentee’s use of the invention. There is no requirement in this country that a patentee make, use, or sell its patented invention. If a patentee’s failure to practice a patented invention frustrates an important public need for the invention, a court need not enjoin infringement of the patent. *See* 35 U.S.C. § 283 (1988). Accordingly, courts have in rare instances exercised their discretion to deny injunctive relief in order to protect the public interest. Whether a patentee sells its patented invention is not crucial in determining lost profits damages. Normally, if the patentee is not selling a product, by definition there can be no lost profits. However, in this case, Rite-Hite did sell its own patented products, the MDL-55 and the ADL-100 restraints.

Kelley next argues that to award lost profits damages on Rite-Hite’s ADL-100s would be contrary to precedent. Citing *Panduit*, Kelley argues that case law regarding lost profits uniformly requires that “the intrinsic value of the patent in suit is the only proper basis for a lost profits award.” Kelley argues that each prong of the *Panduit* test focuses on the patented invention; thus, Kelley asserts, Rite-Hite cannot obtain damages consisting of lost profits on a product that is not the patented invention.

Generally, the *Panduit* test has been applied when a patentee is seeking lost profits for a device covered by the patent in suit. However, *Panduit* is not the *sine qua non* for proving “but for” causation. If there are other ways to show that the infringement in fact caused the patentee’s lost profits, there is no reason why another test should not be acceptable. Moreover, other fact situations may require different means of evaluation, and failure to meet the *Panduit* test does not *ipso facto* disqualify a loss from being compensable.

In any event, the only *Panduit* factor that arguably was not met in the present fact situation is the second one, absence of acceptable non-infringing substitutes. Establishment of this factor tends to prove that the patentee would not have lost the sales to a non-infringing third party rather than to the infringer. That, however, goes only to the question of proof. Here, the only substitute for the patented device was the ADL-100, another of the patentee’s devices. Such a substitute was not an “acceptable, non-infringing substitute” within the meaning of *Panduit* because, being patented by Rite-Hite, it was not available to customers except from Rite-Hite. Rite-Hite therefore would not have lost the sales to a third party. The second *Panduit* factor thus has been met. If, on the other hand, the ADL-100 had not been patented and was found to be an acceptable substitute, that would have been a different story, and Rite-Hite would have had to prove that its customers would not have obtained the ADL-100 from a third party in order to prove the second factor of *Panduit*. . . .

Kelley has thus not provided, nor do we find, any justification in the statute, precedent, policy, or logic to limit the compensability of lost sales of a patentee’s device that directly competes with the infringing device if it is proven that those lost sales were caused in fact by the infringement. Such lost sales are reasonably foreseeable and the award of damages is necessary to provide adequate compensation for infringement under 35 U.S.C. § 284. Thus, Rite-Hite’s ADL-100 lost sales are legally compensable and we affirm the award of lost profits on the 3,283 sales lost to Rite-Hite’s wholesale business in ADL-100 restraints.

NIES, Circuit Judge, with whom ARCHER, Chief Judge, SMITH, Senior Circuit Judge, and MAYER, Circuit Judge join, dissenting-in-part.

The majority uses the provision in 35 U.S.C. § 284 for “damages” as a tool to expand the property rights granted by a patent. I dissent.

No one disputes that Rite-Hite is entitled to “full compensation for any damages suffered as a result of the infringement.” *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 653-54 (1983). “Damages,” however, is a word of art. “Damages in a legal sense means the compensation which the law will award for an injury done.” *Recovery in Patent Infringement Suits: Hearings on H.R. 5231 [later H.R. 5311] Before the Committee on Patents*, 79th Cong., 2nd Sess. 9 (1946) (statement of Conder C. Henry, Asst. Comm’r of Patents) (hereinafter “House Hearings”). Thus, the question is, “What are the injuries for which full compensation must be paid?”

The majority divorces “actual damages” from injury to patent rights. The majority holds that a patentee is entitled to recover its lost profits caused by the infringer’s competition with the patentee’s business in ADL restraints, products not incorporating the invention of the patent in suit but assertedly protected by other unlitigated patents. Indeed, the majority states a broader

rule for the award of lost profits on any goods of the patentee with which the infringing device competes, even products in the public domain.

I would hold that the diversion of ADL-100 sales is not an injury to patentee's property rights granted by the '847 patent. To constitute legal injury for which lost profits may be awarded, the infringer must interfere with the patentee's property right to an exclusive market in goods embodying the invention of the patent in suit. The patentee's property rights do not extend to its market in other goods unprotected by the litigated patent. Rite-Hite was compensated for the lost profits for 80 sales associated with the MDL-55, the only product it sells embodying the '847 invention. That is the totality of any possible entitlement to lost profits. Under 35 U.S.C. § 284, therefore, Rite-Hite is entitled to "damages" calculated as a reasonable royalty on the remainder of Kelley's infringing restraints. . . .

C. Property Rights Granted by Patent

An examination of pre-1946 Supreme Court precedent discloses that the legal scope of actual damages for patent infringement was limited to the extent of the defendant's interference with the patentee's market in goods embodying the invention of the patent in suit. This limitation reflects the underlying public policy of the patent statute to promote commerce in new products for the public's benefit. More importantly, it protects the only property rights of a patentee which are protectable, namely those granted by the patent. The patentee obtained as its property an exclusive market in the patented goods. "[I]nfringement was a tortious taking of a part of that property." *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 648 (1915).

[I]n the United States, the grant of a patent did not convey to the inventor a right to make, use and vend his invention despite the statutory language originally to that effect. In interpreting a patentee's rights in *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 26 (1923), the Supreme Court explained that an inventor has a natural right to make, use and sell his invention, and that a patent augments an inventor's position by making that natural right *exclusive* for a limited time. The statutory language was interpreted to give a right to *preclude others* from interfering with the patentee's exclusivity in providing the patented goods to the public. *Id.* at 34.

An inventor is entitled to a patent by meeting the statutory requirements respecting disclosure of the invention. Prior commercialization of the invention has never been a requirement in our law to *obtain* a patent. An inventor is merely required to teach others his invention in his patent application. Thus, when faced with the question of whether a patentee was entitled to enjoin an infringer despite the patentee's failure to use its invention, the Supreme Court held for the patentee. *Continental Paper Bag*, 210 U.S. at 424-430. Congress provided a right to exclusive use and to deny that privilege would destroy that right. *Id.* at 430. An injunction preserves the patentee's exclusive right to market embodiments of the patented invention.

These clearly established principles, however, do not lead to the conclusion that the patentee's failure to commercialize plays no role in determining damages. That the *quid pro quo* for *obtaining* a patent is disclosure of the invention does not dictate the answer to the question of the legal scope of damages. The patent system was not designed merely to build up a library of

information by disclosure, valuable though that is, but to get new products into the marketplace during the period of exclusivity so that the public receives full benefits from the grant. The Congress of the fledgling country did not act so quickly in enacting the Patent Act of 1790 merely to further intellectual pursuits. . . .

Like the owner of a farm, a patentee may let his property lay fallow. In doing so, “he has but suppressed his own.” *Bement*, 186 U.S. at 90. But it is anomalous to hold that Congress, by providing an incentive for the patentee to enter the market, intended the patentee to be rewarded the same for letting his property lay fallow during the term of the patent as for making the investment necessary to commercializing a new product or licensing others to do so, in order that the public benefits from the invention. The *status quo* may serve the patentee’s interest, but that is not the only consideration. The patent grant “was never designed for [an inventor’s] exclusive profit or advantage.” *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858). . . .

G. “Foreseeability” Is Not the Test for Patent Damages

In the majority’s view, the consideration of patent rights ends upon a finding of infringement. The separate question of damages under its test does not depend on patent rights but only on foreseeable competitive injury. This position cannot be squared with the premise that compensation is due only for injury to patent rights. Thus, the majority’s foreseeability standard contains a false premise, namely, that the “relevant market” can be “broadly defined” to include all competitive truck restraints made by the patentee. The *relevant* market for determining damages is confined to the market for the invention in which the patentee holds exclusive property rights. . . . To paraphrase *Brunswick Corp.*, 429 U.S. at 489, “[Plaintiffs] must prove more than injury causally linked to any illegal presence in the market [*i.e.*, the infringing goods]. Plaintiffs must prove [patent infringement] injury, which is to say injury of the type the [patent] laws were intended to prevent.” The injury, thus, must be to the protected market in goods made in accordance with the patent, not unprotected truck restraints. In sum, patent rights determine not only infringement but also damages.

The majority does not give a passing nod to long-standing precedent restricting a patentee’s legal injury to diversion of sales it would have made of products containing the patented invention, much less does it explain why the precedent should be abandoned. It simply declares *ipse dixit*: “Whether a patentee sells its patented invention is not crucial in determining lost profits damages.” While proximate cause limitations are acknowledged, the majority sees no problem here because the infringing devices were designed to compete with the ADL-100 devices and the “clear purpose of the patent law [is] to redress competitive damages resulting from infringement of the patent.” This reasoning awards patent infringement damages as if for a kind of unfair competition with the patentee’s business. However, infringement of a patent is not a species of common law unfair competition; it is a distinct and independent federal statutory claim. Moreover, the clear purpose of the patent system is to stimulate a patentee to put new products into the marketplace during the patent term, not to compensate the patentee “fully” while the public benefit from the invention is delayed until the invention falls into the public domain. Compensation in the form of lost profits for injury to the

exclusive market in patented goods has provided the incentive to achieve that objective. . . .

Nothing in the statute supports the majority's "foreseeability" rule as the sole basis for patent damages. To the contrary, no-fault liability is imposed on "innocent" infringers, those who have no knowledge of the existence of a patent until suit is filed. Damages are recoverable for up to six years of unknowing infringement before suit. 35 U.S.C. § 286 (1988). "Foreseeability" is a wholly anomalous concept to interject as the basis for determining legal injury for patent infringement. While unknowing infringers cannot "foresee" any injury to the patentee, they are subject to liability for damages, including lost profits, for competition with the patentee's patented goods. Now they will be liable for diverting sales of the patentee's unprotected competitive products as well. . . .

The majority goes on to find the award of damages for lost sales of ADL-100s a *foreseeable* injury for infringement of the '847 patent. This is a remarkable finding. The facts are that Rite-Hite began marketing its ADL-100 motorized restraint in 1980. Kelley put out its Truk Stop restraint in June 1982. There is no dispute in this case that Kelley "designed around" the protection afforded by any patent related to the ADL-100 with which Kelley's Truk Stop restraint was intended to compete. Two years later, the '847 patent in suit issued on the later-developed alternative hook technology used in the MDL-55. Kelley would have to have had prescient vision to foresee that it would be held an infringer of the unknown claims of the subsequently issued '847 patent and that its *lawful competition* with the ADL-100 would be transformed into a compensable injury.

Kelley would also have had to foresee that, for the first time in over 200 years of patent infringement suits, a court would extend protection to a part of a patentee's business which is not dependent on the patentee's use of the patented technology. Moreover, the Supreme Court and all sister circuits which have spoken on the legal scope of damages have, without exception, rejected the majority's expansive view that the only limitations on patent infringement damages are (1) satisfaction of a "but-for" test applied to "foreseeable" injuries, and (2) the amount must not be too low. . . .

If damages are awardable based on lost sales of a patentee's business in established products not protected by the patent in suit, the patentee not only has an easier case as a matter of proof, but also would receive *greater* benefits in the form of lost profits on its established products than if the patentee had made the investment necessary to launch a new product. That lost profits on an established line are likely to be greater than on a new device cannot be gainsaid. This result is not in accordance with the purpose of the patent statute. Actual damages are meant to compensate a patentee for losing the reward of the marketplace which the patentee's use of the invention would otherwise reap. Without such loss, Congress has mandated compensation in the form of a reasonable royalty.

H. The ADL-100 Patents

Not only is the majority's basic idea of legal injury unsound based on "foreseeability" but also its specific test is equally flawed. For convenience, I have referred to the ADL-100 as "unprotected," meaning not covered by the patent in suit. However, a key factor in the majority's decision awarding

damages for lost sales of the ADL-100 is that the “device” is “patented”. The majority does not, nor did the parties, discuss what inventions the one or more patents on the ADL-100 cover. Nevertheless, the majority declares the ADL-100 provides the only alternative technology. While it is inappropriate for an appellate court to make findings, the finding by the majority is erroneous if one examines the record independently. There are other mechanisms for securing trucks to loading docks. Indeed, the Patent Office considered Kelley’s Truk-Stop sufficiently different from the prior ’847 patent to grant Kelley its own patent. Unfortunately for Kelley, this court earlier upheld the finding that its different structure was sufficient similar to the ’847 patent to constitute infringement. But there were other alternatives which could be substituted. In any event, the one or more patents on technology used in the ADL-100 were never asserted against Kelley, and the validity of those patents is untested. If those patents are invalid, the majority’s analysis collapses. As stated in *Lear, Inc. v. Adkins*, 395 U.S. 653, 668 (1969): “[F]ederal law requires that all ideas in general circulation be dedicated to the common good unless they are protected by a *valid* patent.” (Emphasis added).

GRAIN PROCESSING CORP. v. AMERICAN MAIZE-PRODUCTS CO.

185 F.3d 1341 (Fed. Cir. 1999)

RADER, Circuit Judge.

The United States District Court for the Northern District of Indiana denied Grain Processing Corporation lost profits for American Maize-Products’ infringement of U.S. Patent No. 3,849,194 (the ’194 patent). The district court instead awarded Grain Processing a 3% royalty on American Maize’s infringing sales.

The district court found that American Maize proved that a noninfringing substitute was available, though not on the market or for sale, during the period of infringement. The court found further that this substitute was acceptable to all purchasers of the infringing product and concluded that American Maize rebutted the inference of “but for” causation for Grain Processing’s alleged lost sales. Upholding the district court’s findings and conclusions, this court affirms.

I.

This appeal culminates the lengthy and complex history of this case, spanning more than eighteen years and eight prior judicial opinions, three by this court. The patent featured in this infringement suit involves maltodextrins, a versatile family of food additives made from starch. Commercial food manufacturers purchase hundreds of millions of pounds of maltodextrins annually from producers such as Grain Processing and American Maize.

Maltodextrins serve well as food additives because they are bland in taste and clear in solution. They do not affect the natural taste or color of other ingredients in food products. Maltodextrins also improve the structure or behavior of food products. For instance, they inhibit crystal growth, add body, improve binding and viscosity, and preserve food properties in low temperatures. Consequently, food manufacturers use maltodextrins in a wide variety of products such as frostings, syrups, drinks, cereals, and frozen foods.

Maltodextrins belong to a category of chemical products known as “starch hydrolysates.” Producers make starch hydrolysates by putting starch through hydrolysis, a chemical reaction with water. Hydrolysis breaks down the starch and converts some of it to dextrose. With adjustments, this process yields more dextrose. For instance, additional enzymes, time extensions, and increases in temperature or pH enhance the reaction. After hydrolysis, the producer typically refines, spray-dries, and packages the starch hydrolysate for sale in powder form.

Maltodextrins are starch hydrolysates that have a “dextrose equivalence” of less than 20. Dextrose equivalence (D.E.) is a percentage measurement of the “reducing sugars content” of the starch hydrolysate. D.E. reflects the degree to which the hydrolysis process broke down the starch and converted it into dextrose. Converting more starch into dextrose increases the D.E. of the resulting starch hydrolysate. Hence, pure starch has a D.E. of zero, pure dextrose a D.E. of 100. The D.E. value indicates functional properties of a maltodextrin. A 15 D.E. maltodextrin, for example, is slightly sweeter and more soluble than a 5 D.E. maltodextrin. On the other hand, the 5 D.E. maltodextrin has more prevalent binding, bodying, and crystal inhibiting properties.

Grain Processing is the assignee of the '194 patent, “Low D.E. Starch Conversion Products,” which claims maltodextrins with particular attributes, and processes for producing them. The claimed invention represents improvements in the “heavily explored” field of starch hydrolysates. Claim 12, the sole claim on appeal, reads:

12. A *waxy* starch hydrolysate having

1. *a dextrose equivalent value between about 5 and about 25;*
2. *a descriptive ratio greater than about 2, said descriptive ratio being the quotient obtained by dividing the sum of the percentage of saccharides, dry basis, having a degree of polymerization of 1 to 6, by the dextrose equivalent value;*
3. *a monosaccharide content in the range of from about 0.1 percent by weight, to about 2.4 percent by weight, dry basis;*
4. *a disaccharide content in the range of from about 1.3 percent to about 9.7 percent, by weight, dry basis; and*
5. *being further characterized as capable of producing an aqueous solution of exceptional clarity and substantially complete lack of opaqueness when said hydrolysate is added to water.*

(Emphasis added.)

Grain Processing has manufactured and sold a line of maltodextrins under the “Maltrin” brand name since 1969. The Maltrin line includes “Maltrin M100,” a 10 D.E. maltodextrin. None of the Maltrin products, including M100, fall within claim 12 because they are all made from a non-waxy starch.

American Maize began selling maltodextrins in 1974. It made and sold several types of maltodextrins, including “Lo-Dex 10,” a 10 D.E. waxy starch maltodextrin. American Maize sold Lo-Dex 10 (called Fro-Dex 10 before 1982) during the entire time Grain Processing owned the '194 patent rights, from 1979 until the patent expired in 1991. During this time, however, American Maize used four different processes for producing Lo-Dex 10. The changes in American Maize’s production processes, and the slight chemical differences in the Lo-Dex 10 from each process, are central to the lost profits issue in this appeal.

American Maize used a first process (Process I) from June 1974 to July 1982. In Process I, American Maize used a single enzyme (an alpha amylase) to facilitate starch hydrolysis. American Maize controlled the reaction to produce a starch hydrolysate with the desired properties, including D.E. value.

Grain Processing sued American Maize for infringement on May 12, 1981, based on American Maize's Lo-Dex 10 sales as well as sales of two other maltodextrins, Lo-Dex 5 and ARD 2370. Grain Processing asserted all fourteen claims of the '194 patent, including product and process claims. The district court bifurcated the infringement and damages issues for trial.

In August 1982, while the suit was pending, American Maize reduced the amount of alpha amylase enzyme in its process to lower its production costs. To achieve the same end result with less enzyme, American Maize continued the reaction longer. American Maize used this process (Process II) exclusively to produce Lo-Dex 10 from August 1982 to February 1988. Grain Processing asserted in its lawsuit that Process II Lo-Dex 10 also infringed the '194 patent.

American Maize contended that Lo-Dex 10 (by both Processes I and II) did not infringe claim 12 of the '194 patent because it did not have a "descriptive ratio greater than about 2," as required by the claim. Descriptive ratio (D.R.) is a function of the D.E. measurement. According to the formula in claim 12, D.R. is inversely proportional to D.E. Because different scientific tests yield slightly different D.E. measurements, the resulting D.R. values derived therefrom also vary slightly.

When Grain Processing accused American Maize of infringement, Grain Processing used the "Schoorl test" for measuring the D.E. of Lo-Dex 10. American Maize, on the other hand, used the "Lane-Eynon test," which it believed was the "industry standard," to measure D.E. The Schoorl test tends to yield a lower D.E. and therefore a higher D.R. than Lane-Eynon. Under the Lane-Eynon test, American Maize's measurements revealed that Lo-Dex 10 did not infringe claim 12, because all of its Lo-Dex 10 samples had a D.R. of less than 1.9. Grain Processing's Schoorl tests on the same samples, however, yielded a D.R. of greater than 2.

Following a bench trial, the district court held that Lo-Dex 10 did not infringe any of the claims because it did not meet the "exceptional clarity" limitation. This court reversed, holding that Lo-Dex 10 met the "exceptional clarity" limitation and therefore infringed claim 12 and its dependent claims 13-14. This court's decision, like the district court's, did not resolve the discrepancy between tests for measuring D.E. value. The district court subsequently entered an injunction on October 21, 1988, prohibiting American Maize from making or selling Lo-Dex 10 or any other waxy starch hydrolysate that infringed claims 12-14.

In response to the injunction, American Maize developed yet another process for producing Lo-Dex 10. In this new process (Process III), American Maize used more alpha amylase, adjusted the temperature and pH, and reduced the reaction time. American Maize used Process III exclusively to produce Lo-Dex 10 from March 1988 to April 1991.

American Maize believed Process III would yield a more uniform, non-infringing output of Lo-Dex 10. In fact, American Maize was "determined to avoid shipping a single bag of Lo-Dex 10 with a D.R. exceeding 1.9." Process III worked as American Maize intended. American Maize's measurements — using

the Lane-Eynon test—showed that Process III Lo-Dex 10 samples all had descriptive ratios of less than 1.9 and therefore did not infringe. Moreover, American Maize's customers did not discern any difference between Process III Lo-Dex 10 and Lo-Dex 10 from Processes I or II.

In 1990, Grain Processing tested commercial samples of American Maize's Process III Lo-Dex 10. Grain Processing again used the Schoorl test to measure D.E. Grain Processing's measurements showed that American Maize's Process III output had a D.R. value of greater than 1.9 and therefore infringed. Grain Processing filed a contempt motion in the district court.

The district court initially held American Maize in contempt for continuing to sell an infringing product. However, the district court modified the order in 1991 to allow American Maize to use any scientifically acceptable method to show noninfringement. Because American Maize's Process III output consistently had a D.R. of less than 1.9 using Lane-Eynon, the district court ruled that it did not infringe. Grain Processing appealed. This court reversed in a nonprecedential opinion. Because the prosecution history of the '194 patent indicates that the inventor used the Schoorl test to measure D.E. of his invention, this court held that the Schoorl test, not Lane-Eynon, determines the relevant values in this case.

American Maize then adopted a fourth process (Process IV) for producing Lo-Dex 10. In Process IV, American Maize added a second enzyme, glucoamylase, to the reaction. Glucoamylase breaks down starch to a shorter average saccharide length. This shorter saccharide length yields a smaller D.R. without affecting D.E.

From the time American Maize began experimenting with the glucoamylase-alpha amylase combination, or the "dual enzyme method," it took only two weeks to perfect the reaction and begin mass producing Lo-Dex 10 using Process IV. According to the finding of the district court, this two-week development and production time is "practically instantaneous" for large-scale production. American Maize simply experimented with different combinations of glucoamylase and alpha amylase, along with pH, heat, and time of the reaction. American Maize did not change any equipment, source starches, or other ingredients from Process III. Glucoamylase has been commercially available and its effect in starch hydrolysis widely known since the early 1970's, before the '194 patent issued. American Maize had not used Process IV to produce Lo-Dex earlier because the high cost of glucoamylase makes Process IV more expensive than the other processes.

The parties agree that Process IV yielded only noninfringing Lo-Dex 10 and that consumers discerned no difference between Process IV Lo-Dex 10 and Lo-Dex 10 made by Processes I-III. American Maize used Process IV exclusively to produce Lo-Dex 10 from April 1991 until the '194 patent expired in November 1991, and then switched back to the cheaper Process III.

The district court commenced the damages portion of the trial on July 10, 1995. Grain Processing claimed lost profits in the form of lost sales of Maltrin M100, price erosion, and American Maize's accelerated market entry after the patent expired. Grain Processing further claimed that, for any of American Maize's infringing sales not covered by a lost profits award, Grain Processing should receive a 28% royalty. After a three day bench trial, the district court denied lost profits and determined that a 3% reasonable royalty was adequate to compensate Grain Processing. The royalty applies to all of American

Maize's Lo-Dex 10 sales from May 12, 1981 (when Grain Processing filed suit) to April 1991 (when American Maize converted to Process IV, thereby producing a noninfringing product).

The trial court determined that Grain Processing could not establish causation for lost profits, because American Maize "could have produced" a noninfringing substitute 10 D.E. maltodextrin using Process IV. "With infringing Lo-Dex 10 banned, the customers' substitute is non-infringing Lo-Dex 10." *Id.* at 1392 (emphasis added). American Maize did not actually produce and sell this noninfringing substitute until April 1991, seven months before the '194 patent expired, but the district court nevertheless found that its availability "scotches [Grain Processing's] request for lost-profits damages."

The district court also found that American Maize's production cost difference between infringing and noninfringing Lo-Dex 10 effectively capped the reasonable royalty award. American Maize showed that it cost only 2.3% more to make noninfringing Process IV products than it did to make infringing Process I-III products. The district court also found that "buyers viewed as equivalent" the Process I-III and Process IV output: "Lo-Dex 10 made by Process IV had a lower D.R. [which is what makes it noninfringing] . . . but no one argues that any customer cared a whit about the product's descriptive ratio." The district court concluded that under these facts, American Maize, when faced with a hypothetical offer to license the '194 patent in 1974 (or to renegotiate the rate in 1979, when Grain Processing acquired the patent rights and its ability to collect damages began), would not have paid more than a 3% royalty rate. The court reasoned that this rate would reflect the cost difference between Processes I-III and Process IV, while also taking into account possible cost fluctuations (due to fluctuating enzyme prices) and the elimination of American Maize's risk of producing an infringing product, despite its best efforts. The court concluded that if Grain Processing had insisted on a rate greater than 3% in the hypothetical negotiations, American Maize instead would have chosen to invest in producing noninfringing Lo-Dex 10 with Process IV.

Grain Processing appealed the district court's denial of lost profits, alleging that American Maize cannot escape liability for lost profits on the basis of "a noninfringing substitute that did not exist during, and was not developed until after, the period of infringement." This court reversed and remanded. This court observed that "[t]he [district] court denied [Grain Processing's] request for lost profits because [American Maize] developed a new process of producing Lo-Dex 10 in 1991 [after years of infringement] that did not infringe the '194 patent." This court noted, however, that the mere fact of "switching to a noninfringing product years after the period of infringement [does] not establish the presence of a noninfringing substitute during the period of infringement." (citing *State Indus., Inc. v. Mor-Flo Industries, Inc.*; *Panduit Corp. v. Stahlin Brothers Fibre Works, Inc.*). This court noted that a product or process must be "available or on the market at the time of infringement" to qualify as an acceptable non-infringing substitute.

On remand, the district court again denied Grain Processing lost profits. The district court found that Process IV was "available" throughout the period of infringement. This factual finding, the district court explained, was not based merely on "the simple fact of switching [to Process IV]" but rather on several subsidiary factual findings regarding the technology of enzyme-assisted

starch hydrolysis and the price and market structure for the patentee's and accused infringer's products. The trial court found that American Maize could obtain all of the materials needed for Process IV, including the glucoamylase enzyme, before 1979, and that the effects of the enzymes in starch hydrolysis were well known in the field by that time. American Maize also had all of the necessary equipment, know-how, and experience to implement Process IV whenever it chose to do so during the time of infringement. "The sole reason [American Maize did not use Process IV to produce Lo-Dex 10 prior to 1991] was economic: glucoamylase is more expensive than the alpha amylase enzyme that [American Maize] had been using." *Id.* American Maize did not make the substitution sooner because its test results using the Lane-Eynon method convinced it that it was not infringing.

The district court concluded that "the profit lost from infringement is the cost and market price difference attributable to using glucoamylase." The court did not further address the amount of damages, having already found in that the infringement did not affect the market price of Lo-Dex 10, and having figured the 2.3% cost increase into the 3% royalty award.

The district court also went on to explain its denial of lost profits "from a different angle." The district court stated that *Panduit and Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538 (Fed. Cir. 1995) (en banc) "identify demand for the patented product as an essential element of the patent holder's lost-profits claim." The district court recognized that there was "substantial demand for D.E. 10 maltodextrins." However, the district court stated the dispositive question as "whether there is economically significant demand for a product having all . . . attributes [of the claim in suit]," *i.e.*, whether consumers demand every claimed feature. The court found no such demand in this case because "[t]wo of the essential elements of the claim — that the starch be 'waxy' and that the 'descriptive ratio [be] greater than about 2' — are irrelevant to consumers." The court concluded that Grain Processing "does not have a patent on D.E. 10 maltodextrins, the economically significant product, and therefore cannot recover lost profits damages on account of [American Maize's] infringement."

Grain Processing appeals the district court's decision.

II.

Upon proof of infringement, Title 35, Section 284 provides that "the court shall award [the patent owner] damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 284 (1998). The phrase "damages adequate to compensate" means "full compensation for 'any damages' [the patent owner] suffered as a result of the infringement." *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654 (1983). Full compensation includes any foreseeable lost profits the patent owner can prove. *See Rite-Hite*, 56 F.3d at 1545-47.

To recover lost profits, the patent owner must show "causation in fact," establishing that "but for" the infringement, he would have made additional profits. *See King Instruments Corp. v. Perego*, 65 F.3d 941, 952 (Fed. Cir. 1995). When basing the alleged lost profits on lost sales, the patent owner has an initial burden to show a reasonable probability that he would have made the asserted sales "but for" the infringement. *See id.*; *Rite-Hite*, 56 F.3d at 1545.

Once the patent owner establishes a reasonable probability of “but for” causation, “the burden then shifts to the accused infringer to show that [the patent owner’s ‘but for’ causation claim] is unreasonable for some or all of the lost sales.” *Id.* at 1544.

At trial, American Maize proved that Grain Processing’s lost sales assertions were unreasonable. The district court adopted Grain Processing’s initial premise that, because Grain Processing and American Maize competed head-to-head as the only significant suppliers of 10 D.E. maltodextrins, consumers logically would purchase Maltrin 100 if Lo-Dex 10 were not available. *See Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983) (holding that the patent owner may satisfy his initial burden by inference in a two-supplier market). However, the district court found that American Maize proved that Process IV was available and that Process IV Lo-Dex 10 was an acceptable substitute for the claimed invention. In the face of this noninfringing substitute, Grain Processing could not prove lost profits.

American Maize concedes that it did not make or sell Lo-Dex 10 from Process IV until 1991, after the period of infringement. However, an alleged substitute not “on the market” or “for sale” during the infringement can figure prominently in determining whether a patentee would have made additional profits “but for” the infringement. As this court stated in *Grain Processing VII*, “to be an acceptable non-infringing substitute, the product or process must have been available *or* on the market at the time of infringement.” (emphasis added). This statement is an apt summary of this court’s precedent, which permits available alternatives—including but not limited to products on the market—to preclude lost profits damages.

In *Aro Manufacturing*, the Supreme Court stated that the statutory measure of “damages” is “the difference between [the patent owner’s] pecuniary condition after the infringement, and what his condition would have been if the infringement had not occurred.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964). The determinative question, the Supreme Court stated, is: “had the Infringer not infringed, what would the Patent Holder-Licensee have made?” *Aro*, 377 U.S. at 507. The “but for” inquiry therefore requires a reconstruction of the market, as it would have developed absent the infringing product, to determine what the patentee “would . . . have made.”

Reconstructing the market, by definition a hypothetical enterprise, requires the patentee to project economic results that did not occur. To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture. Within this framework, trial courts, with this court’s approval, consistently permit patentees to present market reconstruction theories showing all of the ways in which they would have been better off in the “but for world,” and accordingly to recover lost profits in a wide variety of forms. *See, e.g., King Instruments*, 65 F.3d at 953 (upholding award for lost sales of patentee’s unpatented goods that compete with the infringing goods); *Rite-Hite*, 56 F.3d at 1550 (holding that a patentee may recover lost profits on components that have a functional relationship with the patented invention); *Brooktree Corp.*, 977 F.2d at 1580 (upholding award for price erosion due to infringer’s marketing activities). In sum, courts have given patentees significant latitude to prove and recover lost profits for a wide variety of foreseeable economic effects of the infringement.

By the same token, a fair and accurate reconstruction of the “but for” market also must take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had he not infringed. Without the infringing product, a rational would-be infringer is likely to offer an acceptable noninfringing alternative, if available, to compete with the patent owner rather than leave the market altogether. The competitor in the “but for” marketplace is hardly likely to surrender its complete market share when faced with a patent, if it can compete in some other lawful manner. Moreover, only by comparing the patented invention to its next-best available alternative(s)—regardless of whether the alternative(s) were actually produced and sold during the infringement—can the court discern the market value of the patent owner’s exclusive right, and therefore his expected profit or reward, had the infringer’s activities not prevented him from taking full economic advantage of this right. Thus, an accurate reconstruction of the hypothetical “but for” market takes into account any alternatives available to the infringer.

Accordingly, this court in *Slimfold Manufacturing Co. v. Kinhead Industries, Inc.* held that an available technology not on the market during the infringement can constitute a noninfringing alternative. 932 F.2d 1453 (Fed. Cir. 1991). In *Slimfold*, the patent owner (Slimfold) claimed lost profits on its bi-fold doors with a patented pivot and guide rod assembly. This court noted, however, that Slimfold did not show “that the alleged infringer [Kinhead] would not have made a substantial portion or the same number of sales *had it continued with its old hardware* or with the hardware utilized by any of the other companies.” *Id.* at 1458 (emphasis added). On the basis of this noninfringing substitute, which was not on the market at the time of infringement, this court affirmed the district court’s denial of lost profits. This court determined that the record supported the district court’s finding that this noninfringing “old hardware” was available to Kinhead at the time of the infringement. Specifically, Kinhead and others had used the substitute technology on other doors before the period of infringement. *See id.* Furthermore, consumers considered Kinhead’s noninfringing alternative an acceptable substitute for the infringing doors. *See id.* Therefore, this court upheld the district court’s award of a “small” royalty, rather than lost profits. *Id.* at 1458-59.

Several opinions of this court have noted that “market sales” provide significant evidence of availability as a substitute. These cases illustrate that market sales of an acceptable noninfringing substitute often suffice alone to defeat a case for lost profits. Focusing exclusively on this market sales principle, these opinions did not address availability without market sales. *See, e.g., Panduit*, 575 F.2d at 1162 (“[t]hat Stahlin’s customers, no longer able to buy the patented product from Stahlin, were willing to buy something else from Stahlin, does not establish that there was *on the market* during the period of infringement a product which customers in general were . . . ‘willing to buy in place of the infringing product.’”) (emphasis added). Because these previous cases addressed only market sales, they did not consider that available substitutes, though not literally on sale, can affect market behavior as in the present case.

Nor does *Zygo* support Grain Processing’s position equating availability with offers for sale. In *Zygo*, this court reviewed for clear error the district court’s factual finding that the infringer’s “SIRIS” interferometer was not an

acceptable noninfringing substitute. *Zygo*, 79 F.3d at 1571. Like the accused infringer in the *Slimfold* case, the infringer in *Zygo* had “stopped marketing” the SIRIS when it began marketing the infringing interferometer. *See id.* In the words of this court, “[t]he central damages issue on appeal is whether . . . Wyko’s SIRIS interferometer was . . . an *acceptable* noninfringing alternative. . . .” *Id.* (emphasis added). On that “central” point, this court noted “the insufficiency of the [district] court’s findings” that the SIRIS interferometer was not acceptable, and observed that “the record evidence, while sparse, suggests a contrary conclusion.” *Id.* Therefore, this court remanded for additional factual findings. *Id.* In addition to holding that the district court’s decision lacked sufficient factual support, this court also opined: “[i]t is axiomatic . . . that if a device is not available for purchase, a defendant cannot argue that the device is an acceptable noninfringing alternative. . . .” *Id.* This statement beyond the premises necessary to resolve the legal issues in *Zygo* did not alter the standards for availability applied in the earlier *Slimfold* case and in subsequent cases. *See Gargoyles, Inc. v. United States*, 113 F.3d 1572 (Fed. Cir. 1997) (denying lost profits because a substitute that was not on sale was “available” to the relevant consumer, the Army); *Minco*, 95 F.3d at 1119 (considering allegedly available substitutes that were not on sale during the infringement); *Minnesota Mining & Mfg. Co.*, 976 F.2d at 1579 (determining that the infringer had an alternative available from a supplier in Europe, but that it was not acceptable). Rather, at most it reflects a finding on the record in *Zygo* that availability of the substitute in that case depended on direct market sales.

Grain Processing asserts that permitting the infringer to show substitute availability without market sales, thereby avoiding lost profits, under compensates for infringement. Section 284, however, sets the floor for “damages adequate to compensate for the infringement” as “a reasonable royalty.” 35 U.S.C. § 284. Thus, the statute specifically envisions a reasonable royalty as a form of adequate compensation. While “damages adequate to compensate” means “full compensation,” *General Motors*, 461 U.S. at 654, “full compensation” does not entitle Grain Processing to lost profits in the absence of “but for” causation. *Rite-Hite*, 56 F.3d at 1545. Moreover, although Grain Processing stresses that American Maize should not reap the benefit of its “choice” to infringe rather than use the more expensive Process IV, Grain Processing does not allege willful infringement and the record shows none. To the extent that Grain Processing feels undercompensated, it must point out a reversible error in the district court’s fact-finding, reasoning, or legal basis for denying lost profits or in its reasonable royalty determination.

III.

This court next turns to the district court’s findings that Process IV was in fact “available” to American Maize for producing Lo-Dex 10 no later than October, 1979, and that consumers would consider Process IV Lo-Dex 10 an acceptable substitute.

The critical time period for determining availability of an alternative is the period of infringement for which the patent owner claims damages, *i.e.*, the “accounting period.” Switching to a noninfringing substitute after the accounting period does not alone show availability of the noninfringing substitute during this critical time. When an alleged alternative is not on the

market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time. The accused infringer then has the burden to overcome this inference by showing that the substitute was available during the accounting period. Mere speculation or conclusory assertions will not suffice to overcome the inference. After all, the infringer chose to produce the infringing, rather than noninfringing, product. Thus, the trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement. Acceptable substitutes that the infringer proves were available during the accounting period can preclude or limit lost profits; substitutes only theoretically possible will not.

In this case, the district court did not base its finding that Process IV was available no later than October 1979 on speculation or possibilities, but rather on several specific, concrete factual findings, none of which Grain Processing challenges on appeal. The district court found that American Maize could readily obtain all of the materials needed for Process IV, including the glucoamylase enzyme, before 1979. The court also found that the effects of the enzymes in starch hydrolysis were well known in the field at that time. Furthermore, the court found that American Maize had all of the necessary equipment, know-how, and experience to use Process IV to make Lo-Dex 10, whenever it chose to do so during the time it was instead using Processes I, II or III. American Maize “did not have to ‘invent around’ the patent,” the district court observed; “all it had to do was use a glucoamylase enzyme in its production process.”

The trial court also explained that “the sole reason [American Maize did not use Process IV prior to 1991] was economic: glucoamylase is more expensive than the alpha amylase enzyme American Maize had been using,” and American Maize reasonably believed it had a noninfringing product. While the high cost of a necessary material can conceivably render a substitute “unavailable,” the facts of this case show that glucoamylase was not prohibitively expensive to American Maize. The district court found that American Maize’s “substantial profit margins” on Lo-Dex 10 were sufficient for it to absorb the 2.3% cost increase using glucoamylase.

Moreover, the district court’s unchallenged finding that there is no “economically significant demand for a product having all of the [claimed] attributes” supports its conclusion of availability. Consumers demand “low-dextrose maltodextrins of which the patented product is just one *exemplar*.” Because consumers find the “waxy” and “descriptive ratio” elements of claim 12 “irrelevant,” the prospect of an available, acceptable noninfringing substitute expands because a competitor may be able to drop or replace the “irrelevant” elements from its product. *Compare Rite-Hite*, 56 F.3d 1538 (upholding lost profits award for patentee’s vehicle restraint — not covered by the patent in suit — because the patentee could exclude alleged substitute products with another patent) *with King Instrument*, 72 F.3d 855 (upholding only a *partial* award of lost profits for patentee’s tape rewinder — not covered by any patent — due to the availability of alternatives acceptable to some consumers). Grain Processing cannot exclude Process IV Lo-Dex 10 because it does not have a patent on 10 D.E. maltodextrins, “the economically significant product” as the district court stated, but rather on a particular variety of 10 D.E. maltodextrins.

This court therefore does not detect, and the parties do not suggest, clear error in the district court's factual findings on the availability of Process IV. These factual findings support the district court's conclusion that Process IV was available to American Maize for making noninfringing Lo-Dex 10, no later than October 1991. American Maize had the necessary chemical materials, the equipment, the know-how and experience, and the economic incentive to produce Lo-Dex 10 by Process IV throughout the entire accounting period. Accordingly, this court holds that the district court did not clearly err in finding that Process IV Lo-Dex 10 was an available alternative throughout the accounting period.

Whether and to what extent American Maize's alleged alternative prevents Grain Processing from showing lost sales of Maltrin 100 depends not only on whether and when the alternative was available, but also on whether and to what extent it was acceptable as a substitute in the relevant market. Consumer demand defines the relevant market and relative substitutability among products therein. Important factors shaping demand may include consumers' intended use for the patentee's product, similarity of physical and functional attributes of the patentee's product to alleged competing products, and price. Where the alleged substitute differs from the patentee's product in one or more of these respects, the patentee often must adduce economic data supporting its theory of the relevant market in order to show "but for" causation. See *BIC*, 1 F.3d at 1218.

In this case, the parties vigorously dispute the precise scope of the relevant market. The district court's uncontroverted factual findings, however, render this dispute moot. In the eyes of consumers, according to the district court, Process IV Lo-Dex 10 was the same product, for the same price, from the same supplier as Lo-Dex 10 made by other processes. Process IV Lo-Dex 10 was a perfect substitute for previous versions, and therefore Grain Processing's efforts to show a distinct 10 D.E. maltodextrin market do not assist its lost profits case.

Market evidence in the record supports the district court's uncontroverted findings and conclusions on acceptability. First, for example, American Maize's high profit margin on Lo-Dex 10 and the consumers' sensitivity to price changes support the conclusion that American Maize would not have raised the price of Process IV Lo-Dex 10 to offset the cost of glucoamylase. Further, American Maize's sales records showed no significant changes when it introduced Process IV Lo-Dex 10 at the same price as previous versions, indicating that consumers considered its important properties to be effectively identical to previous versions. Witness testimony supported this market data. Thus, this court discerns no clear error in the district court's finding that Process IV Lo-Dex 10 was an acceptable substitute in the marketplace.

It follows from the district court's findings on availability and acceptability that Grain Processing's theory of "but for" causation fails. As the district court correctly noted, "[a]n [American Maize] using the dual-enzyme method between 1979 and 1991 . . . would have sold the same product, for the same price, as the actual [American Maize] did . . ." and consequently would have retained its Lo-Dex 10 sales. Grain Processing did not present any other evidence of lost profits, such as individual lost transactions as in *Rite-Hite Corp. v. Kelley Co.* Thus, the district court properly determined that, absent

infringing Lo-Dex 10, Grain Processing would have sold no more and no less Maltrin 100 than it actually did.

IV.

In summary, this court requires reliable economic proof of the market that establishes an accurate context to project the likely results “but for” the infringement. The availability of substitutes invariably will influence the market forces defining this “but for” marketplace, as it did in this case. Moreover, a substitute need not be openly on sale to exert this influence. Thus, with proper economic proof of availability, as American Maize provided the district court in this case, an acceptable substitute not on the market during the infringement may nonetheless become part of the lost profits calculus and therefore limit or preclude those damages.

This court concludes that the district court did not err in considering an alternative not on the market during the period of infringement, nor did it clearly err in determining that the alternative was available, acceptable, and precluded any lost profits. Accordingly, the district court did not abuse its discretion in denying lost profits.

Comments

1. **The Panduit Foundation and Manufacturing Capability.** The *Panduit* test is commonly used for determining lost profits, although not an exclusive test. *Panduit* sets forth a standard “but for” test; that is, the patentee must show a reasonable probability that he would have made the lost sales “but for” the infringing activity. Under *Panduit*,

To obtain lost profits on sales he would have made absent the infringement, *i.e.*, the sales made by the infringer, a patent owner must prove: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made.

575 F.2d at 1156. Thus, proving a causal relationship between the infringing conduct and lost profits is essential. See *BIC Leisure Products, Inc. v. Windsurfing Int’l Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993) (stating “[t]o recover lost profits as opposed to royalties, a patent owner must prove a causal relation between the infringement and its loss of profits. The patent owner must show that ‘but for’ the infringement, it would have made the infringer’s sales. An award of lost profits may not be speculative. Rather the patent owner must show a reasonable probability that, absent the infringement, it would have made the infringer’s sales”).

2. **Non-Infringing Substitutes.** Of *Panduit*’s four factors, the “absence of acceptable non-infringing substitutes” is perhaps the most important and controversial. Under *Panduit*, a patentee cannot recover lost profits if acceptable non-infringing substitutes are available because the consumer may have opted for the substitute — there is no “but for” causality. Historically, the Federal Circuit required the substitute to actually be available on the market at the time of infringement. See *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1571 (Fed. Cir. 1996) (stating “[i]t is axiomatic . . . that if a device is

not available for purchase, a defendant cannot argue that the device is an acceptable noninfringing alternative for the purposes of avoiding a lost profits award. A lost profits award reflects the realities of sales actually lost, not the possibilities of a hypothetical market which the infringer might have created”).

In recent years, the Federal Circuit has modified the second *Panduit* factor. For instance, in *BIC Leisure Prods.*, *supra*, the court stated this factor, “properly applied, ensures that any proffered alternative competes in the same market for the same customers as the infringer’s product.” 1 F.3d at 1219. And in *Grain Processing*, the court—seemingly relaxing *Zygo*—held that a non-infringing substitute can be available—and therefore serve to deny lost profits—even though the substitute is not on the market. 185 F.3d at 1351 (stating “an available technology not on the market during the infringement can constitute a noninfringing alternative”).

3. **The Market-Share Rule.** The *Panduit* test works well in a two-supplier market, where one can assume that consumers would have purchased the product from the patentee absent the infringing activity. See *State Indus., Inc. v. Mor-Flo, Inc.*, 883 F.2d 1573 (Fed. Cir. 1989) (“In the two-supplier market, it is reasonable to assume, provided the patent owner has the manufacturing and marketing capabilities, that it would have made the infringer’s sales. In these instances, the *Panduit* test is usually straightforward and dispositive”).

The inference of the two-supplier assumption is weakened in a multi-supplier scenario because consumers have other options besides the patentee. The Federal Circuit addressed this problem in *State Indus.*, *supra*, by adopting a “market share” approach. The market share rule allows the patentee to recover lost profits based on market share, even though there are available non-infringing substitutes. The patentee is permitted to substitute market share for absence of non-infringing products because it nevertheless can prove, with reasonable probability, sales it would have made “but for” the infringement. See *BIC Leisure*, 1 F.3d at 1219 (“The market share approach allows a patentee to recover lost profits, despite the presence of acceptable, noninfringing substitutes, because it nevertheless can prove with reasonable probability sales it would have made ‘but for’ the infringement.”). This approach assumes that the patentee, who, for example, has 30% of the market, would have made 30% of the sales absent infringing activity. Thus, *State Indus.* rendered neutral the “absence of acceptance non-infringing substitutes” factor.

Importantly, as with the *Panduit* test, the market share approach requires proof that the patentee and the infringer compete in the same market. This assumption was lacking in *BIC Leisure*, because the record reveal[ed] that during the damages period the sailboard market was not a unitary market in which every competitor sold substantially the same product. Windsurfing and BIC sold different types of sailboards at different prices to different customers. [And] their sailboards differed significantly in terms of price, product characteristics, and marketing channels.” *Id.*

4. **Manufacturing Capability.** The third *Panduit* factor requires the patentee have capability to meet market demand. This factor can be satisfied if the

patentee can show that he has manufacturing capacity or although he does not currently have manufacturing capacity, he can increase his capacity or engage in licensing activity.

In *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286 (Fed. Cir. 2007), the Federal Circuit reversed the district court's award of lost profits because the patentee—Wechsler—failed to prove he had the capability to manufacture the patented product during the period of infringement. The alleged infringing activity began in late 1998 and ended in the spring of 2000, but it was “undisputed that Wechsler did not produce a product until April 2001, approximately one year after the period of infringement ended.” Wechsler argued—based on later sales of the patented product—that he did indeed have the capability to manufacture the patented product during the period of infringement. The court was not convinced:

The evidence of later manufacturing and marketing is not dispositive to the determination of whether the patentee had the ability to do so during the period of infringement. Only if it is indicative of the ability to manufacture and market the patented device during the period of infringement is it relevant.

In the present case, the record demonstrates that, despite his later success manufacturing and marketing a product, Wechsler lacked the capability to manufacture his device during the period of infringement. In a letter dated April 24, 2000, Wechsler wrote to his factory stating that he “was disappointed to learn . . . that a rough production sample [of his device would] not be available until early June [2000].” Not until August 2000, four months after the Handi-Drink device was taken off the market, was Wechsler finally successful in producing his own device. As such, Wechsler clearly lacked the ability to manufacture his device during the period of infringement.

486 F.3d at 1293-94.

5. **Foreseeability—Proximate Cause and Lost Profits.** In *Rite-Hite*, the court allowed for recovery of lost profits on products that were in competition with the infringing product, but were not covered by the patent-in-suit. (The patentee also commercialized the claimed invention, the MDL-100.) The key for the court was the foreseeability of the lost sales of the competitive product. As the court noted,

[i]f a particular injury was or should have been reasonably foreseeable by an infringing competitor in the relevant market, broadly defined, that injury is generally compensable absent a persuasive reason to the contrary. . . . Being responsible for lost sales of a competitive product is surely foreseeable; such losses constitute the full compensation set forth by Congress, as interpreted by the Supreme Court, while staying well within the traditional meaning of proximate cause. Such lost sales should therefore clearly be compensable.

Id. at 1546-47. *Rite-Hite* is a departure from *Panduit*, which has traditionally been applied to products covered by the patent-in-suit. But as *Rite-Hite* noted, *Panduit* is not the *sine qua non* for proving “but for” causation. If there are other ways to show that the infringement in fact caused the patentee's lost profits, there is no reason why another test should not be acceptable.” *Id.* at 1548.

In dissent, Judge Nies did not see injury to the patentee's property right in an exclusive market for the patented goods. For her, allowing a patentee to recover lost profits of products not covered by the patent-in-suit is

inconsistent with basic principles of patent law. For Judge Nies and other critics of *Rite-Hite*, patents are intended to cover the subject matter claimed by the patent, not necessarily markets.

A question prompted by *Rite-Hite* is whether a patentee can be compensated for lost profits on product sales it chose not to make; in other words, lost profits in a market it did not engage? The Federal Circuit answered in the affirmative in *King Instruments Corp. v. Perego*, 65 F.3d 941 (Fed. Cir. 1995). In *King*, the Federal Circuit extended the reasoning of *Rite-Hite*. In *King Instruments*, Tapematic was found to infringe claim 12 of King's '461 patent, but King did not sell or manufacture its patented invention, and the machine it did sell—the model 790—was not covered by the '461 patent. (King and Tapematic both sold competing machines that splice and wind magnetic tape.) The district court awarded King lost profits, noting that but for the infringement King would have sold more of its model 790 machine. The court rejected Tapematic's argument that lost profits are only available to patentees who sell or manufacture the claimed invention. The Federal Circuit affirmed:

The 1952 Act, § 154, clarified that a patent empowered its owner “to exclude others from making, using, or selling” the invention. 35 U.S.C. § 154 (1952) (emphasis added). The 1952 amendment should have corrected any mistaken belief that patent rights somehow hinged upon the patentee's exploitation of the invention. Inventors possess the natural right to exploit their inventions (subject to the patent rights of others in a dominant patent) apart from any Government grant. Therefore, patent rights do not depend upon the exercise of rights already in the patentee's possession. Thus, the 1952 Act clarified that a patent confers the right to exclude others from exploiting an invention. It does not confer the right to exploit the invention already possessed by the inventor.

This understanding of the right protected by section 284 informs the purpose and scope of the damages provision. Section 284 protects the right to exclude others from exploiting an invention. To invoke that protection, a patentee need not have exercised its natural right to itself make, use, or sell the invention.

The damages section, section 284, protects the right to exclude, not the right to exploit. A patentee qualifies for damages adequate to compensate for infringement without exploiting its patent. . . . The patentee need not make, use, or sell the invention to sustain an injury to that right.

A patentee may suffer injury resulting from the violation of its right to exclude infringing, competing products. . . . The patentee's sale of a competing product not covered by the patent within that market does not change the policy justifications for restoring the parties to the positions they would have occupied absent the infringement.

The market may well dictate that the best use of a patent is to exclude infringing products, rather than market the invention. A patentee, perhaps burdened with costs of development, may not produce the patented invention as efficiently as an infringer. Indeed, the infringer's presence in the market may preclude a patentee from beginning or continuing manufacture of the patented product. Thus, as apparent in this case, the patentee may acquire better returns on its innovation investment by attempting to exclude infringers from competing with the patent holder's nonpatented substitute.

65 F.3d at 949.

6. **The Entire Market Value Rule.** It is not uncommon for patentees to sell unpatented products with the patented product. For example, a patentee

may sell pepper along with its patented pepper grinder. Another scenario relates to an apparatus that contains several features, only one or so subject to patent protection. In attempting to recover lost profits for infringing activity, a patentee will frequently seek to recover damages on both the unpatented and patented good, because fewer sales of the patented good due to infringement is also accompanied by fewer sales of the unpatented good. Can the patentee recover damages on the unpatented good?

To address these situations, the Federal Circuit employs the “entire market value rule,” which “allows for the recovery of damages based on the value of an entire apparatus including non-patented parts, even though only one of the features in the apparatus is patented.” *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 865 (Fed. Cir. 1985). The court further stated:

This court has recognized that under this rule, “it is ‘the financial and marketing dependence on the patented item under standard marketing procedures’ which determines whether the non-patented features of a machine should be included in calculating compensation for infringement.” The controlling touchstone in determining whether to include the non-patented spare part in a damage award is whether the patentee can normally anticipate the sale of the non-patented component together with the sale of the patented components.

In addition, in *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 901 (Fed. Cir. 1986), the court noted that for the entire market value rule to apply the patented feature must form “the basis of customer demand.” Thus, consumer demand of the patented feature and the patentee’s anticipating selling the unpatented and patented goods together.

2. Reasonable Royalty

Under § 284, “the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty.” Damages are determined using the “reasonable royalty” method when it is too difficult to prove lost profits or if lost profits are simply not claimed. In discerning a reasonable royalty, courts will usually look to established (extant) royalties or, if none exist, a hypothetical negotiation between what is referred to as a willing licensor and willing licensee. The time of the hypothetical negotiation is at the time the infringement began.

The common issues associated with the established royalty method are what constitutes an established royalty, how many licenses must exist before a royalty is “established,” and how similar must the existing licensing agreements be to the relationship between the patentee and infringer.

TRIO PROCESS CORP. v. GOLDSTEIN’S SONS, INC.

612 F.2d 1353 (3rd Cir. 1980)

ROSENN, Circuit Judge.

The infringement has been established and is no longer at issue. We are, however, revisited with the troublesome issue of damages. When this case was last before us on appeal from the original determination of damages, we

vacated the judgment and remanded to the district court with instructions to recalculate the damages. We are now asked to decide whether the district court's action is consistent with our holding in that earlier appeal. We hold that it is not and, therefore, again vacate the district court's judgment.

I.

At the heart of this controversy is a patented process for removing insulation from copper wire in order to allow the copper to be salvaged. This process is covered by United States Patent No. 3,076,421, owned by Trio Process Corporation ("Trio"). In 1972 we upheld the validity of the patent and determined that it had been willfully infringed by L. Goldstein's Sons, Incorporated ("Goldstein"). The case was remanded to the district court for a determination of damages.

On remand the district court appointed a master to assist in the determination of damages. When we last reviewed the proceedings, we observed:

The master approached the damage issue by comparing Goldstein's costs of operating the patented process with the costs of a similar, unpatented process. He found that use of the Trio process saved Goldstein \$52,791 per furnace year in labor costs alone, and that other, smaller savings accrued to Goldstein from use of the patented method as well.

In order to reach a "reasonable royalty" for use of the patent by the infringer, the master halved Goldstein's savings in labor costs, and concluded that \$26,390 was a reasonable royalty for each furnace year. Multiplying this figure by the number of furnace years of infringement and making slight modifications, the master found damages of \$1,564,804. The district court viewed the damage computation not with regard to the money saved by the defendant as a result of the infringement, as the master had, but in terms of what Trio had lost. It looked first to the initial sum of \$2,600 per furnace year the amount actually charged by Trio for licenses in the 1960-1970 era. The district court then increased the \$2,600 figure on the assumption that the open infringement had reduced the market price of the license, and proceeded to set damages at \$7,800 per furnace year for the years prior to the decision by this Court on validity, a figure three times the rate charged by Trio during the 1960's. Damages were set at \$15,000 per furnace year for the period following the 1972 adjudication. The employment of these two figures resulted in total primary damages of \$653,839. The trial judge then proceeded to use a double multiplier in contrast to the master's trebling figure and denied attorneys' fees. With interest, the total damages computed by the district court were \$1,726,525.

"Trio Process III."

On appeal we affirmed in part and reversed in part. *Trio Process III*, supra. We held that there was "no error in the first step of the district court's damage calculation, namely, focusing upon the losses suffered by the patent holder rather than upon the profits illegally made by the patent infringer." *Id.* at 129. We also affirmed the district court in its finding "that the license rate established by Trio in the 1960's may have been artificially depressed by Goldstein's ongoing infringement, and that the reasonable royalty should therefore be set at a level above the actual license rate."¹

1. Contrary to Trio's assertion, however, we did not hold that the reasonable royalty rate was, as a matter of law, higher than the actual license rate. We held only that it might be higher if the

We held, however, that the district court had erred in two respects. First, it had calculated not one royalty rate but two: one for the period before our decision upholding the patent's validity and the second for the period after.² We held that a single reasonable royalty rate should be calculated for the entire period of infringement. The district court has done that and the point is no longer at issue. Second, and most importantly for purposes of deciding this appeal, there was a failure to articulate the reasons underlying the determination of the royalty rate. Thus, the cause was remanded to the trial court for reconsideration of the damages issue. We noted specifically that

on remand, the district court should give proper regard to the rule that the extent of the deviation of existing license fees from a reasonable royalty must be determined solely on the basis of the submitted evidence and upon an evaluation of the factors that could affect the reasonable royalty rate, not upon mere conjecture.

Trio Process III, 533 F.2d at 130. This has not been done, however, and we therefore vacate the determination of damages.

II.

In calculating damages for patent infringement, a patent holder is entitled to receive compensation for the infringement but in no event less than a reasonable royalty. 35 U.S.C. § 284. An exhaustive list of factors relevant to the determination of a reasonable royalty can be found in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). The district court in this case found a number of those factors to be relevant in its own calculation of damages:

- (1) (T)he existing value of the (patented) process to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or conveyed sales.
- (2) The duration of the patent and the term of the license.
- (3) The established profitability of the product made under the patent; its commercial success; and its current popularity.
- (4) The utility and advantages of the patent property over old modes or devices, if any, that had been used for working out similar results.
- (5) The nature of the patent (process) . . . and the benefits to those who have used the (process).
- (6) The extent to which the infringer has made use of the (patented process); and any evidence probative of the value of that use.
- (7) The portion of the realizable profit that should be credited to the invention as distinguished from nonpatented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
- (8) The opinion testimony of qualified experts.

actual license rate had, in fact, been artificially depressed by Goldstein's infringement. Thus, we held in *Trio Process III* that the reasonable royalty should be set at a level above the actual license rate if it was demonstrated, on the basis of the submitted evidence, that Goldstein's infringing activities had artificially depressed the actual license rate established by Trio.

2. The district court had set damages based on a reasonable royalty of \$7,800 per furnace year for the period prior to our adjudication of the patent's validity and \$15,000 per furnace year for the period thereafter.

Applying the “willing buyer and willing seller” rule, the district court considered these factors in the context of hypothetical negotiations between the parties conducted in the absence of the infringing activity. The court found that the first two of the above factors would have had only a “minimal effect” in the determination of a reasonable royalty. As to the remaining factors, the court noted that “(they) all touch upon the benefits obtained by defendant through its infringing use of plaintiff’s patented process.” Thus, the court found that “the license fee the parties would have agreed upon absent defendant’s infringement would to a large extent have been determined by the economic benefits that were obtained through the use of plaintiff’s patented process.”

The court found that Goldstein had obtained four distinct benefits from its use of the Trio process: (1) a reduction in labor costs; (2) an increased recovery of copper from the scrap wire; (3) lower fuel consumption per ton of processed material; and (4) the ability to attract more electrical scrap for processing by advertising the advantages of the Trio process. The court, however, was unable to assign a dollar value to each of these benefits but indicated that “the only dollar figure available is the value of the direct and indirect labor savings achieved by defendant.”

The court began its calculation of the labor savings with expert testimony, credited by the master, which indicated that Goldstein had realized labor savings of \$52,791 per furnace year by virtue of its infringing use of the Trio process.³ Because Goldstein operated a number of infringing furnaces over an eight and one-half year period, the court reduced this figure to \$41,652 per furnace year, reflecting the wages prevailing in 1969, the mid-point in the infringing period. The court then found that “(i)n voluntary royalty negotiations untainted by defendant’s infringing practices, defendant might well have been willing to split this saving with plaintiff and paid plaintiff a royalty of approximately \$20,000 for each furnace year.” For two reasons, however, the court further reduced this to \$15,000 per furnace year. First, the court held that, as a seller of furnaces, “(Trio) would have been willing to accept somewhat less than the maximum royalty negotiable in order to promote its sales.” Second, prior to the lawsuit, “plaintiff was unaware . . . of the exact extent of the labor savings that were obtainable through the use of its process.” After multiplying \$15,000 by the number of infringing furnaces, the court then doubled the primary damages and added interest of 6% per annum. The total damage award was \$2,901,336 plus costs.

Georgia-Pacific lists first among the factors relevant to the determination of a reasonable royalty “(t)he royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.” *Georgia-Pacific*, 318 F. Supp. at 1120. In this case, the district court chose to disregard the license fees received by Trio because “they did not show that there was an established royalty and since the fees received were artificially depressed by defendant’s ongoing infringement.” The court noted its

3. This figure was arrived at by comparing the cost of operating a similar, noninfringing furnace. Goldstein disputes the basis for this comparison but we need not address this issue in view of our disposition of the case.

belief that “a royalty negotiated in the absence of defendant’s infringement would have been several times higher than the license fees actually received by the plaintiff.” We have not, however, been able to discover any evidence in this record to support this conclusion.

It is true that the actual license rate does not necessarily constitute a reasonable royalty. Thus, when the actual license rate is artificially low, a reasonable royalty may be set above that rate. *Trio Process III*, *supra*. Nevertheless, the actual license rate is an important factor in the determination of a reasonable royalty, at least when those royalties prove or tend to prove an established royalty. See *Georgia-Pacific*, 318 F. Supp. at 1120.

We are mindful that the district court concluded that the royalties trio received under the license agreements did not constitute an established royalty. Nevertheless, the existing license rate does tend to show an established license rate. The evidence indicates little, if any, variation in the rate charged before or after the infringement. Further, the district court, in its first consideration of the damage issue, apparently found the actual license rate to be probative, although not conclusive, evidence of a reasonable royalty. Thus, the reasonable royalty rate determined by the district court in its first consideration of the damage issue was related to the actual license rate charged. That approach was correct. As we indicated in our earlier opinion, however, the district court erred in failing to demonstrate, on the basis of the evidence, the extent of the deviation of existing license fees from a reasonable royalty. That same void continues to exist in the district court’s most recent damage calculation.

We are again unable to discover any support for the district court’s conclusion that the existing license rate was depressed by Goldstein’s infringement. Thus, its reliance on the rationale of *Tights, Inc. v. Kayser-Roth Corp.*, 442 F. Supp. 159 (M.D.N.C. 1977), is misplaced. In *Tights* the court disregarded the standard royalty rate, finding it had been artificially depressed “because it was established in an atmosphere of industry-wide infringement of and disrespect for the . . . patent.” *Id.* at 165. The court thereupon calculated a reasonable royalty based on hypothetical negotiations between a “willing licensee” and a “willing licensor.”⁴ Unlike the instant case, the depressing effect in *Tights* was evident. There, the low license rate had been negotiated against a background of open industry-wide infringement. Further, there was evidence that the existing license rate had dramatically declined because of that infringement. Thus, there was a substantial factual basis which justified the court’s decision to disregard the existing license rate. In the case before us, however, such factors are not present. The license rate agreed upon between Trio and Goldstein was arrived at in free and open negotiations conducted prior to any infringing activity by Goldstein.⁵ Furthermore, there are no allegations in this case of industry-wide infringement. Unlike *Tights*, there is

4. In *Georgia-Pacific*, *supra*, the court also determined damages on the basis of the “willing buyer and willing seller” rule. This was used, however, only after the parties agreed there was no established royalty for the patented item. Indeed, the apparent policy of the patent holder was not to enter into licensing agreements but rather, to maintain its patent monopoly.

5. Goldstein and Trio entered into two license agreements in 1960. There is no indication in the record that Goldstein’s infringing activities began any earlier than 1964 when it contracted with a metal fabricator for the construction of a copy of a furnace Goldstein had purchased from Trio.

no indication that the license rates here declined after Goldstein's infringement. Indeed, even after Trio learned of the infringement, it offered Goldstein a license at the same rate as had been earlier agreed upon. Further, in the years following our decision upholding the validity of the patent, there were apparently no new licenses granted. Thus, the thrust of the evidence in this case indicates the absence of a depressing effect caused by Goldstein's infringement. Nor have we been referred to any permissible evidentiary basis to the contrary. Thus, we are compelled to vacate the court's assessment of damages.

* * *

IV.

We begin with the rule that we noted in our last opinion, that the extent of the deviation of the actual licensing rate from a reasonable royalty must be explained solely on the basis of the submitted evidence. In the absence of such an explanation, we must examine the record ourselves to determine whether it contains such evidence.

Trio itself did not utilize the patented process. Instead, its only use of the patent was to license it for use by others. The licenses sold were for five year periods. The first license was sold for \$20,000. This amount covered the license and the furnace necessary to utilize the process; \$7,000 represented the cost of the furnace and \$13,000 the cost of the license, *i.e.*, \$2,600 per furnace year. In 1960, Goldstein purchased two sets of licenses and furnaces, one for \$20,000 and the other for \$15,000. Between 1962 and 1969 four more buyers purchased licenses and furnaces at the \$20,000 rate. In 1967, another company bought the package with a modified furnace for \$25,000. Later that year the package was purchased by another buyer for \$19,500. After a decision by Trio to raise the price, two more were sold in 1972 to purchasers other than Goldstein, for a price of \$25,000. Thus, throughout this period, the license rate of \$2,600 per furnace year appears to have remained relatively constant.

Goldstein's infringing activities began in 1965. However, Trio and Goldstein had in free and open negotiations previously agreed to a license rate of \$2,600 per furnace year. The license rate Trio charged other licensees did not decline after Goldstein's infringement began. Consequently, if the infringing activity did have a depressing effect on the license rate it could only have been in deterring Trio from charging the rate it otherwise would have negotiated in the open market. The district court, however, disregarded the license fees received by Trio, because it believed they did not reveal an established royalty, and they were artificially depressed by the ongoing infringement. The court found that Trio was a seller of furnaces and thus in negotiating a royalty rate (prior to the infringement) "would have been willing to accept somewhat less than the maximum royalty negotiable in order to promote its sales." It further observed that prior to this lawsuit, Trio was unaware of the exact extent of the labor savings effected by the patented process. But the record indicates that even after learning of the infringement, Trio offered Goldstein a license for the infringing furnace "Under the same terms and conditions as the previous two incinerators."

It is true that "(a) patentee who has attempted to avoid costly and time-consuming litigation by settling for less than a reasonable royalty should not

be penalized when an infringer forces full litigation.” *Tights*, 442 F. Supp. at 165. Here, however, there is no reason to believe that the license rate negotiated by the parties was anything other than a balanced consideration by both Goldstein and Trio of those competing concerns that normally enter into the determination of price in an open marketplace economy. Trio consistently offered licenses at the rate of \$2,600 per furnace year. Thus, the possibility that Trio, had it chosen to do so, might have obtained a higher license rate than that actually charged, is irrelevant. We believe the rate fixed by the parties prior to any infringement is pertinent and highly persuasive. Further, our examination of the record has not disclosed any reason to distrust the existing license rate as a measure of actual damages. Thus, we hold that the \$2600 per furnace year rate negotiated between Trio and Goldstein prior to the infringement, constitutes a reasonable royalty.

* * *

Comments

1. **Statutory Basis for Reasonable Royalty.** Section 284 of the patent code expressly provides a baseline amount of damages, stating that damages should be “in no event less than a reasonable royalty.” It is up to the court, balancing several factors, to determine what is reasonable.
2. **Reasonable Royalty Factors.** The district court in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), an oft-cited case, listed 15 factors relevant to the determination of the amount of a reasonable royalty. The *Trio Process* court relied on eight of these factors. Perhaps the most important factors are those relating to established conditions within the market or industry. For instance, *Trio Process* placed a great deal of emphasis on the existence of an established royalty as a guide to what rate a willing licensee-willing licensor would have agreed. If the patentee had licensed the patent to five competitors at a 5 percent rate, there is a greater likelihood the patentee and defendant would have agreed on the same rate. Of course, an established royalty rate may not reflect the assumptions of an arms-length negotiation between a willing licensee-willing licensor because the parties to the prior license may not be competitors, the market may not be fully developed at the time the license was negotiated, or the rate may be artificially low due to industry-wide infringement and lack of respect for the patent. See *Tights, Inc. v. Kayser-Roth Corp.* 442 F. Supp. 159 (M.D.N.C. 1977), discussed in *Trio Process*.
3. **Willing Licensor–Willing Licensee.** Courts oftentimes construct a hypothetical negotiation to arrive at a royalty rate. The time frame for this negotiation is at the time defendant began infringing and is based on the assumption that the patent is not invalid. But this fictional construct is not without criticism. In *Georgia-Pacific*, for example, the court warned against placing the negotiation in a “vacuum of pure logic,” outside a marketplace context that includes relative bargaining strength, commercial preferences of the parties, and commercial past performance of the claimed invention. 318 F. Supp. at 1121. And the Federal Circuit in *Fromson v. Western Litho Plate & Supply Co.*,

853 F.2d 1568, 1574 (Fed. Cir. 1988), conceded that the hypothetical negotiation “must be used on occasion for want of a better” device.

B. EQUITABLE RELIEF

Equitable relief can be broken down into two forms of injunctions: (1) preliminary; and (2) permanent. The latter is sought after a final ruling on the defendant’s infringement liability, and is explored in *eBay* and *Commonwealth Scientific*. The preliminary injunction — at issue in *Amazon.com* — is asked for by the patentee before a final ruling on the defendant’s infringement liability. In this instance, the patentee is asserting that he will likely succeed on the merits regarding infringement and validity. Therefore, the court should enjoin the alleged infringing activity before a final ruling lest the patentee suffer irreparable harm.

1. Preliminary Injunctions

AMAZON.COM, INC. v. BARNESANDNOBLE.COM, INC.

239 F.3d 1343 (Fed. Cir. 2001)

CLEVENGER, Circuit Judge.

This is a patent infringement suit brought by Amazon.com, Inc. (“Amazon”) against barnesandnoble.com, inc., and barnesandnoble.com llc (together, “BN”). Amazon moved for a preliminary injunction to prohibit BN’s use of a feature of its web site called “Express Lane.” BN resisted the preliminary injunction on several grounds, including that its Express Lane feature did not infringe the claims of Amazon’s patent, and that substantial questions exist as to the validity of Amazon’s patent. The United States District Court for the Western District of Washington rejected BN’s contentions. Instead, the district court held that Amazon had presented a case showing a likelihood of infringement by BN, and that BN’s challenges to the validity of the patent in suit lacked sufficient merit to avoid awarding extraordinary preliminary injunctive relief to Amazon. The district court granted Amazon’s motion, and now BN brings its timely appeal from the order entering the preliminary injunction.

After careful review of the district court’s opinion, the record, and the arguments advanced by the parties, we conclude that BN has mounted a substantial challenge to the validity of the patent in suit. Because Amazon is not entitled to preliminary injunctive relief under these circumstances, we vacate the order of the district court that set the preliminary injunction in place and remand the case for further proceedings.

I

This case involves United States Patent No. 5,960,411 (“the ’411 patent”), which issued on September 28, 1999, and is assigned to Amazon. On October 21, 1999, Amazon brought suit against BN alleging infringement of the patent and seeking a preliminary injunction.

* * *

The '411 patent describes a method and system in which a consumer can complete a purchase order for an item via an electronic network using only a "single action," such as the click of a computer mouse button on the client computer system. Amazon developed the patent to cope with what it considered to be frustrations presented by what is known as the "shopping cart model" purchase system for electronic commerce purchasing events. In previous incarnations of the shopping cart model, a purchaser using a client computer system (such as a personal computer executing a web browser program) could select an item from an electronic catalog, typically by clicking on an "Add to Shopping Cart" icon, thereby placing the item in the "virtual" shopping cart. Other items from the catalog could be added to the shopping cart in the same manner. When the shopper completed the selecting process, the electronic commercial event would move to the check-out counter, so to speak. Then, information regarding the purchaser's identity, billing and shipping addresses, and credit payment method would be inserted into the transactional information base by the soon-to-be purchaser. Finally, the purchaser would "click" on a button displayed on the screen or somehow issue a command to execute the completed order, and the server computer system would verify and store the information concerning the transaction.

. . . . The '411 patent sought to reduce the number of actions required from a consumer to effect a placed order. . . . How, one may ask, is the number of purchaser interactions reduced? The answer is that the number of purchaser interactions is reduced because the purchaser has previously visited the seller's web site and has previously entered into the database of the seller all of the required billing and shipping information that is needed to effect a sales transaction. Thereafter, when the purchaser visits the seller's web site and wishes to purchase a product from that site, the patent specifies that only a single action is necessary to place the order for the item. . . .

II

The '411 patent has 26 claims, 4 of which are independent. Independent claims 1 and 11 are method claims directed to placing an order for an item, while independent claim 6 is an apparatus claim directed to a client system for ordering an item, and independent claim 9 is an apparatus claim directed to a server system for generating an order. Amazon asserted claims 1-3, 5-12, 14-17, and 21-24 against BN. Although there are significant differences among the various independent and dependent claims in issue, for purposes of this appeal we may initially direct our primary focus on the "single action" limitation that is included in each claim. This focus is appropriate because BN's appeal attacks the injunction on the grounds that either its accused method does not infringe the "single action" limitation present in all of the claims, that the "single action" feature of the patent is invalid, or both.

* * *

BN's Express Lane thus presents a product page that contains the description of the item to be purchased and a "description" of the single action to be taken to effect placement of the order. Because only a single action need be taken to complete the purchase order once the product page is displayed, the district court concluded that Amazon had made a showing of likelihood of success on its allegation of patent infringement.

In response to BN's contention that substantial questions exist as to the validity of the '411 patent, the district court reviewed the prior art references upon which BN's validity challenge rested. The district court concluded that none of the prior art references anticipated the claims of the '411 patent under 35 U.S.C. § 102 (1994) or rendered the claimed invention obvious under 35 U.S.C. § 103 (1994).

III

The grant or denial of a preliminary injunction under 35 U.S.C. § 283 (1994) is within the sound discretion of the district court. *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.* "An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." 77 F.3d at 1367.

As the moving party, Amazon is entitled to a preliminary injunction if it can succeed in showing: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest. "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 (Fed. Cir. 1988).

Irreparable harm is presumed when a clear showing of patent validity and infringement has been made. *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.* "This presumption derives in part from the finite term of the patent grant, for patent expiration is not suspended during litigation, and the passage of time can work irremediable harm." 132 F.3d at 708.

Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes *both* of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm.

In order to demonstrate a likelihood of success on the merits, Amazon must show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) Amazon will likely prove that BN infringes the '411 patent, and (2) Amazon's infringement claim will likely withstand BN's challenges to the validity and enforceability of the '411 patent. If BN raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove "lacks substantial merit," the preliminary injunction should not issue.

Of course, whether performed at the preliminary injunction stage or at some later stage in the course of a particular case, infringement and validity analyses must be performed on a claim-by-claim basis. Therefore, in cases involving multiple patent claims, to demonstrate a likelihood of success on the merits, the patentee must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer.

Both infringement and validity are at issue in this appeal. It is well settled that an infringement analysis involves two steps: the claim scope is first determined, and then the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present

either literally or by a substantial equivalent. Conceptually, the first step of an invalidity analysis based on anticipation and/or obviousness in view of prior art references is no different from that of an infringement analysis. “It is elementary in patent law that, in determining whether a patent is valid and, if valid, infringed, the first step is to determine the meaning and scope of each claim in suit.” *Lemelson v. Gen. Mills, Inc.*, 968 F.2d 1202, 1206 (Fed. Cir. 1992). Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses.

IV

BN contends on appeal that the district court committed legal errors that undermine the legitimacy of the preliminary injunction. In particular, BN asserts that the district court construed key claim limitations one way for purposes of its infringement analysis, and another way when considering BN’s validity challenges. BN asserts that under a consistent claim interpretation, its Express Lane feature either does not infringe the ’411 patent, or that if the patent is interpreted so as to support the charge of infringement, then the claims of the patent are subject to a severe validity challenge. When the key claim limitations are properly interpreted, BN thus asserts, it will be clear that Amazon is not likely to succeed on the merits of its infringement claim, or that BN has succeeded in calling the validity of the ’411 patent into serious question. In addition, BN asserts that the district court misunderstood the teaching of the prior art references, thereby committing clear error in the factual predicates it established for comprehension of the prior art references.

V

It is clear from the district court’s opinion that the meaning it ascribed to the “single action” limitation includes a temporal consideration. The “single action” to be taken to complete the purchase order, according to the district court, only occurs after other events have transpired. These preliminary events required pursuant to the district court’s claim interpretation are the presentation of a description of the item to be purchased and the presentation of the single action the user must take to complete the purchase order for the item.

* * *

[W]e ultimately agree with Amazon and construe all four independent claims (*i.e.*, claims 1, 6, 9, and 11) to call for the single action to be performed immediately after a display of information about an item and without any intervening action, but not necessarily immediately after the first display or every display.

* * *

VI

A

When the correct meaning of the single action limitation is read on the accused BN system, it becomes apparent that the limitations of claim 1 are likely met by the accused system. The evidence on the record concerning the operation of BN’s “Express Lane” feature is not in dispute. At the time that

the '411 patent was issued, BN offered customers two purchasing options. One was called "Shopping Cart," and the other was called "Express Lane." The Shopping Cart option involved the steps of adding items to a "virtual" shopping cart and then "checking out" to complete the purchase. In contrast, the Express Lane option allowed customers who had registered for the feature to purchase items simply by "clicking" on the "Express Lane" button provided on the "detail page" or "product page" describing and identifying the book or other item to be purchased. The text beneath the Express Lane button invited users to "Buy it now with just 1 click!"

* * *

We note that the district court concluded that "[b]arnesandnoble.com infringes claims 1, 2, 3, 5, 11, 12, 12, 14, 15, 16, 17, 21, 22, 23, [and] 24," and "also infringes claims 6-10 of the '411 patent." However, the relevant determination at the preliminary injunction stage is substantial likelihood of success by Amazon of its infringement claims, not a legal conclusion as to the ultimate issue of infringement. We therefore interpret the district court's conclusions as determining that Amazon had demonstrated a substantial likelihood of establishing literal infringement of the enumerated claims.

* * *

E

After full review of the record before us, we conclude that under a proper claim interpretation, Amazon has made the showing that it is likely to succeed at trial on its infringement case. Given that we conclude that Amazon has demonstrated likely literal infringement of at least the four independent claims in the '411 patent, we need not consider infringement under the doctrine of equivalents. The question remaining, however, is whether the district court correctly determined that BN failed to mount a substantial challenge to the validity of the claims in the '411 patent.

VII

The district court considered, but ultimately rejected, the potentially invalidating impact of several prior art references cited by BN. Because the district court determined that BN likely infringed all of the asserted claims, it did not focus its analysis of the validity issue on any particular claim. Instead, in its validity analysis, the district court appears to have primarily directed its attention to determining whether the references cited by BN implemented the single action limitation.

* * *

In this case, we find that the district court committed clear error by misreading the factual content of the prior art references cited by BN and by failing to recognize that BN had raised a substantial question of invalidity of the asserted claims in view of these prior art references.

Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial. The test for invalidity at trial is by evidence that is clear and convincing. To succeed with a summary judgment motion of invalidity, for example, the movant must

demonstrate a lack of genuine dispute about material facts and show that the facts not in dispute are clear and convincing in demonstrating invalidity. In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself. That this is so is plain from our cases.

When moving for the extraordinary relief of a preliminary injunction, a patentee need not establish the validity of a patent beyond question. The patentee must, however, present a clear case supporting the validity of the patent in suit. Such a case might be supported, for example, by showing that the patent in suit had successfully withstood previous validity challenges in other proceedings. Further support for such a clear case might come from a long period of industry acquiescence in the patent's validity. Neither of those considerations benefit Amazon in this case, however, because the '411 patent has yet to be tested by trial, and it was issued only a few weeks before the start of this litigation.

In *Helifix*, we recently confronted the situation in which a district court had granted a motion of summary judgment of invalidity based on allegedly anticipatory prior art references, and shortly thereafter denied a motion for a preliminary injunction based on a validity challenge using the same prior art references. 208 F.3d at 1344-45. On appeal, the patentee sought reversal of the summary judgment and claimed entitlement to a preliminary injunction. We held that the summary judgment could not stand, because disputed issues of material fact on invalidity remained for resolution at trial. *Id.* at 208 F.3d 1352. Nonetheless, we expressly held that the quantum of evidence put forth — while falling short of demonstrating invalidity itself — was sufficient to prevent issuance of the preliminary injunction. *Id.* Particularly instructive for purposes of this case is the treatment of the anticipation issue in *Helifix*. A particular reference which did not on its face disclose all the limitations of the claim in suit was argued to be anticipatory, even though there was a conflict in the testimony as to whether the reference would have taught one of ordinary skill in the art the claim limitations not expressly stated on the face of the reference. Although insufficient to demonstrate invalidity for the purposes of the summary judgment motion, the reference *was* enough to prevent issuance of the preliminary injunction. *Id.* at 208 F.3d 1351-52.

The situation before us is similar. Here, we have several references that were urged upon the court as invalidating the asserted claims. The district court dismissed those references, for purposes of its invalidity analysis, because it did not perceive them to recite each and every limitation of the claims in suit. As we explain below in our review of the asserted prior art in this case, each of the asserted references clearly teaches key limitations of the claims of the patent in suit. BN argued to the district court that one of ordinary skill in the art could fill in the gaps in the asserted references, given the opportunity to do so at trial.

When the heft of the asserted prior art is assessed in light of the correct legal standards, we conclude that BN has mounted a serious challenge to the validity of Amazon's patent. We hasten to add, however, that this conclusion only undermines the prerequisite for entry of a preliminary injunction. Our decision today on the validity issue in no way resolves the ultimate question of

invalidity. That is a matter for resolution at trial. It remains to be learned whether there are other references that may be cited against the patent, and it surely remains to be learned whether any shortcomings in BN's initial preliminary validity challenge will be magnified or dissipated at trial. All we hold, in the meantime, is that BN cast enough doubt on the validity of the '411 patent to avoid a preliminary injunction, and that the validity issue should be resolved finally at trial.

* * *

Comments

1. ***The Federal Circuit's Influence on Irreparable Harm.*** A preliminary injunction has historically been extremely difficult to obtain, particularly in the alleged infringing party was financially solvent. But in 1983, the Federal Circuit dramatically altered the irreparable harm analysis, in turn making it easier to acquire a preliminary injunction. Once validity and continuing infringement are established, a presumption of irreparable harm is likely to follow. This change came soon after the Federal Circuit was created and is consistent with the court's early work in strengthening patent rights.
2. ***Balance of Hardships.*** The balancing test focuses on the hardships of the patentee and the defendant. The Federal Circuit stated the hardship on a manufacturer, who is preliminarily enjoined, can be devastating because he must withdraw his produce from the market before trial. On the other hand, the hardship on a patentee denied an injunction after showing a strong likelihood of success on validity and infringement can also be quite harmful as his patent rights are of limited term.
3. ***The Public Interest.*** This factor can be the most controversial and difficult to apply. It has particular relevance in the pharmaceutical industry. In *Sanofi-Synthelabo, Inc. v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006), for example, the court sided with the name-brand pharmaceutical company — Sanofi — in affirming the district court's grant of a preliminary injunction against a generic manufacturer. In particular, in the context of considering the public interest component, the generic manufacturer, Apotex, argued "that if the generic products were removed from the market, consumers would be inclined not to purchase their medication because of the accompanying price increase for the brand name drug, leading to possible deaths." In response, the Federal Circuit stated:

While Apotex raises legitimate concerns, the district court did not abuse its discretion in concluding that those concerns were outweighed by the public interests identified by Sanofi. We have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the "encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." The district court relied on the testimony of Dr. Hausman in finding that the average cost of developing a blockbuster drug is \$800 million. Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts. We therefore find that the court did not clearly err in concluding that

the significant “public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents” tips the scales in favor of Sanofi.

Id. at 1383-84.

2. Permanent Injunctions

EBAY INC. v. MERCEXCHANGE, L.L.C.

126 S. Ct. 1837 (2006)

Justice THOMAS delivered the opinion of the Court.

Ordinarily, a federal court considering whether to award permanent injunctive relief to a prevailing plaintiff applies the four-factor test historically employed by courts of equity. Petitioners eBay Inc. and Half.com, Inc., argue that this traditional test applies to disputes arising under the Patent Act. We agree and, accordingly, vacate the judgment of the Court of Appeals.

I

Petitioner eBay operates a popular Internet Web site that allows private sellers to list goods they wish to sell, either through an auction or at a fixed price. Petitioner Half.com, now a wholly owned subsidiary of eBay, operates a similar Web site. Respondent MercExchange, L.L.C., holds a number of patents, including a business method patent for an electronic market designed to facilitate the sale of goods between private individuals by establishing a central authority to promote trust among participants. See U.S. Patent No. 5,845,265. MercExchange sought to license its patent to eBay and Half.com, as it had previously done with other companies, but the parties failed to reach an agreement. MercExchange subsequently filed a patent infringement suit against eBay and Half.com in the United States District Court for the Eastern District of Virginia. A jury found that MercExchange’s patent was valid, that eBay and Half.com had infringed that patent, and that an award of damages was appropriate.

Following the jury verdict, the District Court denied MercExchange’s motion for permanent injunctive relief. 275 F. Supp. 2d 695 (2003). The Court of Appeals for the Federal Circuit reversed, applying its “general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.” 401 F.3d 1323, 1339 (2005). We granted certiorari to determine the appropriateness of this general rule.

II

According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. See, e.g., *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311-313, (1982); *Amoco Production Co. v. Gambell*, 480 U.S. 531, 542 (1987). The decision

to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion.

These familiar principles apply with equal force to disputes arising under the Patent Act. As this Court has long recognized, “a major departure from the long tradition of equity practice should not be lightly implied.” *Ibid.* Nothing in the Patent Act indicates that Congress intended such a departure. To the contrary, the Patent Act expressly provides that injunctions “may” issue “in accordance with the principles of equity.” 35 U.S.C. § 283.²

To be sure, the Patent Act also declares that “patents shall have the attributes of personal property,” § 261, including “the right to exclude others from making, using, offering for sale, or selling the invention,” § 154(a)(1). According to the Court of Appeals, this statutory right to exclude alone justifies its general rule in favor of permanent injunctive relief. But the creation of a right is distinct from the provision of remedies for violations of that right. Indeed, the Patent Act itself indicates that patents shall have the attributes of personal property “[s]ubject to the provisions of this title,” 35 U.S.C. § 261, including, presumably, the provision that injunctive relief “may” issue only “in accordance with the principles of equity,” § 283.

This approach is consistent with our treatment of injunctions under the Copyright Act. Like a patent owner, a copyright holder possesses “the right to exclude others from using his property.” *Fox Film Corp. v. Doyal*, 286 U.S. 123, 127 (1932); see also *id.*, at 127-128 (“A copyright, like a patent, is at once the equivalent given by the public for benefits bestowed by the genius and meditations and skill of individuals, and the incentive to further efforts for the same important objects”). Like the Patent Act, the Copyright Act provides that courts “may” grant injunctive relief “on such terms as it may deem reasonable to prevent or restrain infringement of a copyright.” 17 U.S.C. § 502(a). And as in our decision today, this Court has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a copyright has been infringed. See, e.g., *New York Times Co. v. Tasini*, 533 U.S. 483, 505 (2001) (citing *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 578 n.10 (1994)).

Neither the District Court nor the Court of Appeals below fairly applied these traditional equitable principles in deciding respondent’s motion for a permanent injunction. Although the District Court recited the traditional four-factor test, it appeared to adopt certain expansive principles suggesting that injunctive relief could not issue in a broad swath of cases. Most notably, it concluded that a “plaintiff’s willingness to license its patents” and “its lack of commercial activity in practicing the patents” would be sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue. But traditional equitable principles do not permit such broad classifications. For example, some patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves. Such patent holders may be able to satisfy the traditional four-factor test, and we see no basis for categorically

2. Section 283 provides that “[t]he several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.”

denying them the opportunity to do so. To the extent that the District Court adopted such a categorical rule, then, its analysis cannot be squared with the principles of equity adopted by Congress. The court's categorical rule is also in tension with *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 422-430 (1908), which rejected the contention that a court of equity has no jurisdiction to grant injunctive relief to a patent holder who has unreasonably declined to use the patent.

In reversing the District Court, the Court of Appeals departed in the opposite direction from the four-factor test. The court articulated a "general rule," unique to patent disputes, "that a permanent injunction will issue once infringement and validity have been adjudged." The court further indicated that injunctions should be denied only in the "unusual" case, under "exceptional circumstances" and "in rare instances . . . to protect the public interest." Just as the District Court erred in its categorical denial of injunctive relief, the Court of Appeals erred in its categorical grant of such relief. Cf. *Roche Products v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 865 (C.A. Fed. 1984) (recognizing the "considerable discretion" district courts have "in determining whether the facts of a situation require it to issue an injunction").

Because we conclude that neither court below correctly applied the traditional four-factor framework that governs the award of injunctive relief, we vacate the judgment of the Court of Appeals, so that the District Court may apply that framework in the first instance. In doing so, we take no position on whether permanent injunctive relief should or should not issue in this particular case, or indeed in any number of other disputes arising under the Patent Act. We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.

Accordingly, we vacate the judgment of the Court of Appeals, and remand for further proceedings consistent with this opinion.

Chief Justice ROBERTS, with whom Justice SCALIA and Justice GINSBURG join, concurring.

I agree with the Court's holding that "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards," and I join the opinion of the Court. That opinion rightly rests on the proposition that "a major departure from the long tradition of equity practice should not be lightly implied." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982).

From at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases. This "long tradition of equity practice" is not surprising, given the difficulty of protecting a right to *exclude* through monetary remedies that allow an infringer to *use* an invention against the patentee's wishes—a difficulty that often implicates the first two factors of the traditional four-factor test. This historical practice, as the Court holds, does not *entitle* a patentee to a permanent injunction or justify a *general rule* that such injunctions should issue. The Federal Circuit itself so recognized in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 865-867 (1984). At the same time, there is a difference between exercising

equitable discretion pursuant to the established four-factor test and writing on an entirely clean slate. “Discretion is not whim, and limiting discretion according to legal standards helps promote the basic principle of justice that like cases should be decided alike.” *Martin v. Franklin Capital Corp.*, 126 S. Ct. 704, 710 (2005). When it comes to discerning and applying those standards, in this area as others, “a page of history is worth a volume of logic.” *New York Trust Co. v. Eisner*, 256 U.S. 345, 349 (1921) (opinion for the Court by Holmes, J.).

Justice KENNEDY, with whom Justice STEVENS, Justice SOUTER, and Justice BREYER concurring.

The Court is correct, in my view, to hold that courts should apply the well-established, four-factor test — without resort to categorical rules — in deciding whether to grant injunctive relief in patent cases. The Chief Justice is also correct that history may be instructive in applying this test. The traditional practice of issuing injunctions against patent infringers, however, does not seem to rest on “the difficulty of protecting a right to *exclude* through monetary remedies that allow an infringer to *use* an invention against the patentee’s wishes.” (Roberts, C.J., concurring). Both the terms of the Patent Act and the traditional view of injunctive relief accept that the existence of a right to exclude does not dictate the remedy for a violation of that right. (opinion of the Court). To the extent earlier cases establish a pattern of granting an injunction against patent infringers almost as a matter of course, this pattern simply illustrates the result of the four-factor test in the contexts then prevalent. The lesson of the historical practice, therefore, is most helpful and instructive when the circumstances of a case bear substantial parallels to litigation the courts have confronted before.

In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases. An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees. See FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3, pp. 38-39 (Oct. 2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (as visited May 11, 2006, and available in Clerk of Court’s case file). For these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. See *ibid.* When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest. In addition injunctive relief may have different consequences for the burgeoning number of patents over business methods, which were not of much economic and legal significance in earlier times. The potential vagueness and suspect validity of some of these patents may affect the calculus under the four-factor test.

The equitable discretion over injunctions, granted by the Patent Act, is well suited to allow courts to adapt to the rapid technological and legal developments in the patent system. For these reasons it should be recognized that district courts must determine whether past practice fits the circumstances of the cases before them. With these observations, I join the opinion of the Court.

**COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH
ORGANISATION v. BUFFALO TECHNOLOGY INC.**

492 F. Supp. 2d 600 (June 15, 2007 E.D. Tex.)

MEMORANDUM OPINION AND ORDER

LEONARD DAVIS, District Judge.

Before the Court is Plaintiff Commonwealth Scientific and Industrial Research Organisation's ("CSIRO") Motion for Entry of Permanent Injunction. Having considered the relevant briefing, oral arguments, and the applicable law, the Court GRANTS CSIRO's Motion for Entry of Permanent Injunction.

BACKGROUND

CSIRO is the principal scientific research organization of the Australian Federal Government. Established in 1926, CSIRO conducts scientific research and applies the efforts of that research to benefit the public at large. CSIRO is similar to the United States' National Science Foundation and National Institute of Health. CSIRO has a broad charter to advance health, prosperity, and welfare by conducting strategic scientific research and applying the results of that research to benefit Australia and people everywhere. CSIRO operates its own laboratories and is active in the areas of health, agriculture, energy, information technology, minerals, manufacturing, marine and terrestrial environments, and natural resources. One of CSIRO's broad goals is to develop technology that can be used to create start-up companies and/or be licensed to firms to earn commercial royalties to fund other research.

In the very late 1980's and early 1990's groups throughout the world were trying to design an indoor wireless network. However, the indoor radio environment presented problems with signal interference because radio waves can be reflected by some materials such as walls, furniture, and other indoor items causing them to arrive at the receiver from different paths and at different times. This is known as the "multipath" problem. Studies revealed that minor changes in a room resulted in major changes in the propagation characteristics. Companies all over the world made efforts to solve the multipath problem.

In February 1992, CSIRO engineers identified the key elements to the solution of the multipath problem. Avoiding the multipath problem requires a lengthening of signal duration, which negatively impacts data rate. To overcome the loss of data rate, the use of orthogonal frequency division multiplexing, which permits data to be sent on multiple channels simultaneously, was incorporated. The data is broken into subparts and each subpart is simultaneously transmitted on a different carrier frequency. Because there is simultaneous transmission of all the signal parts, the data transmission rate is higher than with other approaches. Techniques such as error correction and interleaving were used to deliver high reliability in the data transmission.

On November 22, 1992, CSIRO filed a patent application with the Australian Patent Office. On November 23, 1993, CSIRO filed an application for a United States patent based on the same disclosure. U.S. Patent No. 5,487,069 ("the '069 patent") issued on January 23, 1996. CSIRO has also obtained patents in Japan and Europe for its Wireless Local Area Network ("WLAN") invention.

CSIRO's intent from the beginning was to derive revenue from its invention through licensing the '069 patent. In 1997, CSIRO and Macquarie University formed Radiata Communications Pty Ltd., an Australian company, to commercialize the '069 patent. CSIRO licensed the '069 patent to Radiata, and in 2001 Cisco Systems, Inc. acquired Radiata for \$295 million in stock and began paying royalties to CSIRO.

In 1998, the Institute of Electrical and Electronics Engineers ("IEEE") contacted CSIRO to request assurance that CSIRO would license its '069 patent to companies wanting to implement the IEEE's 802.11a standard on reasonable and non-discriminatory ("RAND") terms once the IEEE approved the 802.11 standard, which pertains to WLANs. CSIRO agreed. In 1999, the IEEE ratified the 802.11a standard, which embodies the core technology invention by CSIRO. The IEEE also ratified the 802.11b standard, which differs from CSIRO's invention, and was initially adopted by more companies. In 2003, the IEEE ratified the 802.11g standard, which also embodies CSIRO's invention. In 2003, CSIRO contacted companies who practiced the '069 patent and began license agreement discussions. None of the potential licensees accepted CSIRO's license agreement offer.

On February 2, 2005, CSIRO brought suit against Buffalo Technology, Inc., an American corporation, and Buffalo, Inc., a Japanese corporation, (collectively "Buffalo") alleging infringement of the '069 patent. Buffalo competes in the production and sale of WLAN products that are compliant with the IEEE 802.11a and 802.11g standards. The sale of WLAN products comprise approximately eleven percent of Buffalo Technology's business. In addition to its wireless products, Buffalo sells memory products and network accessories. Buffalo's family of products is sold to distributors and retail outlet stores. Since Buffalo utilizes the IEEE 802.11a and g standards, this suit would serve as a test case to determine whether WLANs compliant with IEEE 802.11a and g standards infringe the '069 patent and to determine the validity of the '069 patent in light of the prior art.

The Court held a *Markman* hearing on February 22, 2006 and issued an opinion construing the claims of the '069 patent on May 8, 2006. At the pretrial hearing on July 20, 2006, CSIRO and Buffalo agreed to submit the case on cross motions for summary judgment on infringement, invalidity over prior art, and invalidity for lack of sufficient written description in lieu of a jury trial. After hearing oral arguments on August 15 and considering all of the summary judgment evidence that was submitted, the Court granted CSIRO's motions for summary judgment of validity and infringement and denied Buffalo's cross motions on November 13, 2006. Although the issue of CSIRO's damages has not been determined, the parties asked the Court to rule on CSIRO's motion for permanent injunction. Accordingly, CSIRO's motion for permanent injunction is now before the Court.

APPLICABLE LAW

When considering whether to award permanent injunctive relief to a prevailing plaintiff in a patent infringement dispute, courts should apply the traditional four-factor test used by courts of equity. *eBay, Inc. v. MercExchange, LLC*, 126 S. Ct. 1837, 1839 (2006). The prevailing plaintiff must demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury;

(3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.” *Id.* The Supreme Court held “the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.” *Id.* at 1841.

ANALYSIS

Irreparable Harm Suffered by CSIRO

CSIRO argues its licensing and research and development programs will be irreparably harmed if a permanent injunction is not granted. CSIRO further argues if it cannot obtain injunctive relief against Buffalo, others will be encouraged to infringe the '069 patent and risk litigation rather than enter into a license agreement. CSIRO argues a patent holder who does not practice its invention may establish irreparable harm “by showing that an existing infringement precludes his ability to license his patent. . . .” *See Roper Corp. v. Litton Sys., Inc.*, 757 F.2d 1266, 1273 (Fed. Cir. 1985); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 73 F. Supp. 2d 1228, 1246 (W.D. Wa. 1999). CSIRO contends a significant factor for its inability to license the '069 patent arises from potential licensees refusing to take a license if their competitors do not also take a license. A licensee’s own licensing payments would put itself at a competitive disadvantage against infringers who are willing to risk detection and enforcement. Once the litigation against Buffalo commenced, there was little chance any company would take a license until Buffalo’s defenses had been shown to be without merit. CSIRO further contends there remains little chance that others will take a license after this Court’s summary judgment ruling since Buffalo announced its plan to appeal this Court’s ruling.

Buffalo argues that since CSIRO and Buffalo are not competitors Buffalo does not irreparably harm CSIRO by depriving it of any profits from the sale of products, nor does Buffalo irreparably harm CSIRO by depriving it of any market share or brand name recognition. Buffalo contends that since *eBay* district courts have typically granted injunctive relief in favor of competitors but denied injunctive relief to non-competing licensors. *See Tivo, Inc. v. Echostar Commc’ns Corp.*, 446 F. Supp. 2d 664, 669 (E.D. Tex. 2006) (Folsom, J.) (highlighting the fact that “Defendants compete directly with Plaintiff . . .” in granting the permanent injunction); *Paice LLC v. Toyota Motor Corp.*, No. 2:04-CV-211-DF, 2006 WL 2385139, *4 (E.D. Tex. Aug. 16, 2006) (Folsom, J.) (noting that “because Plaintiff does not compete for market share . . . concerns regarding loss of brand name recognition and market share similarly are not implicated”); *Visto Corp. v. Seven Networks, Inc.*, No. 2:03-CV-333-TJW, 2006 WL 3741891, *4 (E.D. Tex. Dec. 19, 2006) (Ward, J.) (noting that “[the parties] are not direct competitors, and this fact weighs heavily in the court’s analysis”).

However, in *eBay* the Supreme Court warned against creating broad classifications:

[S]ome patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their work to market themselves. Such

patent holders may be able to satisfy the traditional four-factor test, and we see no basis for categorically denying them the opportunity to do so.

126 S. Ct. at 1840. The majority opinion in *eBay* rejected the conclusion that “a ‘plaintiff’s willingness to license its patents’ and ‘its lack of commercial activity in practicing the patents’ would be sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue.” *Id.*

CSIRO is a research institution and relies heavily on the ability to license its intellectual property to finance its research and development. The revenue from licensing its intellectual property is used to fund further research and development for frontier projects. Every year, CSIRO identifies the portfolio of research and development projects that it will fund, and CSIRO actively maintains a list of frontier project opportunities for investment when additional funding becomes available. When extra funding becomes available, existing frontier projects are expanded to create greater benefits. Frontier projects could be initiated or developed sooner with additional licensing revenue. CSIRO provided many examples in areas of important research and development activities where increased funding would permit its research and development work to be expanded and produce beneficial results earlier including addressing the increasing rate of obesity and the consequential increase of Type 2 diabetes, developing biomaterials that can be used to aid recovery from traumatic damage to the body, and examining the impact of climate change and mitigating its causes.

CSIRO has shown that its harm is not merely financial. While CSIRO does not compete with Buffalo for marketshare, CSIRO does compete internationally with other research groups—such as universities—for resources, ideas, and the best scientific minds to transform those ideas into realities. CSIRO’s reputation is an important element in recruiting the top scientists in the world. Having its patents challenged via the courts not only impugns CSIRO’s reputation as a leading scientific research entity but forces it to divert millions of dollars away from research and into litigation costs. Delays in funding result in lost research capabilities, lost opportunities to develop additional research capabilities, lost opportunities to accelerate existing projects or begin new projects. Once those opportunities have passed, they are often lost for good, as another entity takes advantage of the opportunity. Delays in research are likely to result in important knowledge not being developed at all or CSIRO being pushed out of valuable fields as other research groups achieve critical intellectual property positions. Thus, the harm of lost opportunities is irreparable. They cannot be regained with future money because the opportunity that was lost already belongs to someone else.

Buffalo argues this harm is a past harm, for which injunctive relief is inappropriate. Buffalo also argues that denying a permanent injunction and forcing CSIRO to take a license would give CSIRO the licensing revenue it desires. While this is certainly a harm by Buffalo that CSIRO suffered in the past, it is also harm by others CSIRO will suffer in the future, as discussed in the next section. Similarly, for the reasons discussed in the next section, forcing CSIRO to extend a license to Buffalo will not cure this harm. The irreparable harm factor favors a permanent injunction.

Adequacy of Remedies Available at Law

In addition to harming its research and development programs, CSIRO argues that if the Court does not enter a permanent injunction, the Court will force a compulsory license upon CSIRO. A compulsory license would not contain the negotiated business terms typically used by patent holders to control their inventions. CSIRO contends it has a right to control its licensing program and to choose to whom to license and on what terms. Further, the price of a compulsory license established through a trial on damages would be inadequate since CSIRO's past damages are limited compared to its ongoing damages.

Buffalo argues that a compulsory license would force Buffalo to pay CSIRO licensing royalties—the lack of which is CSIRO's alleged irreparable harm. Since CSIRO says its harm is in not having past royalty payments to fund its projects, Buffalo contends royalty payments today would be an entirely adequate remedy.

In *eBay*, the Supreme Court indicated that the right to exclude alone is not sufficient to support a finding of injunctive relief and that such relief “‘may’ issue only ‘in accordance with the principles of equity’” under § 283 of the patent act. *See eBay*, 126 S. Ct. at 1840. Accordingly, a violation of the right to exclude does not inevitably lead to the conclusion that a patent holder cannot be adequately compensated by remedies at law such as monetary damages without first applying the principles of equity.

The violation of a patent owner's right to exclude can present a situation where monetary damages cannot adequately compensate the patent holder for that injury. For example, when an infringer saturates the market for a patented invention with an infringing product or damages the patent holder's good will or brand name recognition by selling infringing products, that infringer violates the patent holder's exclusionary right in a manner that cannot be compensated through monetary damages. This is because it is impossible to determine the portions of the market the patent owner would have secured but for the infringer's actions or how much damage was done to the patent owner's brand recognition or good will due to the infringement. Although CSIRO has not suffered these particular types of harms, CSIRO's harm is no less important than other recognized forms of harm a competitor might suffer to its brand name or sales position in the market. Its reputation as a research institution has been impugned just as another company's brand recognition or good will may be damaged.

In his concurrence, Justice Kennedy instructed courts to be cognizant of the nature of the patent being enforced and the economic function of the patent holder when applying the equitable factors. *eBay*, 126 S. Ct. at 1842 (Kennedy, J., concurring) (“When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.”); *see also* *z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437, 440-41 (E.D. Tex. 2006) (Davis, J.) (finding the infringing technology was “a small component of [Microsoft's] software” and the infringement did not hinder or exclude z4's sales or licensing of its product). The right to exclude becomes more urgent when the product is the invention.

This case is not the situation that concerned Justice Kennedy; Buffalo's infringing use of CSIRO's technology is not limited to a minor component of the technology. The '069 patent is the core technology embodied in the IEEE's 802.11a and 802.11g standards. Buffalo's products are designed to provide the wireless functionality of the IEEE's 802.11a and 802.11g standards. Since Buffalo's infringement relates to the essence of the technology and is not a "small component" of Buffalo's infringing products, monetary damages are less adequate in compensating CSIRO for Buffalo's future infringement.

A compulsory license will not adequately compensate CSIRO for Buffalo's continued intentional infringement. The royalty payment would be extrapolated from a determination of Buffalo's past sales, which may not adequately reflect the worth of the patent today to Buffalo. Further, such a royalty payment does not necessarily include other non-monetary license terms that are as important as monetary terms to a licensor such as CSIRO. Monetary damages are not adequate to compensate CSIRO for its damages, which are not merely financial.

The Balance of Hardships

If the Court does not issue the injunction, CSIRO will be forced to accept Buffalo as a compulsory licensee. The Court has already discussed how a compulsory license would harm CSIRO. Buffalo argues the issuance of an injunction will force Buffalo out of the WLAN business in the United States.

The hardship to Buffalo of permanently enjoining its infringing conduct is limited to the injury ordinarily expected when an injunction is imposed. Mere hardship incurred in the process of ceasing operations is not sufficient. *See Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986) ("One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."). Buffalo's own damages expert claims "this product, to date, has not proven itself a commercial success in the United States for Buffalo." Since wireless products make up only eleven percent of Buffalo Technology's business, Buffalo's hardship if it is precluded from making future wireless sales in the United States is far from catastrophic. Further, no considerable hardship will be imposed on distributors and resellers by an injunction against Buffalo because those distributors and resellers may continue to sell non-infringing Buffalo products and other competing WLAN products.

The harm Buffalo faces by an injunction is purely monetary, whereas the harm CSIRO faces if no injunction issues has far reaching effects. CSIRO will not only be injured financially, but that financial injury will directly and negatively impact CSIRO's research and development efforts and its ability to bring new technologies into fruition. The balance of hardships favors CSIRO's motion for permanent injunction because the harm that continued infringement would likely cause CSIRO's research and development projects outweighs the harm that an injunction would cause Buffalo in being excluded from competing in the WLAN market.

The Public Interest

CSIRO argues that the public has an interest in upholding patent rights and this is not one of the limited situations where an injunction would be

contrary to the public's interest. Buffalo contends CSIRO has not shown how the public interest would not be served by the imposition of a compulsory license.

The public has an interest in a strong patent system. In general, public policy favors the enforcement of patent rights. See *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006). The public maintains an interest in protecting the rights of patent holders as well as enforcing adequate remedies for patent infringement. Permanent injunctions serve that interest. In order to enforce a patentee's fundamental property right, courts have consistently allowed injunctive relief to patent owners whose patents have been infringed. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246-47 (Fed. Cir. 1989) ("Infringement having been established, it is contrary to the laws of property, of which the patent law partakes, to deny the patentee's right to exclude others from use of his property.").

However, there are rare and limited circumstances in which an injunction would be contrary to a significant public interest such as health and safety concerns. See, e.g., *Hybritech, Inc. v. Abbott Lab.*, 4 U.S.P.Q.2d 1001 (C.D. Cal. 1987) (public interest required that injunction not stop supply of medical test kits that the patentee itself was not marketing), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988); *City of Milwaukee v. Activated Sludge, Inc.*, 21 U.S.P.Q. 69 (7th Cir. 1934) (injunction refused against city operation of sewage disposal plant because of public health danger); see also *z4*, 434 F. Supp. 2d at 444 (finding the possible harm to the public slightly weighed against an injunction of Microsoft's products). No such interests are implicated here since Buffalo's WLAN products are not essential for the public health or public welfare. Buffalo has not shown how the public will be deprived of any benefit if Buffalo's products are enjoined. The public interest would not be disserved by a permanent injunction because WLAN products are obtainable from multiple sources other than Buffalo.

Research institutions, such as CSIRO, make substantial scientific advances. The work of research institutions is often at the forefront of scientific awareness. Although their work may not always have immediate applications, the work of research institutions has produced enormous benefits to society in the form of new products and processes. Because the work of research institutions such as CSIRO is often fundamental to scientific advancement, it merits strong patent protection. Furthermore, the public interest is advanced by encouraging investment by research organizations into future technologies and serves to promote the progress of science and the useful arts. Thus, the public interest factor favors CSIRO's motion for permanent injunction.

CONCLUSION

The balance of equities viewed through the facts of this case warrants injunctive relief. CSIRO has demonstrated it will suffer irreparable harm in the absence of a permanent injunction, harm that cannot be remedied adequately through the recovery of monetary damages. The balance of the hardships weighs in favor of CSIRO. The public has an interest in maintaining a strong patent system, and the public would be harmed more by denying an injunction than granting one. Thus, the public interest weighs in favor of CSIRO. Accordingly, a permanent injunction should issue under the traditional four-factor test recited in *eBay*, and CSIRO's motion is GRANTED. Therefore, the

Court does not reach whether the United States-Australia Free Trade Agreement Implementation Act requires an injunction.

Comments

1. ***A Fractured Supreme Court.*** There were three separate opinions in *eBay*. In the majority, the Court retreated from what was considered “a given” by patent litigators, namely, an injunction would issue upon a finding of infringement (and, of course, that the patent was not invalid). This understanding was reflected in Federal Circuit precedent, and is consistent with treating a patent as a form of property. See *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1246-47 (Fed. Cir. 1989) (“Infringement having been established, it is contrary to the laws of property, of which the patent law partakes, to deny the patentee’s right to exclude others from use of his property. . . . It is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it.”). See also 35 U.S.C. § 261 (stating patents “have the attributes of personal property”).

But in *eBay*, the “Supreme Court has since struck down that general rule . . . making clear that the traditional four-factor test for injunctions applies to patent cases.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 811 (Fed. Cir. 2007). In *eBay*, the court noted that § 261 requires courts to look to other parts of Title 35. Indeed, § 261 states “[s]ubject to the provisions of this title, patents shall have the attributes of personal property.” (Emphasis added). The Court then turned to the permissive statutory language in § 283—An injunction “may” issue only “in accordance with the principles of equity.”

The Court also rejected the district court’s categorical approach that injunctions should be unavailable for patentees who do not commercialize their inventions. Justice Thomas cited university patentees and self-made inventors as entities that “might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves.” This language is important because the Court acknowledged there are entities that do not have the capacity to self-commercialize their inventions, and the patent system should not categorically treat them differently as a result. Thus, the Court implicitly distinguished between, on the one hand, “university patentees and self-made inventors” and, on the other hand, so-called patent trolls who, in the words of Justice Kennedy, “use patents not as a basis for producing and selling goods but, instead, . . . [as a] bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent.”

The two concurrences are interesting because Chief Justice Roberts looks to the past, and Justice Kennedy looks to the future. Chief Justice Roberts thinks district court judges should be informed by history. He looked to the 19th century and found that courts “granted injunctive relief upon a finding of infringement in the vast majority of patent cases.” He found this practice unsurprising, given the “difficulty of protecting a right to *exclude* through monetary remedies that allow an infringer to *use* an invention against the patentee’s wishes.” (Emphasis in original). Justice

Kennedy, while recognizing the importance of history, noted that in contemporary patent cases, “the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases.” He also expressed his concern over so-called “patent trolls” (although he did not use this term), which are entities “that use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.” For them, the injunction is a powerful remedy that can be used as a “bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent.” (This dynamic received a great deal of press during the RIM/NTP litigation over the Blackberry[®] device.) In addition, Justice Kennedy noted that injunctions may have “different consequences” for business method patents, which are of “suspect validity.”

2. ***The Affect on Innovation and Patent Litigation.*** Is giving the district court judge more discretion regarding equitable relief consistent with the right to exclude; will it lead to greater uncertainty, adversely affect innovation incentives, and diminish the likelihood of settlement? The pharmaceutical and biotechnology industries certainly think so. See Amicus Briefs of PhRMA and BIO in the *eBay* case.

But the software and electronics industries supported *eBay*. See Amicus Briefs of Intel, Microsoft, Oracle, and Micron. Justice Kennedy gave voice to the concerns of these industries in writing, “[w]hen the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.” (Not surprisingly, RIM also filed an amicus brief supporting *eBay*.) The concern that an injunction would cause significant economic hardship and disruption can be traced to the mid-19th century. In *Parker v. Brant*, 18 F. Cas. 1117 (1850), the court stated, “we feel a reluctance to stop two hundred mills . . . without giving the defendants a chance of making a settlement or compromise.”

Professor Joseph Miller’s blog, *The Fire of Genius*, has a “running list of the patent, copyright, and trademark cases in which courts have applied the *eBay* four-factor framework to grant or deny injunctive relief.” See <http://www.thefireofgenius.com/injunctions>.

3. ***Direct Competition, “Small Component” Patentees, and the Injunction.*** As Buffalo argued in *Commonwealth Scientific*, district courts are much more likely to issue a permanent injunction if the patentee and infringer are competitors. See *Tivo, Inc. v. Echostar Commc’ns Corp.*, 446 F. Supp. 2d 664, 669 (E.D. Tex. 2006); *Black & Decker Inc. v. Robert Bosch Tool Corp.*, Slip Copy, 2006 WL 3446144 (N.D. Ill.); *O2 Micro International, Ltd. v. Beyond Innovation Technology Co.*, Slip Copy, 2007 WL 869576 *2 (E.D. Tex.) (stating “O2 Micro has demonstrated irreparable injury. O2 Micro competes directly with BiTEK, and this fact weighs heavily in the Court’s analysis. This Court has recognized the high value of intellectual property when it is asserted against a direct competitor in the plaintiff’s market”). Some courts, in the face of a “loss of market share” argument by a patentee, require the patentee to show “specific sales or market data to assist the court” and identify “precisely what market share, revenues, and customers”

the patentee has lost to the infringer. *Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440, 444 (D. Del. 2007).

The patent holding company (oftentimes referred to disparagingly as a “patent troll”) whose patent forms a “small component” of the overall product at issue, has garnered less sympathy from district courts. (The holding company is structured to license its patent rights rather than manufacture or produce the patented product.) This should not be surprising given Justice Kennedy’s concurrence in *eBay*:

In cases now arising trial courts should bear in mind that in many instances the nature of the patent being enforced and the economic function of the patent holder present considerations quite unlike earlier cases. An industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees . . . and [f]or these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent. When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest.

126 S. Ct. at 1842. In *z4 Technologies, Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437 (E.D. Tex. 2006), the court denied injunctive relief even though Microsoft was found to willfully infringe. The court relied heavily on Justice Kennedy’s concurrence, stating the patentee’s invention “is a very small component of the Microsoft Windows and Office software products that the jury found to infringe z4’s patents. The infringing product activation component of the software is in no way related to the core functionality for which the software is purchased by consumers. Accordingly, Justice Kennedy’s comments support the conclusion that monetary damages would be sufficient to compensate z4 for any future infringement by Microsoft.” *Id.* at 441. See also *Paice LLC v. Toyota Motor Corp.*, 2006 WL 2385139 (E.D. Tex.).

4. ***The Public Interest and Irreparable Harm.*** District courts have — post-*eBay* — expressed the public interest consideration largely in favor of patentees and the patentee’s interest in protecting his patent rights. For instance, the court in *O2 Micro International, Ltd. v. Beyond Innovation Technology Co.*, Slip Copy, 2007 WL 869576 *3 (E.D. Tex.), the court stated “the public interest would be served by issuing an injunction to protect the patent rights at issue.” The public interest factor was at issue in *Sanofi-Synthelabo, Inc. v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006), discussed after the *Amazon.com* case above. Recall, the court sided with the name-brand pharmaceutical company — Sanofi — in affirming the district court’s grant of a preliminary injunction against a generic manufacturer. The Federal Circuit stated:

We have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the “encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.” The district court relied on the testimony of Dr. Hausman in finding that the average cost of developing a blockbuster drug is \$800 million.

Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts. We therefore find that the court did not clearly err in concluding that the significant “public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents” tips the scales in favor of Sanofi.

Id. at 1383-84. Does this imply that industries that do not have significant development cost will have greater difficulty obtaining injunctive relief? In *Commonwealth Scientific*, the district court granted CSIRO’s motion for a permanent injunction, despite the fact that Buffalo and CSIRO were not competitors. For the court, “[r]esearch institutions, such as CSIRO, make substantial scientific advances,” and “[a]lthough their work may not always have immediate applications, the work of research institutions has produced enormous benefits to society in the form of new products and processes.” In short, “the public interest is advanced by encouraging investment by research organizations into future technologies and serves to promote the progress of science and the useful arts.”

Unlike the situation in *Commonwealth Scientific*, in *Praxair, Inc. v. ATMI, Inc.*, 479 F. Supp. 2d 440 (D. Del. 2007), the patentee (Praxair) and the infringer (ATMI) were direct competitors, yet the court denied Praxair’s motion for a permanent injunction because Praxair did not present sufficient evidence of irreparable harm and inadequacy of money damages:

Praxair’s Uptime[™] cylinder is in direct and head-to-head competition with ATMI’s VAC[®] cylinder, as Uptime[™] and VAC[®] are the only two mechanical-based systems for the controlled delivery of industrial gases on the market. VAC[®], therefore, is taking sales from Uptime[™], an “important growth product” for Praxair, and (according to Praxair) continues to erode the exclusivity to which Praxair is entitled through the ownership of its patents. This “stolen” market share “work[s] a substantial and unjustifiable hardship on Praxair,” which Praxair asserts cannot be remedied with money damages alone. . . . Praxair asserts that the public interest is generally served by the enforcement of patent rights. ATMI has presented evidence that an injunction would force its customers, semiconductor manufacturers running billion-dollar fabrication plants, to incur significant costs by shutting down operations to qualify an alternative gas source or to switch to alternate cylinders. Praxair has presented evidence that manufacturers could switch to other qualified non-infringing gas delivery sources during routine maintenance.

Under *eBay*, a plaintiff must prove that it is entitled to its statutory right to exclude by demonstrating, *inter alia*, irreparable injury and the inadequacy of legal remedies. Though the quantum of evidence required is relatively unclear, the court finds that Praxair has not met its burden under *eBay* to put forward sufficient proof vis-à-vis the broad scope of the relief requested. Praxair generally argues that VAC[®]’s presence in the market will cause Praxair to “likely lose additional market share, profits, and goodwill,” without further detail. Praxair has not provided or described any specific sales or market data to assist the court, nor has it identified precisely what market share, revenues, and customers Praxair has lost to ATMI.

While money damages are generally considered inadequate to compensate for the violation of a patentee’s right to exclude, Praxair nonetheless had a burden to iterate specific reasons why ATMI’s infringement can not be compensated for with a money award. *TiVo Inc. v. EchoStar Communications*

Corp., 446 F. Supp. 2d 664, 669-70 (E.D. Tex. 2006) (granting permanent injunction where plaintiff was “a relatively new company with only one primary product,” and the parties agreed that customers tend to remain loyal to the company from which they obtained their first DVR recorder, “shaping the market to [p]laintiff’s disadvantage and result[ing] in long-term customer loss”). Praxair has not explained why it may have “difficulties calculating damages going forward,” nor how money damages could not adequately compensate for “lost market share” or any “lost research opportunities.” Both parties cite to evidence demonstrating that the VAC[®]/UpTime[™] sales are not critical to either party’s overall corporate success. Praxair’s desire to become a monopoly supplier in its product’s market is hardly unique, and is not conclusive evidence of any factor.

Id. at 442-44. In *Commonwealth Scientific* the court seemed to be influenced by the fact that CSIRO was a research institution that “relies heavily on the ability to license its intellectual property to finance its research and development” and uses its licensing “to fund further research and development for frontier projects.”

5. ***The Comparison to Copyright Law.*** Justice Thomas looked to copyright law to support a more discretionary role for district court judges in deciding whether to issue an injunction. He cited *Tasini* and *Campbell*, which are cited regularly in academic circles for the proposition that injunctive relief in copyright cases need not be automatic. But in practice the presumption in favor of injunctions in copyright cases seems to be even stronger than it is in patent cases.

POLICY PERSPECTIVE

Property Rules, Liability Rules, and Patent Litigation

A patent is a personal property right that provides its owner with a right to exclude others. 35 U.S.C. §§ 154, 261. Thus, a patent right fits comfortably within a property-rights regime, for which the classic remedy is an injunction. But by giving judges more discretion, the Court opens the door for a liability rule approach whereby infringers infringe now and pay later. In their seminal article, Guido Calabresi and Douglas Melamed argued that when transaction costs are high and valuation is straightforward, a liability rule governs. In contrast, a property rule applies where transaction costs are low (*e.g.*, prospect of a holdout is low) and valuation is difficult for the court. *See* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1106-1110 (1972). *See also* Keith N. Hylton, *Property Rules and Liability Rules, Once Again*, 2 REV. L. & ECON. 137 (2006) (reexamining the property/liability rule question in the light of bargaining theory literature). Was Justice Kennedy alluding to high transaction costs and, therefore, sympathetic to a liability rule approach when he wrote “[a]n industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees” and “[f]or these firms, an injunction, and the potentially serious sanctions arising from its violation, can be employed

as a bargaining tool to charge exorbitant fees to companies that seek to buy licenses to practice the patent.” Are these firms to be treated differently than university patentees and self-made inventors, who, as noted by the majority, frequently do not have the capability to commercialize their inventions on their own?

There are shortcomings with a liability rule. Perhaps the most significant concern is that the market pricing mechanism is replaced by what the court thinks the proper price should be. Thus, the risk of under compensation is significant for no other reason than the state simply is not as familiar with the asset as its owner and the market. *See* Robert P. Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 81 (1994) (stating “a property rule makes sense for patents because . . . a court setting the terms of the exchange would have a difficult time doing so quickly and cheaply, given the specialized nature of the assets and the varied and complex business environments in which the assets are deployed”). For a good discussion of the respective roles of property rules and liability rules in a technological context, see Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information*, 85 TEX. L. REV. 783 (2007).

C. WILLFUL INFRINGEMENT AND ENHANCED DAMAGES

A finding of willful infringement allows for the assessment of treble damages and the awarding of attorney fees to the prevailing party. An alleged infringer may usually preclude a finding of willfulness if he obtained and properly relied on a competent opinion of counsel (the so-called “non-infringement letter”). But, as the *Knorr-Bremse* case holds, failure to obtain a letter will not necessarily lead to an adverse inference of willfulness. And, a few years after *Knorr*, the court, in *In re Seagate Technologies*, raised the standard for a finding of willfulness and, importantly, eliminated the affirmative duty of care that typically accompanied actual notice of the alleged infringement. Both *Knorr* and *Seagate* are en banc opinions.

KNORR-BREMSE SYSTEME v. DANA CORP.

383 F.3d 1337 (Fed. Cir. 2004) (en banc)

NEWMAN, Circuit Judge.

Knorr-Bremse Systeme is the owner of United States Patent No. 5,927,445 (the ‘445 patent) entitled “Disk Brake For Vehicles Having Insertable Actuator,” is sued on July 27, 1999. At trial to the United States District Court for the Eastern District of Virginia, the appellants Dana Corporation, Haldex Brake Products Corporation, and Haldex Brake Products AB were found liable for infringement and willful infringement. No damages were awarded, for there were no sales of the infringing brakes. Based on the finding of willful infringement the court awarded partial attorney fees under 35 U.S.C. § 285.

The appellants seek reversal of the finding of willful infringement, arguing that an adverse inference should not have been drawn from the withholding by Haldex of an opinion of counsel concerning the patent issues, and from the failure of Dana to obtain its own opinion of counsel. Applying our precedent, the district court inferred that the opinion of counsel withheld by Haldex was unfavorable to the defendants. After argument of the appeal we took this case en banc in order to reconsider our precedent with respect to these aspects.

We now hold that no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel. Precedent to the contrary is overruled. We therefore vacate the judgment of willful infringement and remand for re-determination, on consideration of the totality of the circumstances but without the evidentiary contribution or presumptive weight of an adverse inference that any opinion of counsel was or would have been unfavorable.

BACKGROUND

Knorr-Bremse, a German corporation, manufactures air disk brakes for use in heavy commercial vehicles, primarily Class 6-8 trucks known as eighteen wheelers, semis, or tractor-trailers. Knorr-Bremse states that air disk brake technology is superior to the previously dominant technology of hydraulically or pneumatically actuated drum brakes, and that air disk brakes have widely supplanted drum brakes for trucks in the European market.

Dana, an American corporation, and the Swedish company Haldex Brake Products AB and its United States affiliate, agreed to collaborate to sell in the United States an air disk brake manufactured by Haldex in Sweden. The appellants imported into the United States about 100 units of a Haldex brake designated the Mark II model. Between 1997 and 1999 the Mark II brake was installed in approximately eighteen trucks of Dana and various potential customers. The trucks were used in transport, and brake performance records were required to be kept and provided to Dana. Dana and Haldex advertised these brakes at trade shows and in industry media in the United States.

Knorr-Bremse in December 1998 orally notified Dana of patent disputes with Haldex in Europe involving the Mark II brake, and told the appellants that patent applications were pending in the United States. On August 31, 1999 Knorr-Bremse notified Dana in writing of infringement litigation against Haldex in Europe, and that Knorr-Bremse's United States '445 patent had issued on July 27, 1999. Knorr-Bremse filed this infringement suit on May 15, 2000. In September 2000 Haldex presented to the district court a modified brake design designated the Mark III, and moved for a summary declaration of non-infringement by the Mark III brake. Knorr-Bremse in turn moved for summary judgment of literal infringement by the Mark II brake, and infringement by the Mark III either literally or under the doctrine of equivalents. After a hearing in November 2000 the district court granted Knorr-Bremse's motion for summary judgment of literal infringement by the Mark II brake, and set for trial the issues with respect to the Mark III. Before and after the judgment of infringement by the Mark II, Dana and others continued to operate trucks in the United States containing the Mark II brake. Following a bench trial in January 2001, the district court found literal infringement by the Mark III brake.

On the issue of willful infringement, Haldex told the court that it had consulted European and United States counsel concerning Knorr-Bremse's patents, but declined to produce any legal opinion or to disclose the advice received, asserting the attorney-client privilege. Dana stated that it did not itself consult counsel, but relied on Haldex. Applying Federal Circuit precedent, the district court found: "It is reasonable to conclude that such opinions were unfavorable." The court discussed the evidence for and against willful infringement and concluded that "the totality of the circumstances compels the conclusion that defendants' use of the Mark II air disk brake, and indeed Dana's continued use of the Mark II air disk brake on various of its vehicles [after the judgment of infringement] amounts to willful infringement of the '445 patent." Based on the finding of willful infringement the court found that the case was "exceptional" under 35 U.S.C. § 285, and awarded Knorr-Bremse its attorney fees for the portion of the litigation that related to the Mark II brake, but not the Mark III.

The appellants appeal only the issue of willfulness of the infringement and the ensuing award of attorney fees.

I

Willful Infringement

In discussing "willful" behavior and its consequences, the Supreme Court has observed that "[t]he word 'willful' is widely used in the law, and, although it has not by any means been given a perfectly consistent interpretation, it is generally understood to refer to conduct that is not merely negligent," *McLaughlin v. Richland Shoe Co.*, 486 U.S. 128, 133 (1988), the Court citing conventional definitions such as "voluntary," "deliberate," and "intentional." *Id.* The concept of "willful infringement" is not simply a conduit for enhancement of damages; it is a statement that patent infringement, like other civil wrongs, is disfavored, and intentional disregard of legal rights warrants deterrence. Remedy for willful infringement is founded on 35 U.S.C. § 284 ("the court may increase the damages up to three times the amount found or assessed") and 35 U.S.C. § 285 ("the court in exceptional cases may award reasonable attorney fees to the prevailing party").

Determination of willfulness is made on consideration of the totality of the circumstances, and may include contributions of several factors, as compiled, *e.g.*, in *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1110 (Fed. Cir. 1986) and *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826-27 (Fed. Cir. 1992). These contributions are evaluated and weighed by the trier of fact, for, as this court remarked in *Rite-Hite Corp. v. Kelley Co.*, 819 F.2d 1120, 1125-26 (Fed. Cir. 1987), "[w]illfulness' in infringement, as in life, is not an all-or-nothing trait, but one of degree. It recognizes that infringement may range from unknowing, or accidental, to deliberate, or reckless, disregard of a patentee's legal rights."

Fundamental to determination of willful infringement is the duty to act in accordance with law. Reinforcement of this duty was a foundation of the formation of the Federal Circuit court, at a time when widespread disregard of patent rights was undermining the national innovation incentive. Thus in *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983) the court stressed the legal obligation to respect valid patent rights. The court's

opinion quoted the infringer's attorney who, without obtaining review by patent counsel of the patents at issue, advised the client to "continue to refuse to even discuss the payment of a royalty." *Id.* at 1385. The attorney advised that "[c]ourts, in recent years, have—in patent infringement cases—found the patents claimed to be infringed upon invalid in approximately 80% of the cases," and that for this reason the patentee would probably not risk filing suit. *Id.* On this record of flagrant disregard of presumptively valid patents without analysis, the Federal Circuit ruled that "where, as here, a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing," including "the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity." *Id.* at 1389-90.

Underwater Devices did not raise any issue of attorney-client privilege, while applying precedent that a finding of willfulness requires the factfinder to find by clear and convincing evidence "that the infringer acted in disregard of the patent," citing *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1565 (Fed. Cir. 1983). The aspect of privilege arose in *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565 (Fed. Cir. 1986), where the Federal Circuit observed that the infringer "has not even asserted that it sought advice of counsel when notified of the allowed claims and [the patentee's] warning, or at any time before it began this litigation," and held that the infringer's "silence on the subject, in alleged reliance on the attorney-client privilege, would warrant the conclusion that it either obtained no advice of counsel or did so and was advised that its importation and sale of the accused products would be an infringement of valid U.S. patents." *Id.* at 1580. Thus arose the adverse inference, reinforced in *Fromson v. Western Litho Plate & Supply Co.*, 853 F.2d 1568 (Fed. Cir. 1988), and establishing the general rule that "a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer's desire to initiate or continue its use of the patentee's invention." *Id.* at 1572-73. Throughout this evolution the focus was not on attorney-client relationships, but on disrespect for law. However, implementation of this precedent has resulted in inappropriate burdens on the attorney-client relationship.

We took this case en banc to review this precedent. . . . The adverse inference that an opinion was or would have been unfavorable, flowing from the infringer's failure to obtain or produce an exculpatory opinion of counsel, is no longer warranted. Precedent authorizing such inference is overruled.

Question 1

When the attorney-client privilege and/or work-product privilege is invoked by a defendant in an infringement suit, is it appropriate for the trier of fact to draw an adverse inference with respect to willful infringement?

The answer is "no." Although the duty to respect the law is undiminished, no adverse inference shall arise from invocation of the attorney-client and/or work product privilege. The Supreme Court describes the attorney-client privilege as "the oldest of the privileges for confidential communications known to common law," and has stressed the public purpose

to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and

administration of justice. The privilege recognizes that sound legal advice or advocacy serves public ends and that such advice or advocacy depends upon the lawyer's being fully informed by the client.

Upjohn Co. v. United States, 449 U.S. 383, 389 (1981). Professor Wigmore has elaborated:

The lawyer must have the whole of his client's case, or he cannot pretend to give any useful advice. . . . That the whole will not be told to counsel unless the privilege is confidential, is perfectly clear. A man who seeks advice, seeks it because he believes that he may do so safely; he will rarely make disclosure which may be used against him; rather than create an adverse witness in his lawyer, he will refuse all private arbitration, and take the chance of a trial.

8 J. Wigmore, *Evidence in Trials at Common Law* § 2291 at 548 (McNaughton rev. 1961).

Although this court has never suggested that opinions of counsel concerning patents are not privileged, the inference that withheld opinions are adverse to the client's actions can distort the attorney-client relationship, in derogation of the foundations of that relationship. We conclude that a special rule affecting attorney-client relationships in patent cases is not warranted. There should be no risk of liability in disclosures to and from counsel in patent matters; such risk can intrude upon full communication and ultimately the public interest in encouraging open and confident relationships between client and attorney. As Professor McCormick has explained, the attorney-client privilege protects "interests and relationships which . . . are regarded as of sufficient social importance to justify some sacrifice of availability of evidence relevant to the administration of justice." 1 *McCormick on Evidence* § 72, 299 (5th ed. 1999).

There is precedent for the drawing of adverse inferences in circumstances other than those involving attorney-client relationships; for example when a party's refusal to testify or produce evidence in civil suits creates a presumption of an intent to withhold damaging information that is material to the litigation. However, the courts have declined to impose adverse inferences on invocation of the attorney-client privilege. We now hold that this rule applies to the same extent in patent cases as in other areas of law. A defendant may of course choose to waive the privilege and produce the advice of counsel. However, the assertion of attorney-client and/or work-product privilege and the withholding of the advice of counsel shall no longer entail an adverse inference as to the nature of the advice.

Question 2

When the defendant had not obtained legal advice, is it appropriate to draw an adverse inference with respect to willful infringement?

The answer, again, is "no." The issue here is not of privilege, but whether there is a legal duty upon a potential infringer to consult with counsel, such that failure to do so will provide an inference or evidentiary presumption that such opinion would have been negative.

Dana Corporation did not seek independent legal advice, upon notice by Knorr-Bremse of the pendency of the '445 application in the United States and of the issuance of the '445 patent, followed by the charge of infringement. In tandem with our holding that it is inappropriate to draw an adverse

inference that undisclosed legal advice for which attorney-client privilege is claimed was unfavorable, we also hold that it is inappropriate to draw a similar adverse inference from failure to consult counsel. The amici curiae describe the burdens and costs of the requirement, as pressed in litigation, for early and full study by counsel of every potentially adverse patent of which the defendant had knowledge, citing cases such as *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1364 (Fed. Cir. 1998), wherein the court held that to avoid liability for willful infringement in that case, an exculpatory opinion of counsel must fully address all potential infringement and validity issues. Although other cases have imposed less rigorous criteria, the issue has occasioned extensive satellite litigation, distorting the “conceptual underpinnings” of *Underwater Devices* and *Kloster Speedsteel*. Although there continues to be “an affirmative duty of due care to avoid infringement of the known patent rights of others,” *L.A. Gear Inc. v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1127 (Fed. Cir. 1993), the failure to obtain an exculpatory opinion of counsel shall no longer provide an adverse inference or evidentiary presumption that such an opinion would have been unfavorable.

Question 3

If the court concludes that the law should be changed, and the adverse inference withdrawn as applied to this case, what are the consequences for this case?

A

The district court based its willfulness determination on several factors in addition to the adverse inference arising from the assertion of attorney-client privilege by Haldex and the failure of Dana to obtain legal advice. This court has explained that “there are no hard and fast per se rules” with respect to willfulness of infringement. Precedent illustrates various factors, some weighing on the side of culpability and some that are mitigating or ameliorating. See *Read v. Portec*, *supra*.

The district court found, on the evidence presented, that literal infringement by the Mark II brake was reasonably clear and did not present close legal or factual questions. As for the validity of the '445 patent, the court found that “given the quantity and quality of the evidence presented by defendants at trial on the issues of obviousness and indefiniteness, it cannot fairly be said that defendants, throughout the litigation, had a good faith belief that the '445 patent would ultimately be found invalid on these grounds.” The court also found that the appellants failed to take prompt remedial action to terminate infringement after the judgment of literal infringement by the Mark II, stating that “Dana deliberately yielded to market pressures in deciding to continue using the infringing Mark II air disk brakes on test vehicles pending future receipt of replacement Mark III air disk brakes.” *Id.* The court also found that “although Haldex indeed developed the Mark III air disk brake in a good faith effort to design around the '445 patent, Haldex nonetheless continued to use the Mark II air disk brake throughout the redesign effort, including displaying Mark II air disk brakes at various automotive conferences in the United States and distributing Mark II promotional literature to potential customers at these conferences,” the court also noted that infringement was not then enjoined.

The district court also considered Haldex’s invocation of the attorney-client privilege in order to withhold its opinions of counsel, and Dana’s failure to

obtain an independent legal opinion despite the warning and notice of infringement. The appellants argue that but for the adverse inference of unfavorable opinions drawn from these actions, the finding of willfulness of infringement is not supported. Knorr-Bremse responds that willful infringement is well supported by the remaining findings. Because elimination of the adverse inference as drawn by the district court is a material change in the totality of the circumstances, a fresh weighing of the evidence is required to determine whether the defendants committed willful infringement. This determination is the primary responsibility and authority of the district court. We therefore vacate the finding of willful infringement and remand for re-determination of the issue.

Several amici curiae raised the question of whether the trier of fact, particularly a jury, can or should be told whether or not counsel was consulted (albeit without any inference as to the nature of the advice received) as part of the totality of the circumstances relevant to the question of willful infringement. The amici pointed to various hypothetical circumstances in which such information could be relevant, even when there was no issue of attorney-client privilege. That aspect is not raised by this case, was not before the district court, and has not been briefed on this appeal. Today we resolve only the question of whether adverse inferences of unfavorable opinions can be drawn, and hold that they can not.

B

The appellants also argue that the award of attorney fees is a matter of punitive damages, and is therefore improper. Precedent and statute do not support this position. 35 U.S.C. § 285 provides that “the court in exceptional cases may award reasonable attorney fees to the prevailing party”; and the court has confirmed that a finding of willful infringement may qualify a case as exceptional under § 285. *See, e.g., Modine Mfg. Co. v. The Allen Group, Inc.*, 917 F.2d 538, 543 (Fed. Cir. 1990). That there were not actual damages does not render the award of attorney fees punitive. Attorney fees are compensatory, and may provide a fair remedy in appropriate cases. Upon a finding of willful infringement, the award of attorney fees is within the district court’s sound discretion.

In view of our vacatur of the finding of willful infringement, the award of attorney fees is also vacated. On remand the award may be reconsidered, should the judgment of willful infringement be restored.

SUMMARY

An adverse inference that a legal opinion was or would have been unfavorable shall not be drawn from invocation of the attorney-client and/or work product privileges or from failure to consult with counsel. Contrary holdings and suggestions of precedent are overruled.

IN RE SEAGATE TECHNOLOGY, LLC

497 F.3d 1360 (Fed. Cir. 2007) (en banc)

MAYER, Circuit Judge.

Seagate Technology, LLC (“Seagate”) petitions for a writ of mandamus directing the United States District Court for the Southern District of

New York to vacate its orders compelling disclosure of materials and testimony that Seagate claims is covered by the attorney-client privilege and work product protection. We ordered en banc review, and now grant the petition. We overrule *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (1983), and we clarify the scope of the waiver of attorney-client privilege and work product protection that results when an accused patent infringer asserts an advice of counsel defense to a charge of willful infringement.

The en banc order set out the following question[]:

3. Given the impact of the statutory duty of care standard announced in *Underwater Devices, Inc. v. Morrison-Knudsen Co.* on the issue of waiver of attorney-client privilege, should this court reconsider the decision in *Underwater Devices* and the duty of care standard itself?

DISCUSSION

Because patent infringement is a strict liability offense, the nature of the offense is only relevant in determining whether enhanced damages are warranted. Although a trial court's discretion in awarding enhanced damages has a long lineage in patent law,³ the current statute, similar to its predecessors, is devoid of any standard for awarding them. Absent a statutory guide, we have held that an award of enhanced damages requires a showing of willful infringement. This well-established standard accords with Supreme Court precedent. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 479, 508 (1961) (enhanced damages were available for willful or bad faith infringement). But, a finding of willfulness does not require an award of enhanced damages; it merely permits it. See 35 U.S.C. § 284.

This court fashioned a standard for evaluating willful infringement in *Underwater Devices Inc. v. Morrison-Knudsen Co.*, 717 F.2d at 1389-90: "Where . . . a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, *inter alia*, the duty to seek and obtain competent legal advice from counsel *before* the initiation of any possible infringing activity." This standard was announced shortly after the creation of the court, and at a time "when widespread disregard of patent rights was undermining the national innovation incentive." *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004) (en banc). Indeed, in *Underwater Devices*, an attorney had advised the infringer that "[c]ourts, in recent years, have—in patent infringement cases—found [asserted patents] invalid in approximately 80% of the cases," and on that basis the attorney concluded that the patentee would not likely sue for infringement. 717 F.2d at 1385. Over time, our cases evolved to evaluate willfulness and its duty of due care under the totality of the circumstances, and we enumerated factors informing the inquiry.

3. Trial courts have had statutory discretion to enhance damages for patent infringement since 1836. 35 U.S.C. § 284 (2000); Act of Aug. 1, 1946, 60 Stat. 778; Patent Act of 1870, ch. 230, § 59, 16 Stat. 198, 207 (1870) (providing that "the court may enter judgment thereon for any sum above the amount found by the verdict as the actual damages sustained, according to the circumstances of the case, not exceeding three times the amount of such verdict, together with the costs"); Patent Act of 1836, ch. 357, 5 Stat. 117 (1836) (stating that "it shall be in the power of the court to render judgment for any sum above the amount found by such verdict . . . not exceeding three times the amount thereof, according to the circumstances of the case").

In light of the duty of due care, accused willful infringers commonly assert an advice of counsel defense. Under this defense, an accused willful infringer aims to establish that due to reasonable reliance on advice from counsel, its continued accused activities were done in good faith. Typically, counsel's opinion concludes that the patent is invalid, unenforceable, and/or not infringed. Although an infringer's reliance on favorable advice of counsel, or conversely his failure to proffer any favorable advice, is not dispositive of the willfulness inquiry, it is crucial to the analysis. *E.g.*, *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1056 (Fed. Cir. 1994) ("Possession of a favorable opinion of counsel is not essential to avoid a willfulness determination; it is only one factor to be considered, albeit an important one.").

Since *Underwater Devices*, we have recognized the practical concerns stemming from our willfulness doctrine, particularly as related to the attorney-client privilege and work product doctrine. For instance, *Quantum Corp. v. Plus Development Corp.*, 940 F.2d 642, 643 (Fed. Cir. 1991), observed that "[p]roper resolution of the dilemma of an accused infringer who must choose between the lawful assertion of the attorney-client privilege and avoidance of a willfulness finding if infringement is found, is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege." We cautioned there that an accused infringer "should not, without the trial court's careful consideration, be forced to choose between waiving the privilege in order to protect itself from a willfulness finding, in which case it may risk prejudicing itself on the question of liability, and maintaining the privilege, in which case it may risk being found to be a willful infringer if liability is found." *Id.* at 643-44. We advised that *in camera* review and bifurcating trials in appropriate cases would alleviate these concerns. *Id.* However, such procedures are often considered too onerous to be regularly employed.

Recently, in *Knorr-Bremse*, we addressed another outgrowth of our willfulness doctrine. Over the years, we had held that an accused infringer's failure to produce advice from counsel "would warrant the conclusion that it either obtained no advice of counsel or did so and was advised that its [activities] would be an infringement of valid U.S. Patents." *Knorr-Bremse*, 383 F.3d at 1343. Recognizing that this inference imposed "inappropriate burdens on the attorney-client relationship," *id.*, we held that invoking the attorney-client privilege or work product protection does not give rise to an adverse inference, *id.* at 1344-45. We further held that an accused infringer's failure to obtain legal advice does not give rise to an adverse inference with respect to willfulness. *Id.* at 1345-46.

More recently, in *Echostar* we addressed the scope of waiver resulting from the advice of counsel defense. First, we concluded that relying on in-house counsel's advice to refute a charge of willfulness triggers waiver of the attorney-client privilege. *Echostar*, 448 F.3d at 1299. Second, we held that asserting the advice of counsel defense waives work product protection and the attorney-client privilege for all communications on the same subject matter, as well as any documents memorializing attorney-client communications. *Id.* at 1299, 1302-03. However, we held that waiver did not extend to work product that was not communicated to an accused infringer. *Id.* at 1303-04. *Echostar* did not consider waiver of the advice of counsel defense as it relates to trial counsel.

In this case, we confront the willfulness scheme and its functional relationship to the attorney-client privilege and work product protection. In light

of Supreme Court opinions since *Underwater Devices* and the practical concerns facing litigants under the current regime, we take this opportunity to revisit our willfulness doctrine and to address whether waiver resulting from advice of counsel and work product defenses extend to trial counsel.

I. Willful Infringement

The term willful is not unique to patent law, and it has a well-established meaning in the civil context. For instance, our sister circuits have employed a recklessness standard for enhancing statutory damages for copyright infringement. Under the Copyright Act, a copyright owner can elect to receive statutory damages, and trial courts have discretion to enhance the damages, up to a statutory maximum, for willful infringement. 17 U.S.C. § 504(c). Although the statute does not define willful, it has consistently been defined as including reckless behavior.

Just recently, the Supreme Court addressed the meaning of willfulness as a statutory condition of civil liability for punitive damages. *Safeco Ins. Co. of Am. v. Burr*, 127 S. Ct. 2201 (2007). Addressing the willfulness requirement, the Court concluded that the “standard civil usage” of “willful” includes reckless behavior. *Id.* Significantly, the Court said that this definition comports with the common law usage, “which treated actions in ‘reckless disregard’ of the law as ‘willful’ violations.” *Id.*

In contrast, the duty of care announced in *Underwater Devices* sets a lower threshold for willful infringement that is more akin to negligence. This standard fails to comport with the general understanding of willfulness in the civil context, *Richland Shoe Co.*, 486 U.S. at 133 (“The word ‘willful’ . . . is generally understood to refer to conduct that is not merely negligent.”), and it allows for punitive damages in a manner inconsistent with Supreme Court precedent, *see, e.g., Safeco*, 127 S. Ct. at 2209, 2214-15 n.20. Accordingly, we overrule the standard set out in *Underwater Devices* and hold that proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness. Because we abandon the affirmative duty of due care, we also reemphasize that there is no affirmative obligation to obtain opinion of counsel.

We fully recognize that “the term [reckless] is not self-defining.” *Farmer v. Brennan*, 511 U.S. 825, 836 (1994). However, “[t]he civil law generally calls a person reckless who acts . . . in the face of an unjustifiably high risk of harm that is either known or so obvious that it should be known.” *Id.* Accordingly, to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. *See Safeco*, slip op. at 19 (“It is [a] high risk of harm, objectively assessed, that is the essence of recklessness at common law.”). The state of mind of the accused infringer is not relevant to this objective inquiry. If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer. We leave it to future cases to further develop the application of this standard.⁵

5. We would expect that the standards of commerce would be among the factors a court might consider.

Comments

1. ***The Demise of the Adverse Inference Rule and Affirmative Duty of Care.*** The *Knorr* court, citing *Underwater Devices*, stated that actual notice of another's patent right triggers an affirmative duty of due care. But in a unanimous en banc decision, the Federal Circuit eliminated the duty of care, as well as the duty to obtain opinion of counsel. See *In re Seagate Technology, LLC*, 497 F.3d at 1371 (Fed. Cir. 2007) (en banc) (stating "we abandon the affirmative duty of due care, [and] also reemphasize that there is no affirmative obligation to obtain opinion of counsel"). And in *Knorr*, the court held failure to obtain an exculpatory opinion of counsel or claiming attorney-client privilege for such a letter shall no longer provide an adverse inference or evidentiary presumption that such an opinion would have been unfavorable. (Although on remand, Judge Ellis of the E.D. of Virginia found willfulness, even in the light of the "now proscribed adverse inference." 372 F. Supp. 2d 833 (E.D. Va. 2005).)

Moreover, in *Seagate*, the Federal Circuit stated "proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness." 497 F.3d at 1371. As such, "to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.*

Seagate and *Knorr* make it more difficult for patentees to prove willfulness, and reduce the need for accused infringers to obtain an opinion of counsel relating to the alleged infringement. Thus, it is arguable that less time will be expended on establishing defenses to a willfulness charge, are more time spent on the nature of the alleged infringement.

2. ***District Court Discretion.*** Section 285 allows for treble damages, but says nothing about willfulness. As part of its common law, the Federal Circuit identified willful infringement as one instance where treble damages would be justified. Yet a finding of willful infringement does not require that damages be enhanced. Rather, this decision is left to the discretion of the district court judge. See *Modine Mfg. Co. v. Allen Group, Inc.*, 917 F.2d 538, 543 (Fed. Cir. 1990) (stating "a finding of willful infringement merely authorizes, but does not mandate, an award of increased damages") (emphasis in original).
3. ***Attorneys Fees.*** Under § 285, a court may award attorney fees to the prevailing party in "exceptional cases." In *Waymark Corp. v. Porta Systems Corp.*, 334 F.3d 1358, 1362-63 (Fed. Cir. 2003), the court stated:

We have held that "[t]he determination of whether a case is exceptional and, thus, eligible for an award of attorney fees under § 285 is a two-step process. First, the district court must determine whether a case is exceptional, a factual determination reviewed for clear error." The second step is that "the district court must determine whether attorney fees are appropriate, a determination that we review for an abuse of discretion."

Typically, an exceptional case is based on a finding of bad faith or utterly baseless claim. See *Interspiro USA, Inc. v. Figgie Int'l Inc.*, 18 F.3d 927, 934 (Fed. Cir. 1994) (stating "[t]he district court's finding of an exceptional case

was premised on the court's determination that the question of infringement "was not close").

D. MARKING AND CONSTRUCTIVE NOTICE

To recover damages, a patentee must either mark its patented good or provide the infringer with notice of the infringement. According to § 287, "in the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice." The *Maxwell* case explores the marking requirement.

MAXWELL v. J. BAKER, INC.

86 F.3d 1098 (Fed. Cir. 1996)

LOURIE, Circuit Judge.

J. Baker, Inc. appeals from the final judgment of the United States District Court for the District of Minnesota in which the court denied J. Baker's motion for judgment as a matter of law after a jury verdict of infringement of claims 1, 2, and 3 of U.S. Patent 4,624,060, owned by the inventor, Susan M. Maxwell.

BACKGROUND

In retail shoe stores, pairs of shoes must be kept together to prevent them from becoming disorganized and mismatched. Typically, manufacturers connect pairs of shoes using plastic filaments threaded through each shoe's eyelets. However, some shoes do not have eyelets and cannot be connected in this manner. Thus, manufacturers have resorted to other methods of keeping the shoes together such as making a hole in the side of each shoe and threading a filament through these holes. This method creates problems for retailers and manufacturers because the shoes are damaged by the process.

Maxwell, an employee at a Target retail store, recognized this problem and invented a system for connecting shoes that do not have eyelets. She secured tabs along the inside of each shoe and connected the shoes with a filament threaded through a loop or hole in each tab. By securing the tabs inside the shoe, she preserved the integrity and appearance of the shoes.

Maxwell filed a patent application entitled "System for Attaching Mated Pairs of Shoes Together," which issued as the '060 patent on November 25, 1986.

* * *

J. Baker sells and distributes shoes through leased footwear departments in retail stores. Under a typical leasing arrangement, a retail store provides J. Baker with the exclusive right to operate a shoe department within the store. J. Baker selects the merchandise, stocks the shelves at the stores, and

serves the customers. In exchange, the retail store receives a portion of the sales receipts.

J. Baker purchases the shoes it sells from independent manufacturers. Between the mid-1980's and 1990, J. Baker instructed its manufacturers to connect shoes together for sale using a fabric loop inserted under a shoe's sock lining (the "under the sock lining" version). In June 1990, Maxwell informed J. Baker's in-house counsel that she believed that J. Baker infringed the '060 patent. In response, J. Baker designed two alternate shoe connection systems. In the "counter pocket" version, a tab was stitched into the counter pocket of the shoe between the sole and the top of the shoe.

Maxwell sued J. Baker on December 12, 1990, alleging infringement of the '060 patent. After a month long trial, a jury returned a special verdict finding that the '060 patent was valid; J. Baker infringed claims 1, 2, and 3 of the patent; and J. Baker's infringement was willful after June 1990, when it received actual notice of the '060 patent. The jury also determined that Maxwell complied with the marking requirements of 35 U.S.C. § 287(a) as of November 1987. Thus, it awarded over \$1.5 million in damages based on its determination that a reasonable royalty for use of Maxwell's patent was \$.05 per pair of shoes and J. Baker sold 31 million infringing pairs of shoes.

J. Baker filed a motion for judgment as a matter of law and a motion for a new trial arguing, *inter alia*, that the marking date fixed by the jury was not supported by substantial evidence. The court denied J. Baker's motion.

DISCUSSION

* * *

C. Marking

J. Baker argues that the court erred by denying its JMOL motion on the issue of patent marking under 35 U.S.C. § 287(a). J. Baker asserts that, as a matter of law, no damages may be awarded for infringement occurring before it had actual notice of the alleged infringement in June 1990, and that substantial evidence does not support the jury's verdict that Maxwell complied with the marking statute as of November 1987. In support, J. Baker relies on evidence that at least 5% of the shoes sold by Maxwell's licensee, Target, were not properly marked because Target failed to instruct some of its manufacturers to mark the patented systems.

In response, Maxwell argues that substantial evidence supports the jury's verdict. In particular, Maxwell asserts that she was diligent in enforcing Target's duty to mark, and Target successfully marked 95% of the shoes sold with the attachment system. Thus, she maintains that the court did not err when it denied J. Baker's JMOL motion on the issue of marking. We agree.

Section 287(a) of the Patent Act provides:

Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.," together with the number of the patent. . . . In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which

event damages may be recovered only for infringement occurring after such notice.

35 U.S.C. § 287(a) (1994). Thus, the statute defines that “[a patentee] is entitled to damages from the time when it either began marking its product in compliance with section 287(a)[, constructive notice,] or when it actually notified [the accused infringer] of its infringement, whichever was earlier.” *American Medical Sys., Inc. v. Medical Eng’g Corp.*, 6 F.3d 1523, 1537 (Fed. Cir. 1993). We have construed section 287(a) to require that “once marking has begun, it must be substantially consistent and continuous in order for the party to avail itself of the constructive notice provisions of the statute.” *Id.* As the patentee, Maxwell had the burden of pleading and proving at trial that she complied with the statutory requirements. Compliance with section 287(a) is a question of fact, and we review the court’s denial of JMOL on the jury’s resolution of the issue for substantial evidence.

A patentee who makes, uses, or sells its own invention is obligated to comply with the marking provisions to obtain the benefit of constructive notice. *See American Medical*, 6 F.3d at 1538 (“Full compliance was not achieved until [the patentee] consistently marked substantially all of its patented products, and it was no longer distributing unmarked products.”). The marking provisions also apply to “persons making or selling any patented article for or under [the patentees].” 35 U.S.C. § 287(a). Thus, licensees, such as Target, and other authorized parties, such as Target’s manufacturers, must also comply. However, with third parties unrelated to the patentee, it is often more difficult for a patentee to ensure compliance with the marking provisions. A “rule of reason” approach is justified in such a case and substantial compliance may be found to satisfy the statute. Therefore, when third parties are involved, the number of shoes sold without proper marking is not conclusive of the issue whether the patentee’s marking was “substantially consistent and continuous.” When the failure to mark is caused by someone other than the patentee, the court may consider whether the patentee made reasonable efforts to ensure compliance with the marking requirements. The rule of reason is consistent with the purpose of the constructive notice provision—to encourage patentees to mark their products in order to provide notice to the public of the existence of the patent and to prevent innocent infringement.

Here, Maxwell, the patentee, made extensive and continuous efforts to ensure compliance by Target. There is evidence that Target, as licensee of Maxwell’s patent, marked at least 95% of the shoes sold using the patented system. Because Target sold millions of pairs of shoes using the patented system, it is true that a numerically large number of shoes were sold without proper marking. Despite this, however, the evidence supports the jury’s finding that Maxwell complied with the statute. Before the patent issued, Target agreed to mark “Patent Pending” on all pairs of shoes using Maxwell’s shoe attachment system. After the patent issued on November 26, 1986, Maxwell notified Target to mark the patent number on all shoes using the patented system, as required by their license agreement. Initially, Target made no effort to change the marking from “Patent Pending” to recite the patent number. In response, Maxwell notified Target’s manufacturers of the need to properly mark. Subsequently, Target agreed to properly mark shoes using the patented system by November 1987. Thereafter, on several

occasions when Maxwell learned of Target's failure to properly mark shoes using the patented system after November 1987, she notified Target of the errors and requested that the shoes be properly marked in the future. Maxwell also presented evidence that, in response to her urging, Target used its best efforts to correct its failure to mark by instructing its manufacturers to properly mark in the future.

Thus, we find that substantial evidence supports the jury's determination that Maxwell complied with the marking statute as of November 1987. Most pairs of shoes using the patented attachment system were properly marked. Any deficiency in the marking was not due to Maxwell or any failure on her part to ensure compliance by her licensees; she diligently attempted to comply with the statutory marking requirements. Therefore, we affirm the district court's denial of J. Baker's JMOL motion on the issue of marking, [and] affirm the jury's conclusions that the '060 patent was not proved invalid and that Maxwell complied with the marking requirements of 35 U.S.C. § 287(a) as of November 1987.

Comments

1. **The Policy of Marking.** The marking requirement has its origins in the 1842 Patent Act. And the policies underlying this duty have not changed much since then. These policies include: (1) helping to avoid innocent infringement; (2) encouraging patentees to give notice to the public that the article is patented; and (3) aiding the public to identify whether an article is patented. See *Nike, Inc. v. Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1443 (Fed. Cir. 1998). The role of notice was made clear in the Federal Circuit's decision in *American Medical Systems, Inc. v. Medical Engineering Corporation*, 6 F.3d 1523 (Fed. Cir. 1993):

[C]ases under the 1952 Act have interpreted section 287(a) to allow damages from the time when marking begins in compliance with the statute or actual notice is given, whichever comes first. The plain language of section 287(a) does not provide any time limit by which marking must begin, nor does the legislative history indicate any such limitation. Congress structured the statute so as to tie failure to mark with disability to collect damages, not failure to mark *at the time of issuance* with disability to collect damages. Furthermore, allowing recovery of damages from the point of full compliance with the marking statute furthers the policy of encouraging marking to provide notice to the public, even if initial marking after issuance of the patent is delayed. The sooner one complies with the marking requirements, the more likely one is to maximize the period of time for recoverable damages. To prevent recovery of damages for failure to immediately mark, however, provides no incentive for a patentee who inadvertently or unavoidably fails to mark initially to mark in the future.

* * *

In light of the permissive wording of the present statute, and the policy of encouraging notice by marking, we construe section 287(a) to preclude recovery of damages only for infringement for any time prior to compliance with the marking or actual notice requirements of the statute. Therefore, a

delay between issuance of the patent and compliance with the marking provisions of section 287(a) will not prevent recovery of damages after the date that marking has begun. We caution, however, that once marking has begun, it must be substantially consistent and continuous in order for the party to avail itself of the constructive notice provisions of the statute.

* * *

The date that AMS began marking its products is irrelevant for purposes of the statute, because marking alone without distribution provides no notice to the public where unmarked products are continuing to be shipped. The purpose of the constructive notice provision is “to give patentees the proper incentive to mark their products and thus place the world on notice of the existence of the patent.” *Laitram Corp. v. Hewlett-Packard Co.*, 806 F. Supp. 1294, 1296 (E.D. La. 1992). The world cannot be “put on notice” if the patentee marks certain products, but continues to ship unmarked products. Therefore, AMS was not in full compliance with the marking statute while it continued to ship its unmarked products, which continued to mislead the public into thinking that the product was freely available. Full compliance was not achieved until AMS consistently marked substantially all of its patented products, and it was no longer distributing unmarked products.

Id. at 1537-38.

2. **Constructive Notice.** A patentee can mark his goods at any point after issuance of the patent. Naturally, a patentee has an incentive to mark sooner than later so as to provide constructive notice and to begin the damages clock. Constructive notice is provided when the patentee consistently marks substantially all of its patented products. Thus, infringers will be liable for damages even if they do not know of the existence of a patent. Such is the power of constructive notice. In addition, the notice must come from the patentee. *See American Medical*, 6 F.3d at 1537 n.18 (in response to patentee’s argument that notice was satisfied because the infringer was notified that he was infringing by its own counsel, the court stated, “[t]his is clearly not what was intended by the marking statute. Section 287(a) requires a party asserting infringement to either provide constructive notice (through marking) or actual notice in order to avail itself of damages. The notice of infringement must therefore come from the patentee, not the infringer).

Section 287 allows for the patentee to mark either the product or the packaging of the product. Package marking is permitted “when, from the character of the article” marking the product “can not be done.” The key is that notice is provided. Not surprisingly, the marking requirement is not applicable to process or method inventions. How do you physically mark these types of inventions? *See American Medical, supra*, at 1538 (“The law is clear that the notice provisions of section 287 do not apply where the patent is directed to a process or method.”); *State Contracting & Engineering Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1074 (Fed. Cir 2003) (“We have not previously held that a patent containing only method claims is examined to see if something could have been marked in order to assess whether the notice provision applies, and we decline to do so now.”)

3. **Patent Law’s “Statute of Limitations.”** Section 286 of the patent code provides a six-year “statute of limitations.” But this provision is not a typical

statute of limitations because it does not bar the patentee from bringing a patent infringement action. Rather, § 286 is a damages limitation rule, which states, “no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action.” *Standard Oil Co. v. Nippon Shokubai Kagaku Kogyo Co.*, 754 F.2d 345, 348 (Fed. Cir. 1985) (“Since § 286 cannot properly be called a ‘statute of limitations’ in the sense that it defeats the right to bring suit, it cannot be said that the statute ‘begins to run’ on some date or other. In the application of § 286, one starts from the filing of a complaint or counterclaim and counts *backward* to determine the date before which infringing *acts* cannot give rise to a right to recover damages.”) (emphasis in original); *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1030 (Fed. Cir. 1992) (explaining that § 286 is “not a statute of limitations in the sense of barring a suit for infringement” . . . but rather is a “limit to recovery to damages for infringing acts committed within six years of the date of the filing of the infringement action.”).

SELECTED PATENT STATUTES AND REGULATIONS

SELECTED STATUTES FROM TITLE 35 (THE PATENT CODE)

35 U.S.C. § 100 Definitions

When used in this title unless the context otherwise indicates

- (a) The term “invention” means invention or discovery.
- (b) The term “process” means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.
- (c) The terms “United States” and “this country” mean the United States of America, its territories and possessions.
- (d) The word “patentee” includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

35 U.S.C. § 101 Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 102 Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless —

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor’s certificate filed more than twelve months before the filing of the application in the United States, or
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language, or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 103 Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)—

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term “biotechnological process” means—

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to—

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 104 Invention made abroad

(a) In General. —

(1) Proceedings. — In proceedings in the Patent and Trademark Office, in the courts, and before any other competent authority, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country other than a NAFTA country or a WTO member country, except as provided in sections 119 and 365 of this title.

(2) Rights. — If an invention was made by a person, civil or military —

(A) while domiciled in the United States, and serving in any other country in connection with operations by or on behalf of the United States,

(B) while domiciled in a NAFTA country and serving in another country in connection with operations by or on behalf of that NAFTA country, or

(C) while domiciled in a WTO member country and serving in another country in connection with operations by or on behalf of that WTO member country, that person shall be entitled to the same rights of priority in the United States with respect to such invention as if such invention had been made in the United States, that NAFTA country, or that WTO member country, as the case may be.

(3) Use of information. — To the extent that any information in a NAFTA country or a WTO member country concerning knowledge, use, or other activity relevant to proving or disproving a date of invention has not been made available for use in a proceeding in the Patent and Trademark Office, a court, or any other competent authority to the same extent as such information could be made available in the United States, the Director, court, or such other authority shall draw appropriate inferences, or take other action permitted by statute, rule, or regulation, in favor of the party that requested the information in the proceeding.

(b) Definitions. — As used in this section —

(1) the term “NAFTA country” has the meaning given that term in section 2(4) of the North American Free Trade Agreement Implementation Act; and

(2) the term “WTO member country” has the meaning given that term in section 2(10) of the Uruguay Round Agreements Act.

35 U.S.C. § 112 Specification

[¶ 1] The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[¶ 2] The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[¶ 3] A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form. Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

[¶ 4] Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

[¶ 5] A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

[¶ 6] An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 116 Inventors

When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

If a joint inventor refuses to join in an application for patent or cannot be found or reached after diligent effort, the application may be made by the other inventor on behalf of himself and the omitted inventor. The Director, on proof of the pertinent facts and after such notice to the omitted inventor as he prescribes, may grant a patent to the inventor making the application, subject to the same rights which the omitted inventor would have had if he had been joined. The omitted inventor may subsequently join in the application. Whenever through error a person is named in an application for patent as the inventor, or through an error an inventor is not named in an application, and

such error arose without any deceptive intention on his part, the Director may permit the application to be amended accordingly, under such terms as he prescribes.

35 U.S.C. § 119 Benefit of earlier filing date; right of priority

(a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

(b)(1) No application for patent shall be entitled to this right of priority unless a claim is filed in the Patent and Trademark Office, identifying the foreign application by specifying the application number on that foreign application, the intellectual property authority or country in or for which the application was filed, and the date of filing the application, at such time during the pendency of the application as required by the Director.

(2) The Director may consider the failure of the applicant to file a timely claim for priority as a waiver of any such claim. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed claim under this section.

(3) The Director may require a certified copy of the original foreign application, specification, and drawings upon which it is based, a translation if not in the English language, and such other information as the Director considers necessary. Any such certification shall be made by the foreign intellectual property authority in which the foreign application was filed and show the date of the application and of the filing of the specification and other papers.

(c) In like manner and subject to the same conditions and requirements, the right provided in this section may be based upon a subsequent regularly filed application in the same foreign country instead of the first filed foreign application, provided that any foreign application filed prior to such subsequent application has been withdrawn, abandoned, or otherwise disposed of, without having been laid open to public inspection and without leaving any rights outstanding, and has not served, nor thereafter shall serve, as a basis for claiming a right of priority.

(d) Applications for inventors' certificates filed in a foreign country in which applicants have a right to apply, at their discretion, either for a patent or for an inventor's certificate shall be treated in this country in the same manner and have the same effect for purpose of the right of priority under this section as applications for patents, subject to the same conditions and requirements of

this section as apply to applications for patents, provided such applicants are entitled to the benefits of the Stockholm Revision of the Paris Convention at the time of such filing.

(e)(1)An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application. No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this subsection during the pendency of the application.

35 U.S.C. § 120 Benefit of earlier filing date in the United States

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

35 U.S.C. § 154 Contents and term of patent; provisional rights

(a) In General. —

(1) Contents. — Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United

States, products made by that process, referring to the specification for the particulars thereof.

(2) Term.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

35 U.S.C. § 251 Reissue of defective patents

Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

The Director may issue several reissued patents for distinct and separate parts of the thing patented, upon demand of the applicant, and upon payment of the required fee for a reissue for each of such reissued patents.

The provisions of this title relating to applications for patent shall be applicable to applications for reissue of a patent, except that application for reissue may be made and sworn to by the assignee of the entire interest if the application does not seek to enlarge the scope of the claims of the original patent.

No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

35 U.S.C. § 252 Effect of reissue

The surrender of the original patent shall take effect upon the issue of the reissued patent, and every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form, but in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent.

A reissued patent shall not abridge or affect the right of any person or that person's successors in business who, prior to the grant of a reissue, made, purchased, offered to sell, or used within the United States, or imported into the United States, anything patented by the reissued patent, to continue the use of, to offer to sell, or to sell to others to be used, offered for sale, or sold, the specific thing so made, purchased, offered for sale, used, or imported unless the making, using, offering for sale, or selling of such thing infringes a

valid claim of the reissued patent which was in the original patent. The court before which such matter is in question may provide for the continued manufacture, use, offer for sale, or sale of the thing made, purchased, offered for sale, used, or imported as specified, or for the manufacture, use, offer for sale, or sale in the United States of which substantial preparation was made before the grant of the reissue, and the court may also provide for the continued practice of any process patented by the reissue that is practiced, or for the practice of which substantial preparation was made, before the grant of the reissue, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue.

35 U.S.C. § 256 Correction of named inventor

Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

35 U.S.C. § 261 Ownership; assignment

Subject to the provisions of this title, patents shall have the attributes of personal property.

Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.

A certificate of acknowledgment under the hand and official seal of a person authorized to administer oaths within the United States, or, in a foreign country, of a diplomatic or consular officer of the United States or an officer authorized to administer oaths whose authority is proved by a certificate of a diplomatic or consular officer of the United States, or apostille of an official designated by a foreign country which, by treaty or convention, accords like effect to apostilles of designated officials in the United States, shall be *prima facie* evidence of the execution of an assignment, grant, or conveyance of a patent or application for patent.

An assignment, grant, or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage.

35 U.S.C. § 262 Joint owners

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.

35 U.S.C. § 271 Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

(1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent;

(2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent;

(3) sought to enforce his patent rights against infringement or contributory infringement;

(4) refused to license or use any rights to the patent; or

(5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit —

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2) —

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after —

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term “whoever” includes any State, any instrumentality of a State, any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an “offer for sale” or an “offer to sell” by a person other than the patentee or any assignee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

35 U.S.C. § 282 Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement, or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure —

(1) by the applicant for the extension, or

(2) by the Director, to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

35 U.S.C. § 283 Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

35 U.S.C. § 284 Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

35 U.S.C. § 285 Attorney fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

35 U.S.C. § 286 Time limitation on damages

Except as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action.

In the case of claims against the United States Government for use of a patented invention, the period before bringing suit, up to six years, between

the date of receipt of a written claim for compensation by the department or agency of the Government having authority to settle such claim, and the date of mailing by the Government of a notice to the claimant that his claim has been denied shall not be counted as a part of the period referred to in the preceding paragraph.

**35 U.S.C. § 287 Limitation on damages and other remedies;
marking and notice**

(a) Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word “patent” or the abbreviation “pat.”, together with the number of the patent, or when, from the character of the article, this cannot be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

**SELECTED STATUTES FROM TITLE 28
(JUDICIARY AND JUDICIAL PROCEDURE)**

**28 U.S.C. § 1338(a) Patents, plant variety protection, copyrights, mask works,
designs, trademarks, and unfair competition**

(a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

**28 U.S.C. § 1295 Jurisdiction of the United States Court of Appeals for the
Federal Circuit**

(a) The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—

(1) of an appeal from a final decision of a district court of the United States, the United States District Court for the district of the Canal Zone, the District Court of Guam, the District Court of the Virgin Islands, or the District Court for the Northern Mariana Islands, if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title, except that a case involving a claim arising under any Act of Congress relating to copyrights, exclusive rights in mask works, or trademarks and no other claims under section 1338(a) shall be governed by sections 1291, 1292, and 1294 of this title;

(4) of an appeal from a decision of—

(A) the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office with respect to patent applications and interferences, at the instance of an applicant for a patent or any party to a patent interference, and any such appeal shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35;

(B) the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office or the Trademark Trial and Appeal Board with respect to applications for registration of marks and other proceedings as provided in section 21 of the Trademark Act of 1946 (15 U.S.C. 1071); or

(C) a district court to which a case was directed pursuant to section 145, 146, or 154(b) of title 35;

28 U.S.C. § 1391 Venue generally

(a) A civil action wherein jurisdiction is founded only on diversity of citizenship may, except as otherwise provided by law, be brought only in (1) a judicial district where any defendant resides, if all defendants reside in the same State, (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (3) a judicial district in which any defendant is subject to personal jurisdiction at the time the action is commenced, if there is no district in which the action may otherwise be brought.

(b) A civil action wherein jurisdiction is not founded solely on diversity of citizenship may, except as otherwise provided by law, be brought only in (1) a judicial district where any defendant resides, if all defendants reside in the same State, (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (3) a judicial district in which any defendant may be found, if there is no district in which the action may otherwise be brought.

(c) For purposes of venue under this chapter, a defendant that is a corporation shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced. In a State which has more than one judicial district and in which a defendant that is a corporation is subject to personal jurisdiction at the time an action is commenced, such corporation shall be deemed to reside in any district in that State within which its contacts would be sufficient to subject it to personal jurisdiction if that district were a separate State, and, if there is no such district, the corporation shall be deemed to reside in the district within which it has the most significant contacts.

28 U.S.C. § 1400 Patents and copyrights, mask works, and designs

(b) Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.

SELECTED REGULATION FROM 37 CODE OF FEDERAL REGULATIONS

37 C.F.R. § 1.56 Duty to disclose information material to patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office,

or

(ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
 - (2) Each attorney or agent who prepares or prosecutes the application;
- and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
 - (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.
 - (e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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