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POLICY LEVERS IN PATENT LAW*

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INTRODUCTION

PATENT law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge. To accomplish this end, the patent statute creates a general set of legal rules that govern a wide variety of technologies.¹ With only a few exceptions,² the statute does not distinguish between different technologies in setting and applying legal standards. Rather, the United States Supreme Court has held that patent standards in the United States are designed to adapt flexibly to both old and new technologies, encompassing "anything under the sun that is made by man."³ In theory, then, we

¹ 35 U.S.C. §§ 100-376 (2000).

² See, e.g., id. § 103(b) (2000) (special nonobviousness provision for biotechnology).

³ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)). For a contrary approach, see *Harvard Coll. v. Comm'r*, [2002] D.L.R. 577 (holding that the Canadian Patent Act, unlike the

have a uniform patent system that provides technology-neutral protection to all kinds of innovation.

Technology is anything but uniform, however, and it displays highly diverse characteristics across different sectors. A wealth of empirical evidence demonstrates deep structural differences in how industries innovate. Industries vary in the speed and cost of research and development (“R&D”), in the ease with which inventions can be imitated by others, in the need for cumulative or interoperative innovation rather than stand-alone development, and in the extent to which patents cover entire products or merely components of products. We will begin this paper by examining these differences in Part I. We will show that there is no reason to assume that a unitary patent system will optimally encourage innovation in the wide range of diverse industries that it is expected to cover.

This seeming paradox—a monolithic legal incentive for wildly disparate industries—is resolved by the realization that, despite the appearance of uniformity, patent law is actually as varied as the industries it seeks to foster. A closer examination of patent law demonstrates that it is unified only in concept. In practice the rules actually applied to different industries increasingly diverge. The best examples of such divergence are found in biotechnology and computer software cases, where the courts have applied the common legal standards of obviousness, enablement, and written description to reach radically different results. As a practical matter, it appears that although patent law is technology-neutral in theory, it is technology-specific in application. We will summarize these technology-specific divergences in Part I; we have explored them in detail elsewhere.⁴ Unfortunately, there is no reason to believe that these differences in the law represent a reasoned response to industry differences. The United States Court of Appeals for the Federal Circuit has generally not acknowledged that it is designing

United States Patent Act, does not automatically cover new technologies and specifically does not encompass transgenic higher organisms).

⁴See Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 *Berkeley Tech. L.J.* 1155 (2002) [hereinafter Burk & Lemley, *Technology-Specific*].

industry-specific patent policy,⁵ and it is possible to read its patent cases as merely following legal precedents from different industries to their logical conclusions. At least in the industries of biotechnology and software, however, the Federal Circuit has gotten the policy precisely backwards, perhaps because it is not making industry-specific patent policy intentionally.⁶

The differential application of patent standards to different industries correlates with a larger theoretical confusion in patent law. While most theorists agree on the general utilitarian framework of patent law—that is, they agree on the goals the patent statute is intended to achieve—they have offered radically different ideas for interpreting patent law to achieve those goals. In Part II, we will examine the various different theoretical approaches to patent law. We suggest that none of these theories is entirely correct. Neither are they entirely wrong. Rather, like the blind men examining the proverbial elephant, theorists have approached patent law with the needs and characteristics of particular industries in mind, and have developed a general theory of patent law based on an understanding of innovation that is industry-specific and, therefore, necessarily incomplete. Part II will show how various different theories of patent law succeed in explaining the application of patent law to particular industries but fail when applied outside the narrow context of those industries.

The fact that economic evidence, patent doctrine, and legal theory all vary by industry leads us to question whether patent law should explicitly attempt to tailor protection to the needs of specific industries, as many have suggested. We point out a number of risks inherent in such a technology-specific approach, particularly as it has been applied in the legislature. These risks suggest that policy-makers should be cautious about trading our uniform patent system for an industry-specific one. In particular, concerns about rent seeking and the inability of industry-specific statutes to respond to changing circumstances will lead us to conclude in Part II

⁵ One judge, Judge Randall Rader, has begun to recognize what is occurring. See, e.g., *Moba, B.V. v. Diamond Automation*, 325 F.3d 1306 (Fed. Cir. 2003) (Rader, J., concurring) (noting the industry-specific nature of written description doctrine).

⁶ See Burk & Lemley, *Technology Specific*, *supra* note 4, at 1190–96 (suggesting this explanation).

that we should not jettison our nominally uniform patent system in favor of specific statutes that protect particular industries.

Nonetheless, there are other ways the law can take account of the needs of different industries. In Part III, we will argue that it makes sense to take economic policy and industry-specific variation into account explicitly in applying general patent rules to specific cases. Precedent set by the Supreme Court in the landmark case, *Diamond v. Chakrabarty*, places with the courts the responsibility of adapting the patent statute to evolving technologies.⁷ Patent law gives the courts substantial freedom to do this by means of flexible legal standards we call “policy levers.” Part III will identify ten sets of policy levers that already exist in patent law, and the ways in which they implicitly or explicitly permit the courts to take account of different types of innovation in different industries. Some of these levers operate at an industry-wide or “macro” level, treating different industries differently as a whole. Other levers work at a case-by-case “micro” level, treating some kinds of inventions differently than others without explicit regard to industry, but in a way that has disproportionate effects on certain industries. We will also identify a variety of other places where the statute grants the courts substantial discretion, and we will suggest ways that those discretionary standards could serve as policy levers.

Unfortunately, while the patent statute leaves ample room for courts to consider the needs of particular industries, the Federal Circuit has proven somewhat reluctant to embrace its role in setting patent policy. Not only has it proven unwilling to pay much attention to the empirical evidence about innovation, but it has also taken a number of steps toward eliminating the flexible standards of the patent common law in favor of bright-line rules. We will argue in Part III that eliminating policy levers needlessly discards a valuable opportunity to optimize patent law. Further, the Federal Circuit has, whether consciously or not, been applying industry-specific legal rules for some time—and getting the rules wrong. We will argue that courts are much better off setting policy consciously and correctly than accidentally and haphazardly.

⁷ See 447 U.S. at 303 (extending patent law to cover living organisms and any other subject matter made by humans).

Finally, in Part IV, we will move from our general discussion of policy levers to a specific discussion of their applications in various settings. Having identified certain policy levers and the method of their employment, we will consider the economic characteristics of innovation in five different industries that appear to be likely candidates for industry-specific rules: chemistry, pharmaceuticals, biotechnology, semiconductors, and software. Drawing on the framework developed in the previous Sections, we will offer concrete suggestions as to how the court can and should apply particular policy levers to help encourage innovation in these very different industries.

I. HETEROGENEITY IN INNOVATION AND PATENT LAW

There is virtually unanimous agreement that the purpose of the patent system is to promote innovation by granting exclusive rights to encourage invention. The standard account of the patent system recounts how such exclusive rights address the public goods nature of inventions that are expensive to produce but easy to appropriate. The consensus position has been that such legal restraints on patentable inventions are justifiable if they offer a net benefit to society, trading the disutility of restricted output and higher prices for the greater social utility of inventions that might otherwise not be produced. There is no unanimity, however, about whether the patent system actually succeeds. Among legal and economic theorists, the patent system has staunch defenders,⁸ vocal critics,⁹ and those who cannot decide whether the system is good or bad.¹⁰ Both

⁸ See, e.g., Gerald J. Mossinghoff & Vivian S. Kuo, *World Patent System Circa 20XX, A.D.*, 38 *IDEA* 529, 529 (1998) (discussing the importance of global patent protection).

⁹ See, e.g., John H. Barton, *Reforming the Patent System*, 287 *Sci.* 5460 (2000); Daryl Lindsey, *The AIDS-Drug Warrior*, at <http://archive.salon.com/news/feature/2001/06/18/love/> (discussing views of Jamie Love) (June 1, 2001) (on file with the Virginia Law Review Association).

¹⁰ See, e.g., Staff of Subcomm. on Patents, Trademarks, and Copyrights of the Senate Comm. on the Judiciary, 85th Cong., *An Economic Review of the Patent System: Study No. 15*, at 76–80 (Comm. Print 1958) (prepared by Fritz Machlup) (concluding that if we did not have a patent system, it would be irresponsible to create one, but that since we have one, it would be irresponsible to eliminate it); cf. George L. Priest, *What Economists Can Tell Lawyers About Intellectual Property: Comment on Cheung*, 8 *Res. L. & Econ.* 19, 24 (1986) (concluding that economists can tell lawyers essentially nothing about intellectual property).

defenders and critics of the system seem to have adopted their positions about the patent system's merits or demerits as articles of faith rather than as conclusions drawn from hard evidence.

This situation has slowly begun to change. In the last twenty years, legal and economic scholarship has provided valuable evidence about the complex process of innovation and how the patent system affects innovation. Rather than resolve the debate over how well the patent system works, however, this evidence has painted a more complex picture.¹¹ Different industries vary greatly in how they approach innovation, the cost of innovation, and the importance of innovation to continued growth. For innovation, one size definitely does not fit all. This observation is graphically illustrated by examples from several industries, whose characteristics we sketch here and will develop further in Part IV below.

A. The Industry-Specific Nature of Innovation

The industry-specific components of innovation fall into several categories. First, the cost of R&D varies widely from industry to industry and from innovation to innovation. Some inventions are accidental or the result of a flash of insight and require essentially no research budget.¹² Others require years of work by large teams of scientists methodically trying different approaches to a problem. While there are examples of both types of inventions in many industries,¹³ some industries spend significantly more on R&D than others. In the pharmaceutical industry, for example, the R&D, drug design, and testing of a new drug can take a decade or more and cost, on average, hundreds of millions of dollars.¹⁴ Some of this

¹¹ See generally Brett Frischmann, *Innovation and Institutions: Rethinking the Economics of U.S. Science and Technology Policy*, 24 Vt. L. Rev. 347, 351 (2000) (arguing that innovation is more complicated than traditionally understood by policy makers).

¹² Even in such a case, however, the invention requires that the researcher be in a position both to think of and to appreciate the invention. Frequently, such a scientist will be part of a larger R&D project.

¹³ For example, in the field of chemistry, many patents result from programmed research, while others (like the patent for the Post-It Note, U.S. Patent No. 5,153,041 (1992)) are serendipitous.

¹⁴ The precise statistics are disputed. See *infra* notes 130–33, 383. Part of the dispute centers on what components of cost should be included. The pharmaceutical industry tends to include marketing costs, which can be substantial and which do not really count as innovation-related expenditures.

cost is a result of the labyrinthine regulatory process and the detailed study that is required to sell a drug for consumption by humans. A major additional part of the cost stems from the uncertainty of the R&D efforts. Pharmaceutical companies may try hundreds of compounds before identifying a possible drug, and they may not know for years whether they have chosen the right one for testing.

Another example is found in the semiconductor industry. As microprocessors have gotten smaller, their design as well as the facilities and processes needed to create them have grown exponentially more complex. Designing a new microprocessor requires not only painstaking work on circuit design—work that can cost tens of millions of dollars—but also the design and construction of an entirely new fabrication process in a new facility. The need for both highly skilled labor and a dedicated physical plant makes microprocessor development highly resource intensive. Ultimately, the design of a new generation of microprocessor takes years of planning and construction and can cost more than four billion dollars.¹⁵

By contrast, other industries require significantly less investment in R&D. In the computer industry, for example, it has long been possible for two programmers working in a garage to develop a commercial software program.¹⁶ While the cost of writing code has gone up in recent years, particularly for operating systems,¹⁷ it is still possible to hire a team of programmers to write a new applications program in many cases for less than a million dollars. While

¹⁵ See, e.g., Katherine Derbyshire, *Building a Fab—It's All About Tradeoffs*, 3 *Semiconductor Mag.*, (June 2002), at <http://www.semi.org/web/wmagazine.nsf/4f55b97743c2d02e882565bf006c2459/e0137dd2c4442ff988256bce007eecca!OpenDocument> (on file with the Virginia Law Review Association) (time); Mark LaPedus, *Leading-Edge Fab Costs Soar to \$4 Billion*, <http://www.siliconstrategies.com/story/OEG20030310S0067> (Mar. 10, 2003) (on file with the Virginia Law Review Association) (cost); see also Steve Lohr, *World-Class Chip, but a Fragile Business*, N.Y. Times, Aug. 4, 2003, at C1 (noting that fabs cost two to three billion dollars each).

¹⁶ Indeed, Steve Jobs and Steve Wozniak are famous for having started Apple Computer in a garage, and Bill Hewlett and David Packard for starting Hewlett-Packard in a garage. Michael Dell started Dell Computer from his college dorm room. See Michael S. Dell & Patricia R. Olsen, *Executive Life: The Boss; More Fun Than School*, N.Y. Times, Mar. 9, 2003, at B12.

¹⁷ Operating systems tend to be more complex than applications programs, because they must be written to run a variety of computer programs and to control various hardware devices.

debugging a new program is still a significant undertaking, writing such a program takes considerably less time than developing a new drug or producing a computer chip.

In software and in many other industries, particularly biotechnology and the manufacture of machines and consumer products, much of the innovation process has been automated in the last fifteen years. While computer-assisted design and manufacturing tools ("CAD/CAM") do not replace the need for innovative ideas, they make the process of prototyping and testing those ideas much easier and faster. Similarly, powerful bioinformatics databases and the development of mass-production techniques like polymerase chain reaction ("PCR") have revolutionized the biotechnology industry, making the identification of gene sequences and the development of related therapies much cheaper and quicker than they were in preceding decades. The use of automated tools that actually generate sections of code to help design simple programs such as web sites has made computer programming simpler.¹⁸ The result of this increased simplicity is that industries in which innovation was largely an iterative process of optimizing prototypes today require less R&D expenditure than those that require either live testing or a new manufacturing process. The systematic variation in R&D expenditures across industries naturally affects the need for patent protection; industries that must spend more time and money in R&D generally have a greater need for patent protection.

Economic evidence has also shown industry-specific variation in the corporate nature of innovation. The prototypical innovation contemplated by the patent law is made by an individual inventor working in his garage after hours. Alexander Graham Bell is in many ways the icon of the patent system.¹⁹ By contrast, innovation in most industries today is generally collaborative, and much of it requires large laboratories. The role of individual inventors is much greater in some industries, such as mechanics and software,

¹⁸ Cf. Mark A. Lemley & David W. O'Brien, Encouraging Software Reuse, 49 *Stan. L. Rev.* 255 (1997) (arguing that this is not always the case).

¹⁹ Vestiges of the patent law's focus on individual inventors can be found in the rule that patents can issue only in the names of individuals, not companies, 35 U.S.C. § 118 (2000), and in the different response to individual and corporate excuses for delay in reducing an invention to practice. See *Griffith v. Kanamaru*, 816 F.2d 624 (Fed. Cir. 1987).

than in others, like biotechnology and semiconductors.²⁰ Not surprisingly, corporate innovation tends to cost more than innovation by individuals.

The importance of patent protection is not simply a linear function of R&D cost, however. Rather, it is dependent on the ability of an inventor to appropriate the returns from her invention through means other than patent law. Appropriability is itself an amalgam of a complex set of variables, many of which are themselves industry-specific. One such variable is the cost and speed of imitation. Some products disclose their know-how on their face; a seller of such a product necessarily gives its competitors information on how to imitate the product.²¹ Other inventions may be more effectively concealed within a product. Even if the product clearly contains the invention—if the results are visible, for example—competitors may face an arduous and uncertain process of reverse-engineering in order to discover how the invention works. Some software inventions have this character, for instance. The standard example of such an invention is the formula for Coca-Cola, which has not been successfully reverse-engineered by competitors despite repeated efforts. Process as opposed to product inventions may be even easier to protect without patent protection, because competitors have no legal opportunity to observe the process even once it is in use. Trade secret law may provide ample protection in such a case. Indeed, survey evidence from R&D managers across a range of industries shows that some industries rely more heavily on trade secrets than on patents to protect their innovation, particularly the chemical industry, which emphasizes process innovation.²²

²⁰ See, e.g., John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 *Vand. L. Rev.* 2099, 2117, 2128–30 (2000) (finding that the number of patents owned by individuals and small entities, and the number of inventors on each patent, varied significantly from industry to industry). [hereinafter Allison & Lemley, *Who's Patenting What?*].

²¹ See, e.g., Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 *Colum. L. Rev.* 2308 (1994) (discussing how certain types of software innovations are disclosed on the face of the product and are therefore easy to imitate, and arguing that new legal regimes are needed to protect such innovations).

²² Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 *Brookings Papers on Economic Activity* 783, 794–95.

A more refined measure, then, might be the ratio of R&D cost to imitation cost.²³ If imitation is impossible even in the absence of patent protection, there is little need for the incentives patents provide.²⁴ Even assuming imitation is possible, if it is sufficiently expensive or time consuming the inventor may be able to make enough money to justify the cost of R&D. Whether this will be true depends on the time and cost of imitation—factors that are likely to differ by invention and by industry—as well as on the importance of first-mover advantages in an industry.²⁵ In some industries, being first to market is critically important, either because it allows the first entrant to establish strong brand recognition or because network effects reward those who are first to build a customer base.²⁶ In those industries, even a modest amount of lead time re-

²³ See also Michael W. Carroll, *The Uneasy Case Revisited: A Sectoral Approach to Intellectual Property* 29 (2003) (working paper, on file with the Virginia Law Review Association) (adopting a similar measure).

²⁴ Even in such a case, patent law would sometimes provide more protection than trade secret law because a patent forbids even independent discovery by a competitor. But it does not follow that patents would be optimal for society in such a case. Preventing independent discovery is a side effect of the patent system, not its goal.

²⁵ Innovators who are first to market often enjoy substantial advantages over later imitators even when access is not physically, electronically, or legally restricted. This first mover advantage is not premised on any direct effort to restrict access to proprietary information; it results from practical limitations on access and delays associated with incomplete knowledge. Empirical data shows that such first mover advantages function as innovation incentives. For example, one study of large corporations in various industries concluded that head start advantages, including the establishment of production and distribution facilities, were more effective than the use of patents in enabling firms to reap returns from innovation. Levin et al., *supra* note 22, at 815–16 (concluding that the patent system and related institutions “improve the appropriability of returns from innovation,” but “are not the only nor necessarily the primary barriers that prevent general access to what would otherwise be pure public goods”). See also Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *Mgmt. Sci.* 173, 176–77 (1986) (examining the extent to which various firms and industries rely on the patent system to protect their innovations). In fact, Nancy Dorfman argues that the first mover advantage has been the primary reason for innovation in the computer hardware and semiconductor industries. See Nancy S. Dorfman, *Innovation and Market Structure: Lessons from the Computer and Semiconductor Industries* 235–39 (1987).

²⁶ For literature on network effects, see generally Joseph Farrell & Garth Saloner, *Standardization, Compatibility, and Innovation*, 16 *RAND J. Econ.* 70, 70 (1985) (discussing “whether . . . standardization benefits can ‘trap’ an industry in an obsolete or inferior standard”); Michael L. Katz & Carl Shapiro, *Network Externalities, Competition, and Compatibility*, 75 *Am. Econ. Rev.* 424 (1985) (using oligopoly models to understand markets with network externalities); Michael L. Katz & Carl Shapiro, *Sys-*

sulting from the cost of imitation may provide enough incentive to innovate.

Another significant factor affecting the importance of patent protection in an industry is the availability of alternative incentives to create. Intellectual property promises a market-based reward for creativity, but it is not the only possible *ex post* reward system.²⁷ Inventors may be motivated by the prospect of prestige among peers, by prizes (such as the Nobel) based on inventive activity, or by the academic rewards of promotion and tenure. They may also be motivated by the desire to do good, particularly in fields like medicine, or by the love of science.²⁸ Indeed, it seems clear that at least some innovation would continue in the absence of any patent protection.²⁹

In addition to *ex post* rewards for successful innovation, a number of *ex ante* subsidies to support R&D exist. Government agen-

tems Competition and Network Effects, 8 J. Econ. Persp. 93 (1994) (examining behavior and performance of public and private institutions in systems markets); Mark A. Lemley & David McGowan, Legal Implications of Network Economic Effects, 86 Cal. L. Rev. 479, 479 (1998) (examining network theory in the context of "antitrust law, intellectual property law, telecommunications law, Internet law, corporate law, and contract law") [hereinafter Lemley & McGowan, Networks]; S.J. Liebowitz & Stephen E. Margolis, Network Externalities: An Uncommon Tragedy, 8 J. Econ. Persp. 133 (1994) (arguing that the concept of network externalities as market failures is questionable).

²⁷ Indeed, there is a significant literature on the economic value of rewards rather than intellectual property rights. See, e.g., Michael Abramowicz, Perfecting Patent Prizes, 56 Vand. L. Rev. 115 (2003) (advocating a reward system to complement existing intellectual property protection); Steven Shavell & Tanguy van Ypersele, Rewards Versus Intellectual Property Rights, 44 J.L. & Econ. 525 (2001) (concluding that an optimal reward system is more effective than intellectual property rights). Rebecca Eisenberg and others have explored in detail the tension between the system of reputational rewards and that of intellectual property rights in the scientific research community. See Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 Yale L.J. 177 (1987).

²⁸ See, e.g., Robert P. Merges et al., Intellectual Property in the New Technological Age 10-18 (3d ed. 2003) (discussing such incentives).

²⁹ Nineteenth-century experiments by Switzerland and the Netherlands in eliminating patent protection confirm that innovation will occur even in the absence of patents, though the evidence is mixed on the success of these experiments. See Eric Schiff, Industrialization Without National Patents: The Netherlands 1869-1912, Switzerland 1850-1907, at 40-41 (1971); Fritz Machlup & Edith Penrose, The Patent Controversy in the Nineteenth Century, 10 J. Econ. Hist. 1, 1-6 (1950). For a discussion of the history of arguments for patent abolition, see Mark D. Janis, Patent Abolitionism, 17 Berkeley Tech. L.J. 899 (2002).

cies such as the National Science Foundation and the National Institutes of Health spend billions of dollars funding R&D; universities spend even more.³⁰ These rewards and subsidies encourage R&D even in the absence of patent protection. There is good reason to believe that the effects of these alternative incentives vary by industry. The government spends far more on health-related research than on semiconductor or software R&D, for example.³¹ As a result, the amount of nonpatent incentives to innovate varies by industry.

Related to innovation incentives is the question of positive externalities or “spillovers.” In some industries, innovation by one firm may leak out to others, naturally subsidizing the productivity of other firms without direct governmental intervention. It is well established that the social returns to innovation exceed the private returns.³² In part, this is because the benefits of innovation “spill over” to other firms in ways that cannot be fully internalized. Important recent work by Dietmar Harhoff has demonstrated that the

³⁰ The National Institutes of Health spent approximately \$21.6 billion to support research in fiscal year 2002 (an estimate based on ninety-three percent of the total budget of \$23.2 billion being spent for research). See Nat'l Insts. of Health, Summary of the FY 2004 President's Budget, Feb. 3, 2003, available at <http://www.nih.gov/news/budgetfy2004/fy2004presidentsbudget.pdf> (on file with the Virginia Law Review Association). The ninety-three percent statistic is based on Nat'l Inst. of Health, Setting Research Priorities at the National Institutes of Health, Figure 1 at <http://www.nih.gov/about/researchpriorities.htm>, (June 18, 2003) (on file with the Virginia Law Review Association). Universities spend about thirty billion dollars in direct research support, see Science and Engineering Indicators—2002, at app. tbl.4-4, <http://www.nsf.gov/sbe/srs/seind02/append/c4/at04-01.xls> (Apr. 2002) (on file with the Virginia Law Review Association), as well as other forms of indirect research support, such as faculty salaries.

³¹ Indeed, unlike governmental funding of biomedical research, governmental forays into research subsidies for technologies such as semiconductors have been notably unsuccessful. Consortia like Sematech, founded in the 1980s to help the U.S. semiconductor industry stay competitive in the international environment, have not generated substantial new innovations, and in the meantime the U.S. semiconductor industry did quite well on its own. See Elias G. Carayannis & Jeffery Alexander, Revisiting SEMATECH: Profiling Public and Private Sector Cooperation, 12 Eng. Mgmt. J. 3342 (2000) (discussing the resurgence of the U.S. semiconductor industry and noting that “it is still difficult to identify any ways in which SEMATECH may have supported the renewal of the U.S. semiconductor industry”).

³² See Morton I. Kamien & Nancy L. Schwartz, *Market Structure and Innovation* (1982).

level of these spillovers also varies by industry.³³ Further, he shows that sector-specific productivity is directly and positively related to the level of spillover.³⁴ In other words, the inherent “leakiness” of intellectual property law has a positive effect on innovation in some, but not all, industries. Relatedly, Ashish Arora and others argue that the “patent premium”—the additional payoff to a private firm of patenting an invention—has a differential effect on R&D in different industries. They find that increasing patent protection gives a substantial boost to R&D in drugs and biotechnology but leads to much less additional innovation in other fields such as electronics and semiconductors.³⁵

Finally, industries differ in the importance of continued innovation. Innovation is, in general, socially valuable. In many industries, especially young ones, innovation is critical to welfare. But innovation may also impose costs. It may inhibit standardization, and therefore slow product adoption in a network market.³⁶ Innovation in interrelated fields such as computer software may affect product stability, since each new component can interact in unpredictable ways with existing components. And innovation in the biomedical fields, while critical to human health, also poses concerns for health and safety until the long-term effects of new drugs can be determined. Each of these concerns is industry-specific.

In short, innovation differs by industry in a variety of ways. Each distinct technology displays an idiosyncratic profile of technical and economic determinants for research, development, and return on investment. Given this, there is no *a priori* reason to believe that a single type of legal incentive will work best for every industry. Indeed, there is every reason to believe that achieving optimal

³³ Dietmar Harhoff, R&D Spillovers, Technological Proximity, and Productivity Growth—Evidence from German Panel Data, 52 *Schmalenbach Bus. Rev.* 238 (2000) (on file with the Virginia Law Review Association); accord Ruslan Lukach & Joseph Plasman, Measuring Knowledge Spillovers Using Patent Citations: Evidence from the Belgian Firm's Data (CESifo, Working Paper No. 754, 2002).

³⁴ Harhoff, *supra* note 33, at 238.

³⁵ Ashish Arora et al., R&D and the Patent Premium 1, 33 *tbl.4* (2002) (working paper, on file with the Virginia Law Review Association).

³⁶ See, e.g., David Dranove & Neil Gandal, The DVD v. DIVX Standard War: Empirical Evidence of Network Effects and Preannouncement Effects, 12 *J. Econ. & Mgmt. Strategy* (forthcoming fall 2003), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=361041 (providing evidence that consumers delayed purchasing digital video players because of a standards competition).

innovation in different industries will require greater or lesser measures of legal incentive, and in some cases perhaps even no legal incentive at all. The ability of the patent system to accommodate these different needs is the subject of the next Section.

B. The Industry-Specific Nature of the Patent System

The relationship between patents and innovation is at least as complex as the profile of technological and economic factors that determine innovation. There is no simple or universal correlation between the availability of patents and the incentive to innovate. This is due in part to the fact that the patent system interacts with industries at several different points in the innovation process. Recent evidence has demonstrated that this complex relationship is also industry-specific at each stage of the patent process: deciding to seek protection, obtaining a patent, setting the scope of the patent that results, deciding to enforce a patent, and determining litigation outcomes.

Companies in different industries vary widely in the importance they attribute to patents and in the cost and effort they expend to obtain them. Major cross-sectoral studies by Richard Levin and Wesley Cohen have shown that some industries rely more than others on patents to appropriate the returns from innovation.³⁷ This self-reported data is bolstered by evidence suggesting that start-ups in certain industries, most notably biotechnology, spend far more of their budgets on patents than companies in other industries.³⁸

Industry-specific variation continues when companies choose to apply for patents. John Allison and Mark Lemley studied the pat-

³⁷ 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. Res., Working Paper No. W7552, 2000); Levin et al., *supra* note 22, at 784–86. Both studies surveyed technology managers at companies in different industries, seeking evidence about why they innovate. Both studies found that patents play a major role in supporting innovation in only a few industries, most notably in chemistry and pharmaceuticals. See also Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. Pa. L. Rev. 761, 826–27 (2002) (arguing that weakening patents would damage some industries but not others).

³⁸ One venture capitalist with whom we spoke estimated that his biotechnology companies spent five to ten percent of their total budget on patent protection. See also Orton Huang et al., *Biotechnology Patents and Startups* para. 1 (2003) (unpublished manuscript, on file with the Virginia Law Review Association) (“[P]atents are absolutely essential to the success of traditional biotech startups.”).

ent prosecution process and found that it varied dramatically from industry to industry.³⁹ They concluded:

The U.S. patent prosecution system is not unitary. Rather, different entities experience very different sorts of patent prosecution. For example, chemical, pharmaceutical, and biotechnological patents spend much longer in prosecution than other types of patents. Chemical, medical, and biotechnological patents cite much more prior art than other patents, and are abandoned and refiled much more frequently. . . .

These differences suggest that it is unwise to think of prosecution as a whole when setting patent policy. Objections and proposals for reform that are tailored to the needs of one industry may not fit another well at all.⁴⁰

In a further work, Allison and Lemley determined that this heterogeneity in the patent prosecution process is a recent development. They found that the patent prosecution system was largely unitary in the 1970s, but that by the 1990s, different industries experienced the patent system in fundamentally different ways.⁴¹ Getting a patent is quicker, cheaper, and easier in some industries than in others.

The effective scope of patents that do issue also varies tremendously by industry. This variance results from the relationship between a patent and a product. In some industries, such as chemistry and pharmaceuticals, a single patent normally covers a single product. Much conventional wisdom in the patent system is built on the unstated assumption of such a one-to-one correspondence. For example, we speak of patents covering products and measure damages by the profits lost in the sale of infringing products. Such a correspondence is the exception rather than the rule, however. Machines of even moderate complexity are composed of many different pieces, and each of these components can itself be the subject of one or more patents. No inventor could patent a modern

³⁹ Allison & Lemley, *Who's Patenting What?*, *supra* note 20, at 2124–32.

⁴⁰ *Id.* at 2146–47.

⁴¹ See John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. Rev. 77, 78–81 (2002) [hereinafter Allison & Lemley, *Complexity*].

car, for instance. Rather, they would be required to patent a particular invention—say, intermittent windshield wipers⁴²—that is only one small piece of a much larger product. In industries like semiconductors, new products are so complex that they can incorporate hundreds and even thousands of different inventions—inventions frequently patented by different companies. A patent covering one of those hundreds of components will not effectively protect a product; it is useful, if at all, only as a licensing tool. Some patents present the opposite problem. If products change fast enough, a single patent right that lasts twenty years from the filing of a patent application may cover not just one product but several different generations of products. For obvious reasons, the value of a patent in encouraging R&D will vary depending both on how easy it is to get that patent and on how much protection that patent gives to products that are sold for revenue in the real world.⁴³

Who owns patents also varies from industry to industry. Allison and Lemley find that individual inventors and small companies are much more likely to own patents in certain industries—notably mechanics and medical devices—than in other, “higher technology” industries, such as biotechnology or semiconductors.⁴⁴ And Kimberly Moore has shown that foreign patentees are more likely to own chemical, electronics, and mechanical patents than pharmaceutical patents.⁴⁵ These differences are important not only because they show variation in the corporate structure of innovation across industries, but also because recent studies have demonstrated that individual inventors and small companies are much more likely to enforce their patents,⁴⁶ while foreign owners are much less likely to do so.⁴⁷

⁴² See *Kearns v. Gen. Motors Corp.*, 152 F.3d 945 (Fed. Cir. 1998) (unpublished decision).

⁴³ See, e.g., Deepak Somaya & David J. Teece, *Combining Inventions in Multi-Invention Products: Organizational Choices, Patents, and Public Policy* (2000) (working paper, on file with the Virginia Law Review Association) (discussing the component nature of innovation as a factor affecting patent value). We discuss the economic significance of these differences in more detail in Part II.

⁴⁴ Allison & Lemley, *Who's Patenting What?*, *supra* note 20, at 2128.

⁴⁵ Kimberly A. Moore, *Xenophobia in American Courts: An Empirical Study of Patent Litigation*, 97 Nw. U. L. Rev. 1497 (forthcoming summer 2003).

⁴⁶ See, e.g., John R. Allison et al., *Valuable Patents*, 92 Geo. L.J. (forthcoming Jan. 2004) (on file with the Virginia Law Review Association) (finding that large compa-

Heterogeneity is also evident in the enforcement of patents. While the basic theory of patent law posits that a patent's value lies in the patentee's enforcement of the right to exclude competitors, or at least to compel a license fee, recent work makes it abundantly clear that most patents are never enforced,⁴⁸ and offers a variety of alternative ways in which patents might contribute value to their owners.⁴⁹ The decision to enforce a patent—and hence to make the intended use of patents—is far more likely to occur in some industries than in others. For example, one study found that patentees in the medical device and software industries are far more likely to bring suit than patentees in other industries, such as chemistry or semiconductors.⁵⁰ Patents in these other industries presumably have some value to their owners (at least potential value *ex ante*), but that value appears to lie in signaling or defensive use rather than in excluding competitors or demanding licenses. Similarly, Ashish Arora has found that markets for patent licensing are more likely to develop under some industry structures than others.⁵¹ And Michael Meurer has argued that opportunistic patent litigation by

nies obtain seventy-one percent of all patents but file only thirty-seven percent of patent infringement lawsuits).

⁴⁷ See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 224–25 (1998) [hereinafter Allison & Lemley, *Empirical Evidence*]; Moore, *supra* note 45.

⁴⁸ Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1501 (2001) (citing data showing that only two percent of all patents are ever litigated, and less than 0.2% reach the courtroom) [hereinafter Lemley, *Rational Ignorance*].

⁴⁹ See *id.* at 1503–06 (discussing trophy value and defensive uses); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. Small & Emerging Bus. L. 137 (2000) (discussing value of patents in obtaining venture capital); Clarisa Long, *Patent Signals*, 69 U. Chi. L. Rev. 625 (2002) (examining patents as signaling mechanisms).

⁵⁰ See Allison et al., *supra* note 46 (comparing litigated to issued patents and finding systematic variation by industry in the likelihood that patents will be litigated, a variation so great that patentees in other industries are three times as likely as semiconductor patentees to file suit); see also Jean Olson Lanjouw & Mark A. Schankerman, *Characteristics of Patent Litigation: A Window on Competition*, 32 RAND J. Econ. 1 (2000) (finding that pharmaceutical patents are more likely to be litigated than other types of patents but, using a coarser measure, finding somewhat different results regarding specific industries than Allison et al., *supra* note 46). It is worth noting, however, that even in the most litigation-intensive industries only a very small fraction of patents are ever litigated.

⁵¹ Ashish Arora et al., *Markets for Technology* (2001).

nonmanufacturing “trolls” seeking to extract royalties is more common in some industries than others.⁵²

Finally, in the few cases in which patents are litigated to judgment, the law increasingly treats patents from different industries differently.⁵³ The most striking examples arise in biotechnology and computer software. In biotechnology cases, the Federal Circuit has gone to inordinate lengths to find biotechnological inventions nonobvious, even if the prior art demonstrates a clear plan for producing the invention. At the same time, the court has imposed stringent enablement and written description requirements on biotechnology patents that do not appear in its jurisprudence regarding other technologies. In computer software cases, the situation is reversed. The Federal Circuit has essentially excused software inventions from compliance with the enablement and best mode requirements, but in a manner that raises serious questions about how stringently it will read the nonobviousness requirements.⁵⁴

These categorical differences in the legal treatment of patents do not simply affect the validity of particular patents in particular industries. Patent scope is necessarily interrelated with obviousness and enablement.⁵⁵ The breadth of patent protection is in part a function of how different the invention is from the prior art; lowering the obviousness threshold and granting many different patents may actually constrain the freedom of patentees to operate.⁵⁶ Further, patent claims are invalid if they are not fully described and enabled by the patent specification, so the permissible breadth of a

⁵² Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. Rev. 509, 542 (2003).

⁵³ We demonstrate this in exhaustive detail in Burk & Lemley, *Technology-Specific*, *supra* note 4.

⁵⁴ See *id.* at 1160–73.

⁵⁵ See Donald S. Chisum, *Anticipation, Enablement and Obviousness: An Eternal Golden Braid*, 15 AIPPLA Q.J. 57, 58 (1987). Because a patentee can capture later-developed technologies under the doctrine of equivalents but cannot capture inventions in the prior art, the functional scope of a patent is more closely tied to obviousness than to enablement.

⁵⁶ See John R. Thomas, *Formalism at the Federal Circuit*, 52 Am. U. L. Rev. 771, 773 (2003) (“A lenient view of nonobviousness is ordinarily seen as inventor-friendly and pro-patent. But this trend allows the patenting of marginal inventions, increasing the possibility that primary inventors will have to share the rewards of their pioneering inventions with follow-on inventors of improvements.”) [hereinafter Thomas, *Formalism*].

patent will be determined by how much information the court determines must be disclosed to enable one of ordinary skill in the art to make and use the patented invention. The range of claim equivalents is also a function of obviousness and enablement, since a patentee is not permitted to capture claim scope under the doctrine of equivalents that she would not have been permitted to capture at the time of prosecution.⁵⁷

The Federal Circuit's treatment of software validity issues implies that while the court will find relatively few software patents nonobvious, those that it does approve will be entitled to broad protection. The Federal Circuit's decisions strongly suggest that a patent is nonobvious only if it is the first program to perform a given function.⁵⁸ Of course, most patents will not meet this test. Those that do, however, will not be constrained by prior art to claim only their particular implementation of a function. They can claim the function itself. The fact that they give little or no description of how to achieve this function will not bar the broad claims because the Federal Circuit has proven remarkably unwilling to require software patentees to disclose details. As a result, "we should expect the first programmer to implement a new idea in software to encompass the entire category of software, regardless of how second-comers actually implement the same concept."⁵⁹

The conceptual linkage of obviousness and enablement to the depiction of macromolecular sequences in, respectively, the prior art or the patent disclosure, similarly dictates a predictable result for the availability and scope of biotechnology patents. The result is the opposite of that in the software cases: DNA patents will be numerous but extremely narrow. Under the Federal Circuit's precedent, a researcher will be able to claim only sequences disclosed under the stringent written description rules—the actual sequence in hand. And as Judge Learned Hand observed long ago, a claim that covers only the thing invented is a weak claim indeed.⁶⁰

⁵⁷ See *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.*, 904 F.2d 677, 684 (Fed. Cir. 1990).

⁵⁸ *Burk & Lemley*, *Technology-Specific*, *supra* note 4, at 1170–71.

⁵⁹ See *id.*

⁶⁰ *Philip A. Hunt Co. v. Mallinckrodt Chem. Works*, 177 F.2d 583, 585–86 (2d Cir. 1949) (noting that it is impossible to write claims of appropriate scope without using functional language to describe variants).

At the same time, the inventor is shielded from obviousness by the lack of such explicit and detailed disclosure in the prior art. This lack of effective prior art seems to dictate that anyone who has isolated and characterized a novel DNA molecule is certain to receive a patent on it. But the inventor is certain to receive a patent only on the particular molecule described, as the Federal Circuit appears to regard other related molecules as inadequately described until their sequence is disclosed.⁶¹

We have shown that innovation occurs differently among different industries and that the law treats innovation differently in the various industries. Importantly, however, the differences in patent protection do not appear to result from any conscious policy choice by Congress, the courts, or the Patent and Trademark Office (“PTO”). As a result, there is no reason to believe that the differences in innovation and in patent doctrine are congruent. Indeed, Part IV shows that they generally are not. The recognition of differences in innovation is important for setting optimal patent policy; we explore this theme in detail in Part III. For now, the basic message of Part I is that it makes little sense to speak generally about innovation or about patents. The evidence is overwhelming that, at virtually every stage of both the innovation and patent processes, different industries have different needs and experience the patent system differently. We turn in Part II to the task of relating this heterogeneity to the theoretical confusion that exists today in patent law.

II. HETEROGENEITY IN PATENT THEORY

Despite a surface commitment to basic normative principles, different theories of patent law offer widely disparate explanations for the role of patents and very different predictions as to their optimal division and scope. In this Part, we review the major theories of patent protection and show how their conclusions are fundamentally at odds with one another. We argue that the only way to reconcile this theoretical literature into an integrated whole is to recognize that every different theorist has a different industry in mind, and that each industry requires a unique form of patent protection.

⁶¹ Burk & Lemley, *Technology-Specific*, *supra* note 4, at 1176–77.

A. The Confusion in Patent Theory

Over a decade ago, John Wiley famously wrote that “the doctrine of patent law coheres while the doctrine of copyright does not.”⁶² His basic premise was economic: Patent law was coherent because it started from a widely-shared utilitarian baseline. Copyright law, by contrast, has produced no similar agreement on goals, with the result that, as Jamie Boyle put it, “in copyright law—to a greater extent than in most other fields of legal doctrine—there is a routine *and acknowledged* breakdown of the simplifying assumptions of the discourse, so that mundane issues force lawyers, judges, and policymakers to return to first principles.”⁶³ Indeed, recent Supreme Court jurisprudence suggests that even though congressional power to create patents arises from the same constitutional clause as the power to create copyrights, copyright and patent can be treated differently under the Constitution.⁶⁴

⁶² John Shepard Wiley, Jr., Copyright at the School of Patent, 58 U. Chi. L. Rev. 119, 119 (1991).

⁶³ James Boyle, Shamans, Software and Spleens 19 (1996).

⁶⁴ See *Eldred v. Ashcroft*, 123 S. Ct. 769, 784–85 (2003) (distinguishing statements in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), that were inconsistent with the Court’s holding in *Eldred*, on the grounds that *Graham* was a patent rather than a copyright case). To be sure, the Court’s rejection of the public interest in *Eldred* runs counter to a large number of prior copyright cases which had emphasized the importance of the public domain in copyright. See, e.g., *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (“The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare”); see also *Fogerty v. Fantasy, Inc.*, 510 U.S. 517, 524 (1994) (“The primary objective of the Copyright Act is to encourage the production of original literary, artistic, and musical expression for the good of the public.”); *Feist Publ’ns v. Rural Tel. Serv. Co.*, 499 U.S. 340, 349 (1991) (stating that the “primary objective of copyright” is to “promote the progress of science and useful arts”); *Stewart v. Abend*, 495 U.S. 207, 228 (1990) (noting the Copyright Act’s “balance between the artist’s right to control the work . . . and the public’s need for access”); *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 167 (1989) (noting the “careful balance between public right and private monopoly to promote certain creative activity”); *Sony Corp. v. Universal City Studios*, 464 U.S. 417, 429 (1984) (stating that the limited monopoly conferred by the Copyright Act “is intended to motivate the creative activity of authors and inventors . . . and to allow the public access to the products of their genius after the limited period of exclusive control has expired”); *Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975) (noting that “private motivation must ultimately serve the cause of promoting broad public availability of literature, music, and the other arts”); *Goldstein v. California*, 412 U.S. 546, 559 (1973) (discussing Congress’s ability to provide for the “free and unrestricted distribution of a writing” if required by the national interest); *Fox Film Corp. v. Doyal*, 286

Thus, Wiley's premise is correct as far as it goes. To a greater extent than any other area of intellectual property, courts and commentators widely agree that the basic purpose of patent law is utilitarian: We grant patents in order to encourage invention.⁶⁵ While there have been a few theories of patent law based in moral right, reward, or distributive justice,⁶⁶ they are hard to take seriously as explanations for the actual scope of patent law. The short term of patent protection,⁶⁷ the broad right to prevent independent development of an idea,⁶⁸ and the control patent law can give over prod-

U.S. 123, 127 (1932) ("The sole interest of the United States and the primary object in conferring the monopoly lie in the general benefits derived by the public from the labors of the authors.").

⁶⁵ See, e.g., Ward S. Bowman Jr., *Patent and Antitrust Law* 2-3 (1973) ("Patent law pursues [efficiency] by encouraging the invention of new and better products."); F.M. Scherer, *Industrial Market Structure and Economic Performance* 440 (Edward Jaffe et al. eds., 2d ed. 1980) (describing the promotion of invention as one of three reasons for granting patent rights); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1024-28 (1989) (describing this theory); John S. McGee, *Patent Exploitation: Some Economic and Legal Problems*, 9 J.L. & Econ. 135, 135-36 (1966) (noting the theory that patents encourage innovation). While there is a second utilitarian justification—encouraging the disclosure of inventions that might otherwise be kept secret—it is clearly subordinate to the primary incentive goals. See Eisenberg, *supra*, at 1028-30 (discussing disclosure theory); Scherer, *supra*, at 440.

⁶⁶ For a discussion of reward-based theories of scientific invention stemming from natural law, see A. Samuel Oddi, *Un-Unified Economic Theories of Patents—The Not-Quite-Holy Grail*, 71 Notre Dame L. Rev. 267, 275-77 (1996); Kevin Rhodes, *Comment, The Federal Circuit's Patent Nonobviousness Standards: Theoretical Perspectives on Recent Doctrinal Changes*, 85 Nw. U. L. Rev. 1051, 1077-84 (1991); cf. Lawrence C. Becker, *Deserving to Own Intellectual Property*, 68 Chi.-Kent L. Rev. 609, 609 (1993) (arguing that desert-based arguments for patent law are intuitively appealing, but do not necessarily justify the scope of current patent doctrine).

⁶⁷ Patent terms extend for no more than twenty years in most cases, 35 U.S.C. § 154(a)(2) (2000), while copyright lasts for the life of the author plus seventy years, 17 U.S.C. § 302(a) (2000), and trademarks can last forever as long as the mark is used in commerce. See James E. Hawes, *Trademark Registration Practice* § 25.17 (2d ed. 2003) ("[T]he life of the trademark is potentially infinite.").

⁶⁸ Patent law confers the broad right to prevent others from making, using, selling, offering for sale, or importing the invention. 35 U.S.C. § 271(a) (2000). Unlike copyright or trade secret law, patent law does not treat independent invention as a defense. See Michelle Armond, *Comment, Introducing the Defense of Independent Invention to Motions for Preliminary Injunctions in Patent Infringement Lawsuits*, 91 Cal. L. Rev. 117 (2003). For proposals that it should do so, see, for example, Stephen M. Maurer & Suzanne Scotchmer, *The Independent Invention Defense in Intellectual Property*, 69 *Economica* 535 (2002); Armond, *supra*, at 117; John S. Liebovitz, *Note, Inventing a Nonexclusive Patent System*, 111 Yale L.J. 2251 (2002).

ucts never built or contemplated by the patent owner⁶⁹ are all difficult to square with the idea that a patentee "deserves" to own the

⁶⁹ This occurs in four basic ways. See Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 *Tex. L. Rev.* 989, 1003-05 (1997) [hereinafter Lemley, *Economics of Improvement*]. First, the scope of a patent is defined by its claims, and a patentee can claim to own a class or genus without having actually built or tested all of the species in that genus. Where a number of materials or devices are substitutable because they have similar characteristics, the patentee may claim the generic class of materials, so long as he describes the general class and its characteristics with sufficient precision that others can identify and use them without "undue experimentation." *Sec id.* at 1003 (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) as one example). Thus, in *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984), the court allowed a patent on explosive compounds made from various salts, fuels, and emulsifiers, where the patentee had listed the ingredients that might be used, but had not given any indication of which combinations would work. Even though du Pont had not tried all of the possible combinations (there were thousands), and in practice forty percent of the combinations tried were inert, the court held that du Pont was entitled to claim the generic group of explosives. Lemley, *Economics of Improvement*, *supra*, at 1003 & nn.60-62 (citing *Atlas Powder*, 750 F.2d at 1576-77).

Second, the doctrine of equivalents provides a means for broadening the scope of a patent beyond the literal language of the claims (and hence beyond the invention originally made by the patent owner). See Lemley, *Economics of Improvement*, *supra* at 1003. The doctrine of equivalents today is an integral part of the infringement analysis of every patent, though the scope and application of the doctrine remain a matter of some dispute. As presently conceived, the doctrine of equivalents provides that the accused products or processes that do not fall within the literal scope of the patent claims nonetheless infringe the patent if they are only "insubstantially different" from the patent claims. The effect is to create a "penumbra" around the literal scope of the claims, and therefore to expand the protection given to patent owners. *Id.* at 1003-04 & n.65 (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39-40 (1997)).

Third, "patent claims may reach new and unanticipated inventions made after the patent issues, but which fall within either the literal language of the claims or the doctrine of equivalents." *Id.* at 1005. An example of the former is *In re Hogan*, 559 F.2d 595 (C.C.P.A. 1977), where the court construed claims to "crystalline polypropylene" to cover forms of crystalline polypropylene not contemplated at the time the application was filed. An example of the latter is *Hughes Aircraft Co. v. United States*, 717 F.2d 1351 (Fed. Cir. 1983). In that case, Hughes held a patent on technology developed in the 1970s for controlling the orientation of a communications satellite by sending control signals from a ground control computer to the satellite. When advances in computer technology allowed the necessary processing power to be installed on the satellite itself, the government began to control its satellites using on-board computers. In Hughes's patent suit against the government, the Federal Circuit held that the government's method of on-board computer control infringed the Hughes patent, even though that patent was based on old technology that required communications from the ground. Lemley, *Economics of Improvement*, *supra*, at 1005 & nn.68-69 (citing *Hughes*, 717 F.2d at 1351). In the *Hughes* case, it is clear that the government's technology represented a significant advance over the technology con-

rights granted by the law. We grant patents in order to promote innovation, and so we should grant patents only to the extent necessary to encourage such innovation.⁷⁰

Agreement on basic utilitarian goals has not, however, translated into agreement on how to implement them. Fundamental disagreement remains regarding the proper scope, availability, and even the need for patents to optimize innovation. The growing body of economic literature on patent theory has developed at least five distinct approaches to the proper scope and allocation of patent rights.⁷¹ These approaches exist in considerable tension. The approaches range from "sole and despotic" control over new inventions, on the one hand, to minimal or no property rights in inventions on the other hand. In between these extremes lie several theories that consider patents as both facilitators of and potential impediments to innovation. The theories make different and conflicting predictions about the effect of patents on industries, and dictate different and conflicting prescriptions for the parameters of patent law. In this Section, we briefly consider each major approach.⁷²

ceived by the patentee. Nonetheless, the patentee was entitled to capture the benefits of these subsequent technological improvements. *Id.*

Finally, the patent law permits inventors to obtain patents based entirely on a written description of the invention, without actually constructing or selling the products embodying the invention. See Julie S. Turner, Comment, *The Nonmanufacturing Patent Owner: Toward a Theory of Efficient Infringement*, 86 Cal. L. Rev. 179 (1998).

⁷⁰ See, e.g., Lawrence Lessig, *Intellectual Property and Code*, 11 St. John's J. Legal Comment. 635, 638 (1996) ("[W]hile we protect real property to protect the owner from harm, we protect intellectual property to provide the owner sufficient incentive to produce such property. 'Sufficient incentive,' however, is something less than 'perfect control.'"). For discussion of the innumerable court decisions, statutory provisions, and commentators discussing this proposition, see Mark A. Lemley, *Romantic Authorship and the Rhetoric of Property*, 75 Tex. L. Rev. 873, 888–90 (1997).

⁷¹ Yusing Ko offered a similar taxonomy in 1992, but without the benefit of some of the more recent theoretical work on the patent system, such as the foundational work on anticommons theory and patent thickets. Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 Yale L.J. 777 (1992). Like ours, Ko's work attempts to derive economic principles specific to the biotechnology industry by analyzing different theories of patent protection. *Id.* at 791–804. She is, in our view, ultimately unsuccessful because she attempts to apply a variety of different theories of patent protection to a single industry when some of them simply do not fit the profile of that industry.

⁷² There are other approaches that do not rise to the level of complete theories of the patent system. See, e.g., Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncer-*

1. Prospect Theory

In 1977, Edmund Kitch offered a new theory of the patent system that, he wrote, would "reintegrate[] the patent institution with the general theory of property rights."⁷³ This prospect theory of intellectual property is rooted in many of the same economic traditions as the classic incentive-to-invent theory, but its focus is not on ex ante incentives to create. Rather, it emphasizes the ability of intellectual property ownership to force the efficient management of inventions and creations through licensing once they are made.⁷⁴ The fundamental economic bases of this approach are the "tragedy of the commons" and the hypothetical Coasean world without transactions costs. The tragedy of the commons is a classic economic story in which people with access to common property overuse it because each individual reaps all of the benefits of his personal use, but shares only a small portion of the costs.⁷⁵ For example, lakes open to the public are likely to be overfished, with negative consequences for the public (to say nothing of the fish!) in future years. Likewise, common fields will be overgrazed with similar unfortunate consequences. Any other exhaustible public resource may be similarly overused.

The conventional economic solution to the tragedy of the commons is to assign resources as private property. If everyone owns a small piece of land (or lake) and can exclude others (with real or legal "fences"), then the private and public incentives are aligned. People will not overgraze their own land because if they do, they will suffer the full consequences of their actions.⁷⁶ Further, if deal-

tainty and Non-Injunctive Remedies, 97 Mich. L. Rev. 985 (1999) (analyzing the role of uncertainty and delay in evaluation of patent incentives).

⁷³ Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & Econ. 265, 265 (1977).

⁷⁴ See *id.* at 276-78; Wendy J. Gordon, *Of Harms and Benefits: Torts, Restitution, and Intellectual Property*, 21 J. Legal Stud. 449, 473-74 (1992); Robert P. Merges, *Of Property Rules, Coase, and Intellectual Property*, 94 Colum. L. Rev. 2655, 2660-61 (1994).

⁷⁵ Garrett Hardin, *The Tragedy of the Commons*, 162 Sci. 1243 (1968).

⁷⁶ While in theory it is possible for cattle owners to agree to limit their grazing in the public interest, any such effort at agreement is likely to run into insurmountable problems. Not only will organizing and policing such an agreement take effort that will not be rewarded, but individual grazers have an incentive to free ride, reaping the benefits of reduced grazing by others while refusing to reduce their own grazing. For more on these problems, see Mancur Olson, Jr., *The Logic of Collective Action: Public Goods*

making between neighbors is costless, as Coase postulated but did not believe,⁷⁷ transactions will allow neighbors with large cattle herds to purchase grazing rights from others with smaller herds. Such transactions should occur until each piece of land is put to its best possible use.⁷⁸

In the context of intellectual property, Kitch's article remains one of the most significant efforts to integrate intellectual property with property rights theory.⁷⁹ Kitch argues that the patent system operates not (as traditionally thought) as an incentive-by-reward system, giving exclusive rights to successful inventors in order to encourage future invention, but as a "prospect" system analogous to mineral claims. In this view, the primary point of the patent system is to encourage further commercialization and the efficient use of as yet unrealized ideas by patenting them, just as privatizing land will encourage the owner to make efficient use of it.⁸⁰ Society as a whole should benefit from this equalization of private with social interests.

Fundamental to this conclusion are three assumptions. First, Kitch postulates that:

and the Theory of Groups (1965). One commentator views this internalization of (positive) externalities as a key function of property. Harold Demsetz, *Toward a Theory of Property Rights*, 57 *Am. Econ. Rev. (Papers and Proc.)* 347, 348 (1967).

On the other hand, for a rejection of the tragedy of the commons approach in certain contexts, see Carol Rose, *The Comedy of the Commons: Custom, Commerce, and Inherently Public Property*, 53 *U. Chi. L. Rev.* 711 (1986). Rose is surely correct that private division of land is not always efficient. Consider the problematic task that walking through your neighborhood would be if every piece of sidewalk were owned by a different person, and you were required to obtain permission to take each step. Cf. Dan Hunter, *Cyberspace as Place and the Tragedy of the Digital Anticommons*, 91 *Cal. L. Rev.* 439, 441–42 (2003) (criticizing the excessive division of rights currently taking place online); Mark A. Lemley, *Place and Cyberspace*, 91 *Cal. L. Rev.* 521, 523 (2003) (same).

⁷⁷ See Ronald H. Coase, *The Problem of Social Cost*, 3 *J.L. & Econ.* 1, 15 (1960).

⁷⁸ See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 *Harv. L. Rev.* 1089, 1094–95 (1972) (discussing this implication of the Coase theorem).

⁷⁹ Edmund W. Kitch, *Patents: Monopolies or Property Rights?*, 8 *Res. L. & Econ.* 31 (1986). For other property-based views of intellectual property, see Kenneth W. Dam, *Some Economic Considerations in the Intellectual Property Protection of Software*, 24 *J. Legal Stud.* 321 (1995); Trotter Hardy, *Property (and Copyright) in Cyberspace*, 1996 *U. Chi. Legal F.* 217.

⁸⁰ Kitch, *supra* note 73, at 270–71, 275 (making the analogy to land explicit).

[A] patent "prospect" increases the efficiency with which investment in innovation can be managed. . . . [T]echnological information is a resource which will not be efficiently used absent exclusive ownership. . . .

. . . [T]he patent owner has an incentive to make investments to maximize the value of the patent without fear that the fruits of the investment will produce unpatentable information appropriable by competitors.⁸¹

This is analogous to the tragedy of the commons argument in that only with private ownership do private incentives match social incentives. In the tragedy of the commons, the private incentive to "invest" in a field—for example by letting it lie fallow, or limiting grazing, in order to permit it to grow—is less than the social value of such an investment. In the patent context, Kitch makes an analogous argument: that the private incentive to improve and market an invention will be less than the social value of such efforts unless the patent owner is given exclusive control over all such improvements and marketing efforts.⁸²

Second, Kitch assumes that:

No one is likely to make significant investments searching for ways to increase the commercial value of a patent unless he has made previous arrangements with the owner of the patent. This puts the patent owner in a position to coordinate the search for technological and market enhancement of the patent's value so that duplicative investments are not made and so that information is exchanged among the searchers.⁸³

The Coase theorem is doing Kitch's work here. Under that theorem, giving one party the power to control and orchestrate all subsequent use and research relating to the patented technology should result in efficient licensing, both to end users and to potential improvers—assuming, that is, that information is perfect, all parties are rational, and licensing is costless.⁸⁴

⁸¹ Id. at 276.

⁸² Id. at 285–86.

⁸³ Id. at 276.

⁸⁴ See Anastasia P. Winslow, Rapping on a Revolving Door: An Economic Analysis of Parody and *Campbell v. Acuff-Rose Music, Inc.*, 69 S. Cal. L. Rev. 767, 780 (1996)

Finally, to maximize social benefit, the property owner must make the invention (and subsequent improvements) available to the public at a reasonable price—ideally, one that approaches marginal cost.⁸⁵ A property owner will have no incentive to reduce his prices toward marginal cost, however, unless he faces competition from others. If the property owner is alone in the market, he may be expected to set a higher monopoly price for his goods, to the detriment of consumers and social welfare. Kitch notes this problem, but does not resolve it. He merely points out that not all patents confer monopoly rights, and that in some cases the creators of intellectual property rights will face competition from the makers of other fungible goods and therefore their individual firm demand curves will be horizontal rather than downward-sloping.⁸⁶ If one assumes such competition, intellectual property owners may be expected to price competitively, just as producers of wheat do.⁸⁷

Kitch's prospect theory strongly emphasizes the role of a single patentee in coordinating the development, implementation, and improvement of an invention. The analogy to mining is instructive: Kitch reasons that if we consolidate ownership in a single entity,

(arguing that the Coase theorem suggests that initial assignment of property rights between original creators and improvers is irrelevant). For a discussion of what happens when we relax these unrealistic assumptions, see Lemley, *Economics of Improvement*, *supra* note 69, at 1048–72. On the importance of efficient licensing to the case for intellectual property protection, see Wendy J. Gordon, *Asymmetric Market Failure and Prisoner's Dilemma in Intellectual Property*, 17 *U. Dayton L. Rev.* 853, 857–58 (1992).

⁸⁵ It is not possible to price intellectual property at its marginal cost and still stay in the business of producing new works, since developing those new works requires a fixed investment of resources (time, research money, etc.) that frequently dwarfs the marginal cost of making and distributing copies of the idea once it has been developed.

⁸⁶ Kitch, *supra* note 73, at 274.

⁸⁷ Kitch is surely correct that the vast majority of intellectual property rights do not confer monopoly power in a relevant economic market. See 1 Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 4.2 (Supp. 2003) [hereinafter 1 Hovenkamp et al., *IP and Antitrust*]. It is equally true, however, that intellectual property rights must confer some power to raise prices above the marginal cost of production if they are to serve their acknowledged primary purpose of encouraging creation. Indeed, the “incentive to manage” argument that Kitch adopts also depends on giving patent owners some measure of power over price; without that power, there could be no incentive. Intellectual property most commonly gives this power by permitting some product differentiation and therefore some increase in price. The price is constrained by competing goods, but those goods are imperfectly competitive and so they don't limit price to marginal cost.

that entity will have appropriate incentives to invest in commercializing and improving an invention.⁸⁸ Indeed, on Kitch's theory one might think it appropriate to assign rights to prospect for inventions to companies even before they have invented anything, just as we do for the owners of prospecting rights, because doing so will give them the monopoly incentive to coordinate the search.⁸⁹

Kitch's prospect theory draws on economic literature in the Schumpeterian tradition, which in its strong form holds that companies in a competitive marketplace have insufficient incentive to innovate. On this view, only strong rights to preclude competition will effectively encourage innovation.⁹⁰ A prospect theory therefore suggests that patents should be granted early in the invention process, and should have broad scope and few exceptions.

2. *Competitive Innovation*

The Schumpeterian monopoly model of innovation has not gone unchallenged. In an influential article, Ken Arrow has argued that competition, not monopoly, best spurs innovation because, to simplify greatly, companies in a competitive marketplace will innovate in order to avoid losing, while monopolists can afford to be lazy.⁹¹

⁸⁸ See Kitch, *supra* note 73, at 271–80.

⁸⁹ Of course, patent law does not pre-assign patent rights, in part because we are unsure whether and when the basic assumptions underlying the prospect theory truly apply to innovation. Critics have charged that early assignment of rights may substantially interfere with downstream innovation, especially if the Coasean model of costless transfer does not apply. Transaction barriers may quickly accrue around exclusive patent rights to create the monopoly problems that Kitch elides. It is generally unclear whether the rationale for coordination and management of exhaustible resources can be sensibly applied to intangible, inexhaustible concepts. We discuss all these problems in more detail elsewhere. See *infra* notes 91–105; Lemley, *Economics of Improvement*, *supra* note 69, at 1048–72.

⁹⁰ The classic argument cited in favor of monopolists coordinating innovation is Joseph A. Schumpeter, *Capitalism, Socialism, and Democracy* 106 (6th ed. 1987) (“[P]erfect competition is not only impossible but inferior . . .”). For an application to patent law, see F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 Minn. L. Rev. 697 (2001); cf. Suzanne Scotchmer, *Protecting Early Innovators: Should Second-Generation Products Be Patentable?*, 27 RAND J. Econ. 322 (1996) (suggesting that incentives be weighted towards pioneers). Schumpeter's conclusions have been challenged, both in theoretical and empirical terms. See discussion *infra* notes 91–98 and accompanying text.

⁹¹ See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *The Rate and Direction of Inventive Activity* 609, 619–20 (Nat'l Bureau of Econ. Research ed., 1962); see also Morton I. Kamien & Nancy L. Schwartz, *Market*

Furthermore, unlike tangible property, information is a public good for which consumption is nonrivalrous—that is, one person’s use of the information does not deprive others of the ability to use it. As a result, there is not likely to be a tragedy of the commons problem.⁹² An idea cannot be overgrazed, because using it will not deplete it. Prospect theory is wrong, on this view, because the only reason we need intellectual property rights is to create *ex ante* incentives, not *ex post* control rights. Arrow’s argument suggests a much more limited role for intellectual property rights. If patents are justified at all on Arrow’s theory, they should be narrowly circumscribed to particular implementations of an invention, and should generally not give the patentee the right to control competition in an economic market.⁹³

Empirical evidence offers some support for Arrow’s thesis. As a descriptive matter, it is clear that the overwhelming number of patents do not confer strong rights in an economic market. Rather, they protect particular ways of competing in the market.⁹⁴ Innova-

Structure and Innovation (1982) (noting that monopolists may reduce R&D expenditures); F.M. Scherer & David Ross, *Industrial Market Structure and Economic Performance* 660 (3d ed. 1990) (criticizing Schumpeter’s “less cautious” followers for advocating monopoly to promote innovation); Mark A. Lemley & Lawrence Lessig, *The End of End-to-End: Preserving the Architecture of the Internet in the Broadband Era*, 48 *UCLA L. Rev.* 925, 960–62 (2001) (arguing that the Internet was as innovative as it was because its architecture required competition rather than monopoly bottlenecks); Howard A. Shelanski, *Competition and Deployment of New Technology in U.S. Telecommunications*, 2000 *U. Chi. Legal F.* 85, 87 (finding that competition was a greater spur to innovation than monopoly in ten empirical studies in the telecommunications industry); Michele Boldrin & David K. Levine, *Perfectly Competitive Innovation*, CPER Discussion Paper No. 3274, (Mar. 2002) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=308040 (working paper, on file with the Virginia Law Review Association) (challenging received wisdom that monopoly through copyright and patent is socially beneficial).

⁹² See, e.g., Yochai Benkler, *Overcoming Agoraphobia: Building the Commons of the Digitally Networked Environment*, 11 *Harv. J.L. & Tech.* 287, 359–60 (1998) (noting that the tragedy of the commons does not apply well to renewable resources); Mark A. Lemley, *Ex Ante versus Ex Post Justifications for Intellectual Property*, 71 *U. Chi. L. Rev.* (forthcoming spring 2004).

⁹³ See Michele Boldrin & David Levine, *The Case Against Intellectual Property*, 92 *Am. Econ. Rev. (Papers & Proc.)* 209, 209 (2002) (arguing that strong intellectual property protection may hurt rather than help innovation).

⁹⁴ See, e.g., Herbert Hovenkamp, *Economics and Federal Antitrust Law* § 8.3, at 219 (1985) (“Many patents confer absolutely no market power on their owners The economic case for ‘presuming’ sufficient market power . . . is very weak.”); 1 Hovenkamp et al., *IP and Antitrust*, *supra* note 87, § 4.2 (suggesting the rarity of situations in

tion still occurs in those markets. Indeed, many have argued that in some industries the freedom from patents is much more important to innovation than the incentive provided by patents.⁹⁵ Some empirical evidence suggests that competition is a better spur to innovation than monopoly in the telecommunications industry.⁹⁶ Wil-

which patents confer market power); Nat'l Inst. on Indus. & Intellectual Prop., *The Value of Patents and Other Legally Protected Commercial Rights*, 53 *Antitrust L.J.* 535, 547 (1985) ("Statistical studies suggest that the vast majority of all patents confer very little monopoly power . . ."); William Montgomery, Note, *The Presumption of Economic Power for Patented and Copyrighted Products in Tying Arrangements*, 85 *Colum. L. Rev.* 1140, 1156 (1985) ("More often than not, however, a patent or copyright provides little, if any, market power.") (quoting F.M. Scherer during panel discussion).

⁹⁵ Lawrence Lessig, *The Future of Ideas: The Fate of the Commons in the Digital World* (2001) (arguing that the commons will best promote innovation on the Internet); cf. Lemley & Lessig, *supra* note 91, at 933–38 (arguing that the open nature of the Internet promoted innovation much better than centralized control by the Bell System). Similar arguments have been made against business method patents. See, e.g., Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 *Santa Clara Computer & High Tech. L.J.* 263 (2000) (opposing the patenting of business methods); Alan L. Durham, "Useful Arts" in the Information Age, 1999 *BYU L. Rev.* 1419 (same); John R. Thomas, *The Patenting of the Liberal Professions*, 40 *B.C. L. Rev.* 1139 (1999) (same); Michael J. Meurer, *Business Method Patents and Patent Floods*, 8 *Wash. U. J.L. & Pol'y* 309 (2002) (arguing that business method patents should be construed narrowly). But see John R. Allison & Emerson H. Tiller, *Internet Business Method Patents, in Patents in the Knowledge-Based Economy* 259 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (arguing that business method patents aren't problematic).

The existence of open source software is often cited as an example of how the absence of intellectual property rights can promote innovation. Paradoxically, however, the open source movement depends on the existence of intellectual property—here, copyright—to ensure openness. See Robert W. Gomulkiewicz, *How Copyleft Uses License Rights to Succeed in the Open Source Software Revolution and the Implications for Article 2B*, 36 *Hous. L. Rev.* 179 (1999); David McGowan, *Legal Implications of Open Source Software*, 2001 *U. Ill. L. Rev.* 241. Open source licenses do not address patents directly. But Oren Bar-Gill and Gideon Parchomovsky have suggested that firms might precommit not to seek broad patent protection in an analog to open source software. See Oren Bar-Gill & Gideon Parchomovsky, *The Value of Giving Away Secrets*, 89 *Va. L. Rev.* (forthcoming Dec. 2003) (manuscript at 14–15, on file with the Virginia Law Review Association).

⁹⁶ See Shelanski, *supra* note 91; F.M. Scherer, *FTC Testimony*, at <http://www.ftc.gov/opp/global/scherer.htm> (Nov. 29, 1995) (on file with the Virginia Law Review Association); *supra* note 70 and sources cited therein. While Christopher Yoo has challenged the strength of this evidence, he has done so largely through a rather strained reading of the data, rather than offering empirical data of his own. See Christopher S. Yoo, *Vertical Integration and Media Regulation in the New Economy*, 19 *Yale J. on Reg.* 171, 272–78 (2002).

liam Baumol has argued that oligopoly, rather than either perfect competition or monopoly, is the best spur to innovation more generally.⁹⁷ Competition advocates would argue that, at the very least, patent rights should be narrow and should give less than perfect monopoly control.

3. *Cumulative Innovation*

Both Schumpeter's monopoly incentive theory and Arrow's competition theory involve somewhat stylized models of innovation involving single inventions. A growing number of economists and legal scholars have focused on cumulative innovation, in which a final product results not just from an initial invention, but from one or more improvements to that invention. Where innovation is cumulative, patent law must decide how to allocate rights between initial inventors and improvers.⁹⁸ One way to allocate those rights is to give them all to the initial inventor, as prospect theory would do. But as Lemley has argued, consolidating the rights in such a way is unwise if there is reason to believe either that competition among improvers will work better than centralized control of innovation or that patent owners and potential improvers will not necessarily come to terms.⁹⁹

Robert Merges and Richard Nelson have offered an alternative model that tries to allocate rights between initial inventors and subsequent improvers.¹⁰⁰ Their theory of "tailored incentives"

⁹⁷ William J. Baumol, *The Free Market Innovation Machine: Analyzing the Growth Miracle of Capitalism* (2002); accord Seungwoo Son, *Selective Refusals to Sell Patented Goods: The Relationship Between Patent Rights and Antitrust Law*, 2002 U. Ill. J.L. Tech. & Pol'y 109, 142.

⁹⁸ See Jerry R. Green & Suzanne Scotchmer, *On the Division of Profit in Sequential Innovation*, 26 RAND J. Econ. 20 (1995); see also John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 Antitrust L.J. 449, 453 (1997) (arguing that follow-on innovators deserve more protection); Howard F. Chang, *Patent Scope, Antitrust Policy, and Cumulative Innovation*, 26 RAND J. Econ. 34 (1995) (investigating the most desirable balance of protection between initial and follow-on innovators); Ted O'Donoghue, *A Patentability Requirement for Sequential Innovation*, 29 RAND J. Econ. 654 (1998) (arguing that patent law must give some protection against minor improvements but should permit major improvements).

⁹⁹ See Lemley, *Economics of Improvement*, *supra* note 69, at 1048–72.

¹⁰⁰ Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839, 876–79 (1990).

stands in opposition to prospect theory. Merges and Nelson dispute the presumption of prospect theorists that rivalry in innovation is wasteful. They believe that competition, not monolithic ownership, promotes invention most efficiently. They suggest that "when it comes to invention and innovation, faster is better,"¹⁰¹ and that "we are much better off with considerable rivalry in invention than with too little."¹⁰² They offer empirical evidence to support their position in a variety of industries.¹⁰³ Merges has further elaborated this structure in his discussion of blocking patents and the reverse doctrine of equivalents.¹⁰⁴

Merges and Nelson's approach is consistent with the traditional economic story, in which intellectual property is a creation of limited rights by the government for a specific purpose.¹⁰⁵ Even Wil-

¹⁰¹ *Id.* at 878.

¹⁰² *Id.* at 877.

¹⁰³ *Id.* at 884-908. Merges has argued elsewhere that the history of innovation in almost any field shows the importance of improvement inventions. Robert P. Merges, *Rent Control in the Patent District: Observations on the Grady-Alexander Thesis*, 78 *Va. L. Rev.* 359, 373 n.54 (1992) [hereinafter *Merges, Rent Control*].

¹⁰⁴ Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 *Tenn. L. Rev.* 75 (1994) [hereinafter *Merges, Bargaining Breakdown*].

¹⁰⁵ See Ward Bowman, Jr., *Patent and Antitrust Law: A Legal and Economic Appraisal* 32-34 (1973); F.M. Scherer, *Industrial Market Structure and Economic Performance* 443-50 (2d ed. 1980); Martin J. Adelman, *The Supreme Court, Market Structure, and Innovation*, 27 *Antitrust Bull.* 457, 479 (1982); Lemley, *Economics of Improvement*, *supra* note 69, at 993-1000; Oddi, *supra* note 66, at 273-81 (discussing various theoretical approaches); Kevin Rhodes, *The Federal Circuit's Patent Nonobviousness Standards: Theoretical Perspectives on Recent Doctrinal Changes*, 85 *Nw. U. L. Rev.* 1051, 1053 (1991).

It is important to distinguish the issue discussed in the text from the "property rule-liability rule" framework for remedies introduced by Calabresi and Melamed in their famous article. See Calabresi & Melamed, *supra* note 78. As should be evident from even a cursory review of intellectual property cases, successful plaintiffs in intellectual property cases benefit from a strong "property rule"—they are entitled to injunctive relief in all but the most extraordinary cases. See Merges, *supra* note 74, at 2655. Establishing that intellectual property remedies are governed by a "property rule" does not, however, tell us the extent to which original creators are entitled to real-property-like control over improvements within the scope of their original work. Cf. Louis Kaplow & Steven Shavell, *Property Rules Versus Liability Rules: An Economic Analysis*, 109 *Harv. L. Rev.* 713, 715 (1996) (suggesting that liability rules are appropriate to protect individuals against negative externalities, while property rules are appropriate to protect individuals from a (physical) deprivation of property). Where intellectual property rights fall on Kaplow and Shavell's spectrum is arguable.

liam Landes and Richard Posner, noted advocates of property rights in other contexts, treat intellectual property as primarily concerned with the balancing of incentives rather than the initial allocation of property interests.¹⁰⁶ Whereas prospect theory assigns broad initial rights and then leaves the parties to bargain to an efficient outcome, the tailored incentives approach pays closer attention to the particular allocation of rights. Merges and Nelson's approach, if valid, undermines the fundamental tenets of a property rights approach to intellectual property because, at least in the industries they study, invention and creation are unquestionably cumulative activities.¹⁰⁷

The literature on cumulative innovation argues that patent rights are important, but that they should not confer unlimited power to exclude.¹⁰⁸ Although initial inventors will sometimes be entitled to

In any event, there is a stronger argument for the use of property rules in intellectual property cases: It is extremely difficult for courts to put a value on intellectual property rights. Employing property rather than liability rules allows the parties rather than the courts to make such valuation decisions. For a general discussion of valuation, see A. Mitchell Polinsky, *An Introduction to Law and Economics* 135–38 (Aspen Law & Bus. 2d ed. 1989). We discuss this issue in more detail *infra* notes 335–52 and accompanying text.

¹⁰⁶ For example, Landes and Posner argue:

Copyright protection—the right of the copyright's owner to prevent others from making copies—trades off the costs of limiting access to a work against the benefits of providing incentives to create the work in the first place. Striking the correct balance between access and incentives is the central problem in copyright law. For copyright law to promote economic efficiency, its principal legal doctrines must, at least approximately, maximize the benefits from creating additional works minus both the losses from limiting access and the costs of administering copyright protection.

William M. Landes & Richard A. Posner, *An Economic Analysis of Copyright Law*, 18 J. Legal. Stud. 325, 326 (1989).

¹⁰⁷ See, e.g., Kenneth W. Dam, *Intellectual Property in an Age of Software and Biotechnology* 4 (U. Chi. L. & Econ., Working Paper No. 35, 1995) (on file with the Virginia Law Review Association) (“[I]n the overwhelming majority of instances each innovation builds on past innovations.”).

¹⁰⁸ There are at least three strands to this argument. First, for a variety of reasons, society cannot rely on pioneers to efficiently license to improvers the right to compete with them. See Eisenberg, *supra* note 65, at 1072–73 (1989) (“The risk that the parties will be unable to agree on terms for a license is greatest when subsequent researchers want to use prior inventions to make further progress in the same field in competition with the patent holder, especially if the research threatens to render the patented invention technologically obsolete.”); Lemley, *Economics of Improvement*, *supra* note 69, at 1048–72 (1997) (offering a variety of reasons why granting exclusive control to pioneers is inefficient); Merges, *Bargaining Breakdown*, *supra* note 104, at 82–89 (of-

patent claims that cover later improvements, the later improver also needs incentives to innovate. This literature argues that granting patents to both parties—so-called blocking patents—will normally balance incentives correctly, but that in some cases improvers should be excluded from liability under the reverse doctrine of equivalents.¹⁰⁹ How the balance should be struck depends on the relative importance of the initial invention and the improvement.¹¹⁰ Scholars who discuss cumulative innovation also imply that unfinished products, early versions, and improvements to a subset of a product should all be patentable.¹¹¹ Thus, cumulative innovation theory contemplates patents on smaller inventions, but it would give less complete rights over those inventions than would the prospect theory.

4. *The Anticommons*

Although the economic literature on cumulative innovation has generally suggested the grant of divided entitlements as a means of encouraging innovation by both initial inventors and improvers, a

fering theoretical reasons and examples of cases where patentees and improvers could not come to terms); Merges & Nelson, *supra* note 100. Second, positive “spillovers” from innovation that cannot be appropriated by the innovator actually contribute to further innovation. See Wesley M. Cohen & Daniel A. Levinthal, *Innovation and Learning: The Two Faces of R&D*, 99 *Econ. J.* 569 (1989); Zvi Griliches, *The Search for R&D Spillovers*, 94 *Scand. J. Econ.* S29 (Supp. 1992); Richard C. Levin, *Appropriability, R&D Spending, and Technological Performance*, 78 *Am. Econ. Rev.* 424, 427 (1988); cf. Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 *J. Econ. Persp.* 29, 30 (1991) (noting difficulties in the optimal allocation of rights between pioneers and improvers). Third, granting strong intellectual property rights encourages rent-seeking, which may dissipate the social value of the property rights themselves. In the patent context, giving too strong a right to first inventors could encourage wasteful patent races. See Jennifer F. Reinganum, *The Timing of Innovation: Research, Development, and Diffusion*, in 1 *Handbook of Indus. Org.* 850 (Richard Schmalensee & Robert Willig eds., 1989); Merges, *Rent Control*, *supra* note 103, at 370–71; cf. Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 *Va. L. Rev.* 305 (1992) (arguing that patent doctrine should be understood as a way of avoiding wasteful races).

¹⁰⁹ See Lemley, *Economics of Improvement*, *supra* note 69, at 1010–13; Merges, *Bargaining Breakdown*, *supra* note 104, at 91–99; Merges & Nelson, *supra* note 100, at 911.

¹¹⁰ See Lemley, *Economics of Improvement*, *supra* note 69, at 1007–13 (distinguishing between minor, significant, and radical improvements).

¹¹¹ Were it otherwise, there would be few cases in which the initial inventor and the improver were both entitled to patents.

more recent body of scholarship points out the limits of divided entitlements in circumstances in which transaction costs are positive. Relying on Michael Heller's description of what he calls the "anticommons,"¹¹² a number of patent scholars have argued that granting too many different patent rights can impede the development and marketing of new products where making the new product requires the use of rights from many different inventions.¹¹³ Underlying this argument are concerns about transactions costs and strategic behavior, which these scholars argue will sometimes prevent the aggregation of the necessary rights.

The anticommons is characterized by fragmented property rights, the aggregation of which is necessary to make effective use of the property.¹¹⁴ Although these fragmented rights might represent an instance of cumulative innovation, in which the initial inventor and a series of improvers must integrate their contributions, a pure anticommons involves not improvement but different contributions that must be aggregated together. Aggregating such fragmented property rights entails high search and negotiation costs to locate and bargain with the many rights owners whose permissions are necessary to complete broader development. This type of licensing environment may quickly become dominated by "holdouts" who refuse to license their component unless paid to do so.¹¹⁵ Because a given project will fail without their cooperation, holdouts may demand a bribe close to the value of the entire project.¹¹⁶ Every property holder needed for the project is subject to

¹¹² See Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 Harv. L. Rev. 621 (1998).

¹¹³ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Sci. 698, 698-99 (1998) (identifying anticommons problems in biomedical research); see also Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. Ill. L. Rev. 173, 192-94 (2001) (arguing that upstream patents in biotechnology could lead to bargaining breakdown and impede innovation).

¹¹⁴ See Heller, *supra* note 112, at 670-72.

¹¹⁵ For more on the holdout problem, see generally Mancur Olson, *The Logic of Collective Action* (1961). On its specific application in patent law, see Rochelle Cooper Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course* 4 (Apr. 2003) (working paper, on file with the Virginia Law Review Association).

¹¹⁶ See Lloyd Cohen, *Holdouts and Free Riders*, 20 J. Legal Stud. 351, 356 (1991).

this same incentive, and if everyone holds out, the cost of the project will rise substantially and probably prohibitively.

The anticommons problem is a particular species of a more general problem in economics—the issue of complementarity of products. Complementarity exists where two or more components must be combined into an integrated system. Economists have noted the problem of double (or triple or quadruple) marginalization that can occur when different companies own rights to complementary goods.¹¹⁷ The problem is this: If a product must include components *A* and *B*, and *A* and *B* are each covered by patents that grant different companies monopoly control over the components, each company will charge a monopoly price for its component. As a result, the price of the integrated product will be inefficiently high—and output inefficiently low—because it reflects an attempt to charge two different monopoly prices. The anticommons literature builds on this economic work, offering additional reasons to believe that the companies may not come to terms at all.¹¹⁸

Complements or anticommons problems can arise either horizontally or vertically in an industry. The problem arises horizontally when two different companies hold rights at the same level of distribution—say, inputs into the finished product. It arises vertically if a product must be passed through a chain of independent

¹¹⁷ The double-marginalization theorem shows that it is inefficient to grant two monopolies in complementary goods to two different entities because each entity will price its piece without regard to the efficient pricing of the whole, resulting in an inefficiently high price. For a technical proof of this, see Carl Shapiro, *Setting Compatibility Standards: Cooperation or Collusion?*, in *Expanding the Boundaries of Intellectual Property* 81, 97–101 (Rochelle Cooper Dreyfuss et al. eds., 2001) [hereinafter Shapiro, *Cooperation or Collusion*]. For a description of the problem in practice, see Ken Krechmer, *Communications Standards and Patent Rights: Conflict or Coordination?* 3 (1997), <http://www.csrstds.com/star.html> (on file with the Virginia Law Review Association) (citing examples in which so many different IP owners claim rights in a standard that the total cost to license those rights exceeds the potential profit from the product); see also Douglas Lichtman, *Property Rights in Emerging Platform Technologies*, 29 *J. Legal Stud.* 615, 615 (2000) (making a double-marginalization argument in favor of vertical integration in computer systems).

¹¹⁸ There is some evidence casting doubt on whether patents in fact commonly have debilitating anticommons characteristics. See John P. Walsh et al., *The Patenting and Licensing of Research Tools and Biomedical Innovation* (2000) (working paper, on file with the Virginia Law Review Association) (conducting a survey and finding that anticommons problems in the biotechnology industry have been overcome in practice). The theoretical problem certainly exists, however.

companies (such as a monopoly manufacturer who must sell through an independent monopoly distributor), or if patents on research tools or upstream components must be integrated with downstream innovation in order to make a finished product.

The anticommons literature suggests that too many companies have patents on components or inputs into products.¹¹⁹ The problem is not necessarily the scope of those patents but the number of rights with different owners that must be aggregated. Accordingly, this literature addresses a dimension of patent rights not considered in any of the theories discussed above. It is generally at odds with the divided entitlement proposals of cumulative innovation theory. There are two ways to solve this problem: Consolidate ownership of rights among fewer companies or grant fewer patents. Most legal scholars working in the anticommons literature have assumed that the solution is to grant fewer patents, particularly to developers of upstream products like research tools or DNA sequences.¹²⁰ Economists, by contrast, tend to assume that the solution to vertical complementarity problems is to vertically integrate—that is, to consolidate rights in a single company.¹²¹ Obviously, these two solutions have very different implications for patent policy. As a result, the anticommons theory does not necessarily dictate particular policy results.

¹¹⁹ See Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 *UCLA L. Rev.* 961, 998 (1996) (“[B]y setting stricter limits on gene patentability, the patent system can make the appropriate adjustment to reduce future rent dissipation among gene hunters.”).

¹²⁰ See, e.g., Philippe Jacobs & Geertrui Van Overwalle, *Gene Patents: A Different Approach*, [2001] *Eur. Intell. Prop. Rev.* 505, 505 (arguing that patents should not be granted for DNA, but only for downstream medical products); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 *Berkeley Tech. L.J.* 813, 838 (2001) (arguing that patent law should ensure that “most upstream research remains outside the bounds of patentability,” although Rai would permit the grant of narrow patents).

¹²¹ Alternatively, anticommons licensing rights can be consolidated into a collective rights organization such as the American Society of Composers, Authors, and Publishers (“ASCAP”) or a patent pool, even if the rights themselves remain under separate ownership. For a discussion of collective rights organizations, see Robert P. Merges, *Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 *Cal. L. Rev.* 1293 (1996).

5. Patent Thickets

Closely related to the problem of complementarity is the problem of horizontal overlaps between patents.¹²² Patents are frequently broader than the products the inventors actually make. Multiple patents often cover the same ground, sometimes as an intentional result of the patent system¹²³ and sometimes because patents regularly issue that are too broad or tread on the prior art.¹²⁴ Various parties may be able to lay claim to the same technologies or to aspects of the same technology. Carl Shapiro has termed this overlap of patent claims the “patent thicket.”¹²⁵

Like the anticommons problem, the patent thicket has the potential to prevent all parties from making a final product that incorporates multiple inventions. While the anticommons analysis focuses on the need to aggregate fragmentary property rights and the difficulty of assembling those fragments into a coherent product, the patent thicket analysis focuses on the overlap of existing rights. Particularly in areas like the semiconductor industry, companies need some means for “clearing” the patent thicket, such as cross-licensing all the rights needed for their complex product. Thus, one implication of the patent thicket is that patent law must permit the quick and easy clearance of these overlapping rights. More generally, the patent thicket problem—unlike its anticommons cousin—suggests that patents should be narrowed, so that the problem of overlapping scope will not arise in the first instance. Even with such clearance, patent thickets create a private patent

¹²² Vertical overlaps tend to fit within the “cumulative innovation” category discussed *supra* notes 98–111 and accompanying text.

¹²³ These cases arise where a later-developed improvement fits within the broad scope of an earlier claim.

¹²⁴ Because patent examiners spend very little time with each patent, see Lemley, *Rational Ignorance*, *supra* note 48, at 1500 (noting that examiners spend only eighteen hours per patent on average), patents regularly issue that would not withstand more searching scrutiny. Nearly half of all litigated patents are held invalid. Allison & Lemley, *Empirical Evidence*, *supra* note 47, at 205.

¹²⁵ Carl Shapiro, *Navigating the Patent Thicket: Cross Licensing, Patent Pools, and Standard Setting*, in 1 *Innovation Policy and the Economy* 119, 121 (Adam B. Jaffe et al. eds., 2001) [hereinafter Shapiro, *Thicket*]; accord James Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies* (2003) (working paper, on file with the Virginia Law Review Association) (explaining and discussing patent thickets).

tax on new entrants who cannot bring their own patents to the table.¹²⁶

B. Industry-Specific Patent Theory

The patent theories described in the last Section seem to be fundamentally at odds with one another. Their prescriptions run the gamut of possible policy options. According to various theorists, patents should be broad, narrow, or should not exist at all. They should be granted to initial innovators but not improvers, to downstream but not upstream developers, to both or to neither. Who is right?

The answer, curiously, is: everyone. The key to understanding the wide range of theories for optimizing patent rules is the different industry contexts in which patents exist. The range of patent theories parallels the range of ways in which the patent system affects companies in different industries. Like the proverbial blind men with the elephant, every theorist has focused on one aspect of the patent system, appropriate for one industry but irrelevant to others.¹²⁷ In this Section, we integrate these various theories by relating them to the industries for which they are appropriate.

1. Prospect Theory

Prospect theory is based on the premise that strong rights should be given into the hands of a single coordinating entrepreneur. Accordingly, prospect theory necessarily envisions invention as something done by a single firm, rather than collectively; as the result of significant expenditure on research, rather than the result of serendipitous or inexpensive research; and as only the first step in a long and expensive process of innovation, rather than as an activity close to a final product.¹²⁸ As a result, prospect theory suggests that

¹²⁶ See Bessen, *supra* note 125, at 1.

¹²⁷ Merges and Nelson are a partial exception. They acknowledge that innovation works differently in different industries and examine the characteristics of four different types of industries. Merges & Nelson, *supra* note 100, at 880–908. Nonetheless, they ultimately emphasize only one characteristic of each industry—its dependence on cumulative innovation.

¹²⁸ We follow Joseph Schumpeter in distinguishing between the act of invention, which creates a new product or process, and the broader act of innovation, which includes the work necessary to revise, develop, and bring that new product or process to

patents should be broad, stand alone, and confer almost total control over subsequent uses of the product.¹²⁹

The prospect vision of patents maps most closely onto invention in the pharmaceutical industry. Pharmaceutical innovation is notoriously costly and expensive. The pharmaceutical industry reports that it spends as much as \$800 million on R&D for each new drug produced.¹³⁰ That number is almost certainly inflated,¹³¹ but there is no doubt that R&D is extremely expensive in the pharmaceutical industry.¹³² Furthermore, inventing a new drug is only the beginning of the process, not the end. The Food and Drug Administration ("FDA") requires a lengthy and rigorous set of tests before companies can release drugs to the market.¹³³ While imitation of a drug is reasonably costly in absolute terms, a generic manufacturer who can prove bioequivalency can avoid the R&D cost entirely and can get FDA approval much more quickly than the original manufacturer. The ratio of inventor cost to imitator cost, therefore, is quite large in the absence of effective patent protection. As a result, it is

commercial fruition. See Richard R. Nelson & Sidney G. Winter, *An Evolutionary Theory of Economic Change* 263 (1982) (distinguishing the invention of a product from innovation, a broader process of research, development, testing, and commercialization of that product, and attributing that distinction to Schumpeter).

¹²⁹ See *supra* notes 73–90 and accompanying text.

¹³⁰ See Gardiner Harris, *Cost of Developing Drugs Found to Rise*, *Wall St. J.*, Dec. 3, 2001, at B14.

¹³¹ Among other things, it includes substantial marketing expenditures, which should not count as R&D.

¹³² Estimates of the average cost of drug development and testing range from \$150 million to \$500 million; the latter is the industry's figure. Compare *Pharm. Research & Mfrs. of Am., Why Do Prescription Drugs Cost So Much . . .* (June 2000), <http://www.phrma.org/publications/publications/brochure/questions/> (2000) (on file with the Virginia Law Review Association) (reporting the average cost of bringing one new drug to market as \$500 million) with Pub. Citizen, *Rebuttals to PhRMA Responses to Public Citizen Report Rx R&D Myths: The Case Against the Drug Industry's "Scare Card,"* at http://www.citizen.org/congress/reform/drug_industry/corporate/articles.cfm?ID=6514 (last visited Aug. 13, 2003) (on file with the Virginia Law Review Association) (criticizing industry estimates and offering the lower figure).

¹³³ The Pharmaceutical Research and Manufacturers of America estimates that the total time spent from the beginning of a research project to the marketing of a successful drug is twelve to fifteen years, 1.8 years of which is due to the FDA approval process. See *Pharmaceutical Research and Manufacturers of America, Why Do Prescription Drugs Cost So Much . . .* (June 2000), <http://www.phrma.org/publications/publications/brochure/questions/> (on file with the Virginia Law Review Association). Other estimates range from seven to fifteen years. See Richard J. Findlay, *Originator Drug Development*, 54 *Food & Drug L.J.* 227, 227 (1999) (estimating 14.7 years).

likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection.¹³⁴ As a general rule, the scope of patents in the pharmaceutical industry tends to be coextensive with the products actually sold. Patents do not merely cover small components that must be integrated into a marketable product.¹³⁵ If patents do not cover a group of related products, imitators can easily design around the patent by employing a close chemical analog to the patented drug.

All of these factors suggest that patents in the pharmaceutical industry should look like those prospect theory prescribes. In the pharmaceutical industry, neither cumulative nor complementary innovation poses a serious problem. Strong patent rights are necessary to encourage drug companies to expend large sums of money on research years before the product can be released to the market. And because much of the work occurs after the drug is first identified, it is important to give patentees the right to coordinate downstream changes to the drug. Prospect theory fits best in the pharmaceutical industry.

2. *Competitive Innovation*

The theory of competitive (or at least imperfectly competitive) innovation focuses on the incentives companies have to innovate even if they do not hold a monopoly position and are unlikely to acquire one through innovation. This approach emphasizes the fact that many inventions do not require substantial and sustained R&D expenditures; they may be relatively simple ideas or discoveries happened upon serendipitously. Competitive innovation is

¹³⁴ See, e.g., James W. Hughes et al., "Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare (Nat'l Bureau of Econ. Res., Working Paper No. 9229, 2002) (finding that eliminating patent protection on pharmaceuticals would cost consumers three dollars in lost innovation benefits for every dollar saved in reduced drug prices).

¹³⁵ While pharmaceutical companies have tried to find ways to obtain multiple patents on the same basic invention in an effort to extend the life of their patents, these efforts are aberrations that represent a failure of the system, not its normal function. See Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 233–35 (2001) (documenting efforts by pharmaceutical companies to obtain multiple patents on the same basic drug). The patent doctrine of "double patenting" is designed to prevent this sort of abuse. See, e.g., *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955, 967–68 (Fed. Cir. 2001).

also premised on competition's role in improving products and on the existence of other incentives to innovate, such as lead time or government research funding.

Competitive innovation theory maps well onto a variety of industries that have experienced substantial innovation in the absence of patent protection. One notable example is business methods. Under long-standing precedent, business methods were excluded from patent protection.¹³⁶ That rule changed dramatically in 1998, when the Federal Circuit concluded that business methods were patentable and, indeed, always had been.¹³⁷ As many commentators have noted, however, companies have ample incentives to develop business methods even without patent protection, because the competitive marketplace rewards companies that use more efficient business methods.¹³⁸ Even if competitors copy these methods, first mover advantages and branding can provide rewards to the innovator.¹³⁹ Because new business methods do not generally require substantial investment in R&D, the prospect of even a modest supracompetitive reward will provide sufficient incentive to innovate.

Innovation has flourished in other industries in the absence of patent protection. The early history of the software industry is one in which innovators developed impressive new products at very lit-

¹³⁶ See, e.g., *Hotel Sec. Checking Co. v. Lorraine Co.*, 160 F. 467 (2d Cir. 1908) (rejecting claim to "method of and means for cash-registering and account-checking"); see also Durham, *supra* note 95 (discussing the historic exclusion of business methods from patentability); Thomas, *supra* note 95 (same).

¹³⁷ See *State St. Bank & Trust v. Signature Fin. Group*, 149 F.3d 1368 (Fed. Cir. 1998). The United States is the only country to patent business methods. See, e.g., William van Caenegem, *The Technicality Requirement, Patent Scope and Patentable Subject Matter in Australia*, 13 *Austl. Intell. Prop. J.* 41, 41 (2002) (noting that other countries do not permit patenting of business methods).

¹³⁸ See, e.g., Robert P. Merges, *Patent Law and Policy* 155 (2d ed. 1997) ("[T]he relatively frequent innovations in the financial services industry prior to the era of patentability suggest that firms had adequate means to appropriate the value of their new financial innovations."); Dreyfuss, *supra* note 95 (arguing that business method patents are not necessary for innovation). But cf. Mark A. Lemley et al., *Software and Internet Law* 317-21 (2000) (discussing arguments that the financial services industry may need the incentive provided by patents).

¹³⁹ Cf. Mark A. Lemley & David W. O'Brien, *Encouraging Software Reuse*, 49 *Stan. L. Rev.* 255, 274-75 (1997) (discussing the role of first mover advantages in substituting for intellectual property rights). Federal Express, for instance, has preserved a substantial market share in the overnight package delivery market notwithstanding entry into the market by other companies that copied its business model.

the cost in the absence of patent protection.¹⁴⁰ Some have argued that software should not be patentable even today,¹⁴¹ though that argument ignores some economic changes in the industry¹⁴² and in any event seems unlikely to prevail. More recently, the Internet developed without patent protection for its fundamental protocols, in part because it was based on government-funded work and in part because the academic developers simply did not seek patent protection. A number of scholars have argued that the open, non-proprietary nature of the Internet is directly responsible for the dramatic innovation it fostered in the 1990s. They point out that AT&T, which had a monopoly in telephony and therefore under prospect theory the right incentives to innovate in the field, did not engage in similar innovation.¹⁴³ Open protocols permitted competition, and competition drove innovation. Competitive innovation theory suggests that ownership is not a necessary prerequisite to innovation, and indeed that it is sometimes inimical to innovation. Patent protection is not always appropriate, particularly where expected R&D cost is small, where the ratio of innovator cost to imitator costs is small, or where first mover advantages can provide the needed incentives. Under these conditions, patents should be rare and very modest in scope, in order to allow market forces their fullest latitude. Competitive innovation theory fits business methods, arguably fits the Internet, and—at least in the 1970s—fit software.

3. *Cumulative Innovation*

The theory of cumulative innovation starts by rejecting the proposition that invention is an activity engaged in by a single inventor or company acting in isolation. Rather, cumulative innova-

¹⁴⁰ Patent protection was not available for software until well into the 1980s. See Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 Cal. L. Rev. 1, 7–16 (2001) (discussing the history of software patents). Copyright protection may have been available, though the applicability of copyright was not really settled until Congress amended the statute in 1980. 17 U.S.C. § 101 (defining computer program).

¹⁴¹ See, e.g., *League for Programming Freedom, Software Patents: Is This the Future of Programming?*, Dr. Dobbs J., Nov. 1990, at 56 (“Software patents threaten to devastate America’s computer industry.”).

¹⁴² See *infra* notes 390–93 and accompanying text.

¹⁴³ See Lemley & Lessig, *supra* note 91, at 933–38.

tion is an ongoing, iterative process that requires the contributions of many different inventors, each building on the work of others.¹⁴⁴ Cumulative innovation theory questions the ability of any one inventor to identify and coordinate all the improvers needed to optimize a product over time. Instead, those who emphasize cumulative innovation argue that the law must divide property entitlements in order to provide incentives to each improver in the process.

Cumulative innovation maps very well onto the modern software industry. The computer industry is characterized by a large number of rapid, iterative improvements on existing products.¹⁴⁵ Computer programs normally build on preexisting ideas and often on prior code itself.¹⁴⁶ This incremental improvement is desirable for a variety of reasons. First, it responds to the hardware-based architectural constraints of the software industry. Data storage capacity, processing speed, and transmission rates have all increased steadily over time.¹⁴⁷ Programs written during an older period therefore faced capacity constraints that disappear over time. It makes sense to improve those products progressively as the constraints that limit the functionality of the programs disappear. Second, incremental improvement of existing programs and ideas tends to render programs more stable. It is received wisdom in the industry that customers should avoid version 1.0 of any software product, because its maker is unlikely to have all the bugs worked out. Iterative programs built on a single base tend to solve these problems over time. This is most obviously true when actual computer code is reused,¹⁴⁸ but it is true even when tested algorithms or structures

¹⁴⁴ See Scotchmer, *supra* note 108, at 29.

¹⁴⁵ See Cohen & Lemley, *supra* note 140, at 40–42; Peter S. Menell, Tailoring Legal Protection for Computer Software, 39 *Stan. L. Rev.* 1329, 1369–70 (1987); Samuelson et al., *supra* note 21, at 2376.

¹⁴⁶ For more on the reuse of existing code, both within and across companies, see Lemley & O'Brien, *supra* note 18.

¹⁴⁷ In 1965, Gordon Moore, co-founder of Intel, made the observation that historically the speed of microprocessors has doubled every year. See Webopedia, Moore's Law (Mar. 22, 1998), at http://www.webopedia.com/TERM/M/Mores_Law.html (on file with the Virginia Law Review Association). The current definition of "Moore's Law," as this phenomenon has been dubbed, is that data density doubles every eighteen months. *Id.* Data storage capacity and transmission rates have shown similarly exponential increases.

¹⁴⁸ See Lemley & O'Brien, *supra* note 18, at 265.

are replicated in new programs. Third, iterative improvement helps preserve interoperability, both among generations of the same program and across programs.¹⁴⁹

¹⁴⁹ For the same reason, reverse engineering has had a respected place as a legitimate means of creating interoperability. Virtually all recent copyright decisions have endorsed reverse engineering in some circumstances. See, e.g., *DSC Communications Corp. v. DGI Techs., Inc.*, 81 F.3d 597, 601 (5th Cir. 1996) (holding that the manufacturer was unlikely to succeed on the merits of its claim that a competitor infringed a copyright on an operating system when it downloaded software onto microprocessor cards for testing); *Bateman v. Mnemonics, Inc.*, 79 F.3d 1532, 1539 n.18 (11th Cir. 1996) (affirming acceptability of reverse engineering code); *Lotus Dev. Corp. v. Borland Int'l, Inc.* 49 F.3d 807, 817–18 (1st Cir. 1995) (Boudin, J., concurring) (endorsing reverse engineering); *Sega Enters. Ltd. v. Accolade, Inc.*, 977 F.2d 1510, 1527–28 (9th Cir. 1992) (holding that disassembly is fair use within the scope of that exception under copyright law); *Atari Games Corp. v. Nintendo of Am., Inc.*, 975 F.2d 832, 843–44 (Fed. Cir. 1992) (refusing to find reverse engineering to be copyright infringement); *Vault Corp. v. Quaid Software Ltd.*, 847 F.2d 255, 270 (5th Cir. 1988) (holding unenforceable a provision in a license agreement prohibiting reverse engineering); *Mitel, Inc. v. Iqtel, Inc.*, 896 F. Supp. 1050, 1056–57 (D. Colo. 1995), *aff'd* on other grounds, 124 F.3d 1366 (10th Cir. 1997) (endorsing the Ninth Circuit's approach in *Sega v. Accolade*). A few early decisions rejected compatibility as a justification for copying. See, e.g., *Apple Computer, Inc. v. Franklin Computer Corp.* 714 F.2d 1240, 1253–54 (3d Cir. 1983). A recent Federal Circuit case held that software companies can forbid reverse engineering in a shrinkwrap license, an approach which, if widely adopted, would render the compatibility justification essentially worthless. *Bowers v. Baystate Techs.*, 320 F.3d 1317, 1324–26 (Fed. Cir. 2003); cf. *DSC Communications Corp. v. Pulse Communications, Inc.*, 170 F.3d 1354, 1363 (Fed. Cir. 1999) (acknowledging the right to reverse engineer for some purposes, but holding it unjustified in this case).

As with courts, the overwhelming majority of commentators endorse a right to reverse engineer copyrighted software, at least for certain purposes. See, e.g., Jonathan Band & Masanobu Katoh, *Interfaces on Trial: Intellectual Property and Interoperability in the Global Software Industry* 167–226 (1995); Cohen et al., *supra* note 37; Lawrence D. Graham & Richard O. Zerbe, Jr., *Economically Efficient Treatment of Computer Software: Reverse Engineering, Protection, and Disclosure*, 22 *Rutgers Computer & Tech. L.J.* 61 (1996); Dennis S. Karjala, *Copyright Protection of Computer Software, Reverse Engineering, and Professor Miller*, 19 *U. Dayton L. Rev.* 975, 1016–18 (1994); Maureen A. O'Rourke, *Drawing the Boundary Between Copyright and Contract: Copyright Preemption of Software License Terms*, 45 *Duke L.J.* 479, 534 (1995) (“[T]here is a strong presumption that licensees of publicly distributed products are in fact really ‘purchasers of a product who should be free to do with that product as they please, as long as they do not infringe any applicable intellectual property right.’”); David A. Rice, *Sega and Beyond: A Beacon for Fair Use Analysis . . . At Least as Far As It Goes*, 19 *U. Dayton L. Rev.* 1131, 1168 (1994) (objecting to disallowing compilation); Pamela Samuelson, *Fair Use for Computer Programs and Other Copyrightable Works in Digital Form: The Implications of Sony, Galoob and Sega*, 1 *J. Intell. Prop. L.* 49, 86–98 (1993); Timothy Teter, *Merger and the Machines: An Analysis of the Pro-Compatibility Trend in Computer Software Copyright Cases*, 45 *Stan. L. Rev.* 1061, 1062–63 (1993) (arguing that the value of computer programs

The software industry also has relatively low fixed costs and a short time to market. The archetypal software invention is one made by two people working in a garage.¹⁵⁰ While the costs of writing software have increased substantially over time as programs have become more complex, the costs of writing and manufacturing computer programs remain low relative to the fixed costs of development in many industries. More critically, from the perspective of innovation policy, the ratio of innovation cost to the cost of follow-on competition is not particularly high. While it does cost less to clone someone else's program than to design your own from scratch, the difference is not enormous.¹⁵¹ Furthermore, computer program life cycles are short. Unlike industries such as steel or aircraft, where new generations of products are infrequent and those products may last for decades, computer programs tend to be replaced every few years, often by new versions of the same program.

The implications of these economic characteristics for patent law are threefold. First, the need for strong patent protection is somewhat less for software inventions than it is in other industries. Software patents are important, but the relatively low fixed costs associated with software development, coupled with other forms of overlapping intellectual property protection for software,¹⁵² mean

depends on interoperability); see also Cohen & Lemley, *supra* note 140, at 17–21 (expressing concern that patent law may not protect reverse engineering); Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 *Yale L.J.* 1575, 1579 (2002) (suggesting that reverse engineering should be legal when it promotes interoperability, but not when it permits free riding).

For a contrary view, see generally Anthony L. Clapes, *Confessions of an Amicus Curiae: Technophobia, Law and Creativity in the Digital Arts*, 19 *U. Dayton L. Rev.* 903, 906–07 (1994) (contending that there should be no right to reverse engineer software), and Arthur R. Miller, *Copyright Protection for Computer Programs, Databases, and Computer-Generated Works: Is Anything New Since CONTU?*, 106 *Harv. L. Rev.* 977, 1013–32 (1993) (same).

¹⁵⁰ Hewlett and Packard and Jobs and Wozniak are the classic examples, but the story has taken on a life of its own. See, e.g., Micalyn S. Harris, *UCITA: Helping David Face Goliath*, 18 *J. Marshall J. Computer & Info. L.* 365, 375 (1999).

¹⁵¹ For a contrary view, see Patrick K. Bobko, *Open-Source Software and the Demise of Copyright*, 27 *Rutgers Computer & Tech. L.J.* 51, 58–60 (2001) (arguing that the ratio of development to imitation costs in software is extremely high). It is trivially easy to counterfeit existing software, but it is illegal under copyright law, and the relevant costs are the costs of legal imitation under a regime without patents.

¹⁵² Copyright law is the predominant protection for software, but trade secret and contract law also provide protection. One factor militating in favor of stronger intellectual property protection in software is the ease of duplication of digital information

that innovation in software does not depend critically on strong, broad protection. Second, the rapid, incremental innovation crucial to the software industry may be retarded by older companies that own software patents based on prior generations of products. The danger is that a single patent covers not just a single product, but several generations of products that reflect incremental improvements by a number of different companies. Cohen and Lemley offer several reasons to fear that the doctrine of equivalents may be applied too broadly in the software industry, allowing owners of old software patents to prevent the development of new generations of technology.¹⁵³ It is worth noting, however, that the Federal Circuit decisions on this point are decidedly mixed.¹⁵⁴ Finally, a culture of rapid-fire incremental improvements leads to a large number of low-level innovations. Copyright is not capable of providing effective protection for such innovations because it does not protect functionality.¹⁵⁵ Some form of protection for such innovations is desirable. In the absence of other forms of protection, a large number of narrow software patents may be the best way of protecting these low-level innovations.¹⁵⁶

in the networked world. Copyright protection is much better suited to preventing exact duplication than patent protection, however. Copyright law has also been modified to better prevent such copying in the computer context by allowing copyright owners to control access to copy-protected works. See The Digital Millennium Copyright Act, 17 U.S.C. § 1201 (2003).

¹⁵³ Cohen & Lemley, *supra* note 140, at 39–50.

The pattern of cumulative, sequential innovation and reuse that prevails in the software industry creates the risk that software patents will cast large shadows in infringement litigation. Specifically, we believe that because innovation is especially likely to proceed by building on existing code in other programs, the temptation for the trier of fact to find equivalence of improvements will be correspondingly greater.

Id. at 41.

¹⁵⁴ *Id.* at 54–56.

¹⁵⁵ For a detailed discussion, see Samuelson et al., *supra* note 21, at 2350–56; Pamela Samuelson, *CONTU Revisited: The Case Against Copyright Protection for Computer Programs in Machine-Readable Form*, 1984 *Duke L.J.* 663, 733.

¹⁵⁶ Pamela Samuelson worries that software patents may be too broad, given the incremental nature of software innovation. Samuelson et al., *supra* note 21, at 2345–46; see also Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 *Emory L.J.* 1025 (1990) (arguing against protecting software with patents). As noted below, we share this concern, but believe that the solution is to narrow the scope of those patents.

These characteristics are precisely those suggested by cumulative innovation theory. Because innovation is relatively low-cost but rapid, the need for patent protection is generally modest. Patent protection for such incremental software inventions should be relatively easy to acquire, but it should be narrow. In particular, software patents should not generally extend across several product generations.¹⁵⁷ Cumulative innovation theory makes sense for software.

4. *Anticommons Theory*

Anticommons theory emphasizes the problems of divided entitlements among complements. These problems can occur either horizontally or vertically—horizontally if patents cover different pieces that must be integrated into a product, and vertically if patents cover different steps in a cumulative innovation process. Anticommons theorists point to the risk of a bargaining breakdown whenever the development of a product requires permission from the owners of two or more inputs. Different strands of anticommons theory suggest that the solution to this problem is either to consolidate ownership in a single owner—a result reminiscent of prospect theory—or to preclude patent protection altogether for certain types of inputs, particularly upstream research tools.

Anticommons theory maps very well onto the biotechnology industry. The biotechnology industry has some of the characteristics of the pharmaceutical industry, with which it shares certain products.¹⁵⁸ In particular, the long development and testing lead time

Some might object to a large number of software patents because they increase the transaction costs of inventing. We are not persuaded, however, that software patents of modest scope will increase transaction costs much more than software copyrights do. The only relevant patents are those that are licensed or litigated—less than five percent of the total number—not the whole universe of patents. See Lemley, *Rational Ignorance*, *supra* note 48, at 1507. If those patents are of modest scope, they do not present opportunities for their owners to impede largely unrelated technologies, and the transaction costs should be relatively modest.

¹⁵⁷ See generally Richard R. Nelson, *Intellectual Property Protection for Cumulative Systems Technology*, 94 *Colum. L. Rev.* 2674 (1994) (arguing for a moderate protection scheme to meet the protective needs of the software industry).

¹⁵⁸ Biotechnology products appear in a wide variety of economic sectors, from pharmaceuticals to foodstuffs to industrial processes. See Dan L. Burk, *Introduction: A Biotechnology Primer*, 55 *U. Pitt. L. Rev.* 611, 621–28 (1994). Much of our discus-

characteristic of pharmaceuticals is also evident in DNA-related innovation. These delays are due in part to the stringent regulatory oversight exercised over the safety of new drugs, foods, and biologics, and over the environmental release of new organisms. Another similarity between DNA and pharmaceuticals is that generic drug producers seeking to imitate an innovator's drug face substantially lower costs and uncertainty than do innovators in the industry. Although the FDA imposes regulatory hurdles even on second-comers, the process is substantially more streamlined than it is for innovators. Indeed, the primary regulatory hurdle a generic company faces is to show that its drug is bioequivalent to the innovator's drug.¹⁵⁹ Assuming bioequivalency, the FDA allows the generic to rely on the innovator's regulatory efforts. The uncertainty associated with developing and testing a new drug is also completely absent for generic competitors; they need only replicate the drug the innovator has identified and tested. Similarly, the hard work involved in producing a cDNA sequence coding for a human protein is in identifying and isolating the right sequence; once the sequence is known, a follow-on competitor can quite easily replicate it. And the existence of numerous functional equivalents to a particular DNA sequence means that patent protection must be broad enough to effectively exclude simple design-arounds, just as pharmaceutical patents must be broad enough to cover chemical analogs.

Nonetheless, the total cost of sequencing a particular gene is significantly less than the cost of more traditional drug design, especially since computers have made it possible to automate much of the process.¹⁶⁰ Additionally, DNA sequencing, unlike pharmaceuticals, involves the use of both vertical and horizontal complements. Patentees have acquired thousands of patents on DNA sequences

sion will focus on a subset of biotechnology that includes gene sequences and gene therapy.

¹⁵⁹ For a discussion of this process, see *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

¹⁶⁰ See Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 *Case W. Res. L. Rev.* (forthcoming spring 2004) [hereinafter Burk & Lemley, *Uncertainty Principle*]; Robert A. Hodges, *Black Box Biotech Inventions: When a Mere "Wish or Plan" Should be Considered an Adequate Description of the Invention*, 17 *Ga. St. U. L. Rev.* 831, 832 (2001) (discussing the increasing automation of gene sequencing).

that cover specific genes or in some cases fragments of genes.¹⁶¹ Moreover, biotechnology companies have patented probes, sequencing methods, and other research tools. Any particular gene therapy requires the simultaneous use of many of these patents, leading to anticommons problems. The problem is exacerbated by "reach-through" licenses in which the owners of upstream research tools seek control of and royalties on the downstream uses of the tool.¹⁶²

Scholars have proposed several different ways of solving these aggregation problems. First, vertical integration of companies may make much of the problem disappear. If biotechnology companies are owned by, or allied with, pharmaceutical companies, the resulting company may own enough rights to research tools, gene sequences, and implementation methods to move from research through drug design and manufacture by itself.¹⁶³ Second, if the absolute cost of sequencing DNA is sufficiently low, or if the existence of nonproprietary incentives is sufficiently great, the anticommons problem could be solved by refusing to protect certain types of inventions—such as Expressed Sequence Tags ("ESTs")—at all.¹⁶⁴ Finally, the problem might be solved if bargaining were easy enough. Indeed, one empirical investigation suggests that the anticommons problem is often overcome in practice.¹⁶⁵

¹⁶¹ See, e.g., S.M. Thomas et al., *Ownership of the Human Genome*, 380 *Nature* 387, 387–88 (1996).

¹⁶² See Rebecca S. Eisenberg, *Reaching Through the Genome* (2002) (working paper, on file with the Virginia Law Review Association). Efforts to write patent claims that "reach through" to cover technologies developed with a research tool have been less successful, however. See *Univ. of Rochester v. G.D. Searle, Inc.*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003) (rejecting such a claim on written description grounds).

¹⁶³ See Rai, *supra* note 120, at 833–35. Rai worries that this form of integration may result in a company holding patent rights that are too broad. *Id.* at 835.

¹⁶⁴ See *id.* at 838; cf. Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences*, 23 *AIPLA Q.J.* 1 (1995) (legal opinion concluding that National Institutes of Health patent applications on ESTs are not patentable).

¹⁶⁵ See Walsh, *supra* note 118, at 1 (finding that research tool patents have not impeded drug discovery because industry participants have been able to work around those patents). Notably, Walsh does not deny the existence of the problem in biotechnology, but merely suggests that parties can sometimes get around the problem. For instance, he suggests that litigation that holds patents invalid may be one way—among others—of overcoming the anticommons problem. *Id.*

In short, the structure of the biotechnology industry seems likely to run high anticommons risks. Product development times from creation to market are long and costly, but DNA patents are numerous and narrow.¹⁶⁶ Production of any given product may require bargaining with multiple patent holders. The potential for divided patent entitlements to prevent efficient integration into products is particularly high.¹⁶⁷ Anticommons theory was designed with DNA in mind, and seems to work most effectively there.

5. Patent Thickets

Closely related to the anticommons theory is the concept of patent thickets—the accumulation of overlapping patents that cover the same products and choke out an industry. Those who talk about patent thickets emphasize both the complements problem—the fact that a product must include many different components, each of which may be patented—and the overlap between patent rights covering the same technology, which results from either improvidently granted patents or from the effect of the doctrine of equivalents. Nonetheless, we think that the anticommons and patent thickets, while related, are analytically distinct. Anticommons exist where several different inputs must be aggregated together to make an integrated product. Patent thickets, by contrast, occur when multiple intellectual property rights cover the same technology and therefore overlap. The theory of patent thickets emphasizes the importance of limiting both the issuance and the scope of such overlapping patents and the need for bargaining mechanisms that permit the efficient clearance of patent rights.

The patent thickets problem maps well onto the semiconductor industry.¹⁶⁸ As in the case of pharmaceuticals, developing a new mi-

¹⁶⁶ It is the narrowness of these patents that makes biotechnology look like an anticommons, rather than a patent thicket. Nonetheless, we should note that many commentators worry that biotechnology patents will overlap, creating a patent thicket as well as an anticommons. See Rai, *supra* note 120, at 842.

¹⁶⁷ See Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 *Stan. L. Rev.* 303, 414 (2002) (offering reasons why the proliferation of upstream DNA patents will hurt downstream product innovation).

¹⁶⁸ The semiconductor industry may also be characterized by anticommons problems since integration of many different inputs is necessary to produce a commercial semiconductor product.

croprocessor involves a substantial investment of time and resources in a range of different activities—designing the circuit layout, improving materials, changing packaging, and reconfiguring the manufacturing process. In the last decade, developing a new generation microprocessor has meant building an entirely new fabrication facility using a different manufacturing process, at a cost of billions of dollars.¹⁶⁹ Unlike pharmaceuticals, however, semiconductor chips are not protected by a patent that covers the entire product. Rather, semiconductor companies obtain patents on components that may represent only a minor part of the whole chip. Circuit designs, materials, packaging, and manufacturing processes are all the subject of different patents. Furthermore, because many different companies are attempting to do the same thing—that is, make chips smaller and faster—at about the same time, they will often obtain patents on similar inventions with overlapping claims.

The result is that a new microprocessor likely infringes hundreds of different patents owned by dozens of different companies.¹⁷⁰ Semiconductor companies, therefore, exist in the advanced stages of a “patent arms race,” in which many established companies each possess the power to exclude all others from the market. They rarely exercise this right, however, instead entering into broad cross-licensing deals that permit everyone to make their products without fear of being sued by other established members of the industry.¹⁷¹ This does not mean that semiconductor patents have no value; far from it. Rather, their value is primarily symmetrical, so that the patents tend to be used defensively, to prevent the company from being sued by other patent owners. Where stakes are

¹⁶⁹ See, e.g., LaPedus, *supra* note 15.

¹⁷⁰ See John H. Barton, *Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios*, 69 *Antitrust L.J.* 851, 854 (2002) (characterizing the semiconductor industry as one with “a high level of reciprocal infringement” but “little litigation among oligopolists”); Bronwyn H. Hall & Rosemarie Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–1995*, 32 *RAND J. Econ.* 101, 102 (2001) (arguing that the strengthening of U.S. patent rights caused the surge in patenting by semiconductor firms, which in turn led to patents of overlapping intellectual property rights).

¹⁷¹ See Lemley, *Rational Ignorance*, *supra* note 48, at 1504–05; Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 *J. Small & Emerging Bus. L.* 143 (2000). One study provides evidence that suggests that the rate of actual litigation of semiconductor patents is less than that of other types of patents. See Allison et al., *supra* note 46 (manuscript at 50).

not symmetrical—either because the patentee does not participate in the industry or because the defendant does not have its own stable of patents—litigation is far more likely.¹⁷²

These are the classic characteristics of a patent thicket. Rather than promoting innovation, patents threaten to impede it or, at best, are deployed to counter the impeding patent rights of competitors. Overlapping patent claims covering complementary goods owned by many different parties threaten to paralyze the industry. Companies can make integrated products only if they can find a way to clear the patent thicket. Bargaining mechanisms and patent scope are critical factors in finding such solutions. The theory of patent thickets fits the semiconductor industry.¹⁷³

Existing patent theories, then, are not so much wrong as incomplete. Each tells a plausible story of how patents work or should work in a particular industry. Outside of that industry, however, their utility is limited. Prospect theory works well for the pharmaceutical industry, but its prescriptions are all wrong for software or for the Internet. The concept of patent thickets nicely captures the condition of intellectual property in the semiconductor industry, but it does not adequately describe that of the software or pharmaceutical industries. Just as the use of patents differs by industry,¹⁷⁴

¹⁷² These cross-licensing deals depend on the existence of a symmetrical relationship between the parties. Patentees that want to license their patents for royalties tend to be parties with asymmetric stakes. That is, they are individuals who do not sell products, “licensing shops” whose primary output is patents, or older companies that are no longer major players in the marketplace. Parties in these situations have no need to “trade” patents in the patent arms race described above. For example, independent inventor Jerome Lemelson is famous for having licensed his patents aggressively, and Texas Instruments (“TI”) is the most aggressive licensor of patents in the semiconductor industry. Lemelson did not make any products himself and therefore did not need cross-licenses from anyone. TI, while still a player in many markets, litigated primarily in the area of large scale integrated circuits, an area in which it did not have significant sales by the time of the lawsuits.

If a new entrant without a patent portfolio wants to enter the semiconductor market, recent evidence suggests that the entrant would have to pay \$100–200 million alone in patent licensing fees. Weston Headley, *Rapporteur’s Report, The Stanford Workshop on Intellectual Property and Industry Competitive Standards*, Stanford Law School, at 17 (Apr. 17–18, 1998) (quoting Michael Rostoker).

¹⁷³ One can also imagine it fitting the software industry in the future, if and when markets for tradable software components become a reality. For a discussion of the benefits of such a market and the potential holdout problems it might create, see Lemley & O’Brien, *supra* note 18.

¹⁷⁴ See *supra* Part I.

so too does patent theory. Matching the right model to the right industry allows us not only to make predictions about the use of patents in an industry, but to prescribe optimal patent policy for that industry.¹⁷⁵ The question then becomes whether we can do so under a single patent system or whether we need multiple systems.

III. TAILORING PATENT LAW AND PATENT POLICY

Parts I and II provide a strong indictment of a unitary patent system. If different industries acquire, value, and use patents differently, and if the optimal number, scope, and division of patent rights differ by industry, then it seems easy to conclude that we need different patent statutes for each industry. We resist that conclusion in Section A of this Part, however. In Section B, we argue that the unitary patent statute already gives substantial discretion to courts to build industry-sensitive policy analysis into their decisions, and that courts have latitude to create other such opportunities. These “policy levers”¹⁷⁶ permit patent law to take account of the technology-specific nature of the patent system without inviting the rent-seeking and balkanization that specialized statutes would engender. Unfortunately, as we describe in Section C, the Federal Circuit seems inclined to resist its proper role in setting patent policy. Indeed, it is in the process of dismantling many of the policy levers that can make patent law work properly. We argue that the courts must embrace their role in making the unitary patent system work for widely divergent industries.

A. Industry-Specific Patent Legislation

One obvious response to the different policy prescriptions described above would be to legislate different patent standards for different industries. While patent law has historically been uni-

¹⁷⁵ We wish to emphasize that the mapping of patent theory to industry characteristics is properly a dynamic, rather than a static, process. Industries change over time. The software industry in 2003 looks rather different than it did in the 1970s, and what was appropriate patent policy then might not be so today. See also Clarisa Long, *Patents and Cumulative Innovation*, 2 Wash. U. J.L. & Pol’y 229, 230 (2000) (arguing for dynamic models of innovation and, in support, noting that biomedical research continues to change).

¹⁷⁶ We are indebted to Pam Samuelson and Suzanne Scotchmer for the term “policy levers.” See Samuelson & Scotchmer, *supra* note 149, at 1581.

form, with a single set of legal standards designed to cover “anything under the sun that is made by man,”¹⁷⁷ Congress has shown increased interest in tailoring patent law to the needs of particular industries. In the last twenty years, Congress has lengthened the patent term for most pharmaceutical patents,¹⁷⁸ protected certain experimental uses of pharmaceuticals by generic suppliers from liability,¹⁷⁹ prohibited enforcing patents on medical procedures against doctors,¹⁸⁰ relaxed the obviousness standard for biotechnological processes,¹⁸¹ and created a new defense against business method patents.¹⁸² It has supplemented patent protection for semiconductors with a *sui generis* statute,¹⁸³ and enacted nonpatent statutes granting patent-like exclusive rights in particular industries.¹⁸⁴ It has even passed a “private” patent bill, lengthening the term of one narrow group of patents.¹⁸⁵ In each case, Congress reacted to particular complaints about the perceived unfairness of applying a general legal standard to a particular industry. Still other bills recently introduced in Congress would change the obviousness standards for business method patents or extend the patent for Claritin.¹⁸⁶

¹⁷⁷ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); see also Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 27(1), 33 I.L.M. 81, 93–94 (quoting S. Rep. No. 1979, at 5 (1952)) (requiring that patents be available without discrimination as to the form of technology) [hereinafter TRIPS].

¹⁷⁸ See 35 U.S.C. §§ 155–156 (2000).

¹⁷⁹ See id. § 271(e) (2000).

¹⁸⁰ See id. § 287 (2000).

¹⁸¹ See id. § 103(b) (2000).

¹⁸² See id. § 273(a)(3) (2000).

¹⁸³ See Semiconductor Chip Protection Act, 17 U.S.C. §§ 901–914 (2000).

¹⁸⁴ See Plant Variety Protection Act, 7 U.S.C. §§ 2321–2583 (2000); Rebecca S. Eisenberg, *Reexamining Drug Regulation from the Perspective of Innovation Policy* (2003) (working paper, on file with the Virginia Law Review Association) (examining the many provisions of FDA law that give exclusivity rights to pharmaceutical manufacturers to encourage drug development or testing); see also Plant Patent Act of 1930, 35 U.S.C. §§ 161–164 (adopting industry-specific patent rules).

¹⁸⁵ See 35 U.S.C. § 155A (2000). On the history of private patent legislation, see Robert Patrick Merges & Glenn Harlan Reynolds, *The Proper Scope of the Copyright and Patent Power*, 37 Harv. J. Legis. 45, 46–50 (2000).

¹⁸⁶ See Business Method Patent Improvement Act of 2000, H.R. 5364, 106th Cong. (proposing specific standards for business method patents); Patent Fairness Act of 1999, H.R. 1598, 106th Cong. (proposing to extend the patent for Claritin); Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 Food & Drug L.J. 247, 253 (2002) (discussing the various Claritin patent term extensions).

A number of scholars suggest that patent law needs to be modified to take account of the particular needs of the software industry. Some suggest that software patents are inappropriate altogether,¹⁸⁷ while others contend that only Internet business method patents are.¹⁸⁸ Others suggest that a form of *sui generis* patent-like protection is appropriate for software.¹⁸⁹ Still others who endorse the general framework argue that the courts should apply patent law to software in somewhat different ways than they do in other industries.¹⁹⁰ Similarly, some scholars have explored whether biotechnology deserves its own *sui generis* form of protection,¹⁹¹ while others have suggested that biotechnology patent standards should deviate from the general patent law rules.¹⁹² Some argue that cer-

¹⁸⁷ See, e.g., Samuelson, *supra* note 156 (questioning the desirability of the patent system for protecting program innovations that derive from informational representation, organization, manipulation, and display).

¹⁸⁸ See, e.g., Matthew G. Wells, Internet Business Method Patent Policy, 87 Va. L. Rev. 729, 770-73 (2001) (outlining the arguments for and against the use of business method patents for Internet innovation).

¹⁸⁹ See, e.g., Peter S. Menell, Tailoring Legal Protection for Computer Software, 39 Stan. L. Rev. 1329 (1987) (arguing for *sui generis* protection); Samuelson et al., *supra* note 21, at 2310-12 (proposing an additional form of protection alongside patent and copyright law). For a somewhat different proposal, see Lester C. Thurow, Needed: A New System of Intellectual Property Rights, Harv. Bus. Rev., Sept.-Oct. 1997, at 94 (discussing software and biotechnology industries).

¹⁹⁰ Most commonly, scholars suggest that the rapid market cycles in software justify shorter terms of protection for software patents. For discussion see John C. Phillips, *Sui Generis Intellectual Property Protection for Computer Software*, 60 Geo. Wash. L. Rev. 997 (1992); Leo J. Raskind, The Uncertain Case for Special Legislative Protecting Computer Software, 47 U. Pitt. L. Rev. 1131 (1986); Pamela Samuelson, Modifying Copyrighted Software: Adjusting Copyright Doctrine to Accommodate a Technology, 28 Jurimetrics J. 179 (1988); Richard Stern, The Bundle of Rights Suited to New Technology, 47 U. Pitt. L. Rev. 1229, 1262-67 (1986); cf. Cohen & Lemley, *supra* note 140, at 3 (suggesting ways to avoid overbroad application of the doctrine of equivalents and to protect reverse engineering); Julie E. Cohen, Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of "Lock-Out" Technologies, 68 S. Cal. L. Rev. 1091, 1179 (1995) (suggesting the application of an innovative programmer standard to software patents); Richard H. Stern, Tales From the Algorithm War: *Benson to Iwahashi*, It's Deja Vu All Over Again, 18 AIPLA Q.J. 371, 395 (1991) (same).

¹⁹¹ See, e.g., Dan L. Burk, Copyrightability of Recombinant DNA Sequences, 29 Jurimetrics J. 469 (1989) (arguing that copyright-like protection would be more appropriate for protection of biotechnology); S. Benjamin Pleune, Trouble With the Guidelines: On Urging the PTO to Properly Evolve with Novel Technologies, 2001 J.L. Tech. & Pol'y 365 (arguing for DNA-specific legislation).

¹⁹² For a critical analysis of such proposals, see Dan L. Burk, Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed, 17 Rutgers Computer & Tech.

tain types of biotechnological innovations should be entirely unpatentable.¹⁹³ Others suggest that the disclosure requirements should be loosened for biotechnology patents,¹⁹⁴ that the obviousness standard should be lowered,¹⁹⁵ or that the scope of DNA sequence patents should be restricted.¹⁹⁶ Scholars have variously argued that the Federal Circuit should defer to the PTO¹⁹⁷ or conversely that the PTO should defer to the Federal Circuit.¹⁹⁸

Calls to modify patent law are a natural response to the different effects patent law has on different industries. The economic effects of patents are quite different in software and biotechnology, two of

L.J. 1 (1991). The statutory rules in biotechnology cases already do diverge from the general rules in their treatment of the obviousness of biotechnological processes. 35 U.S.C. § 103(b) (2000).

¹⁹³ See, e.g., Dan L. Burk, Patenting Transgenic Human Embryos: A Nonuse Cost Perspective, 30 Hous. L. Rev. 1597, 1600, 1658–65 (1993) (advancing a utilitarian argument against patenting some human cells); Mark O. Hatfield, From Microbe to Man, 1 Animal L. 5, 6, 9 (1995) (arguing that some biotechnological patents may have serious moral implications); Kojo Yelpaala, Owning the Secret of Life: Biotechnology and Property Rights Revisited, 32 McGeorge L. Rev. 111, 200 (2000) (arguing that moral considerations should be sufficient grounds for rejecting a patent “even when such inventions might satisfy all the technical requirements of patentability”). For a very different argument against the patenting of cDNA sequences, see Eisenberg & Merges, *supra* note 164.

¹⁹⁴ See, e.g., Hodges, *supra* note 160, at 835 (arguing that biotechnology patentees should not have to adhere to the standard written description requirement); Janice M. Mueller, The Evolving Application of the Written Description Requirement to Biotechnological Inventions, 13 Berkeley Tech. L.J. 615, 633–49 (1998) (considering the impact of strict application on the biotechnology industry); Harris A. Pitlick, The Mutation on the Description Requirement Gene, 80 J. Pat. & Trademark Off. Soc’y 209, 222–25 (1998) (criticizing *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) and the written description requirement); Cliff D. Weston, Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol, 4 J. Small & Emerging Bus. L. 377, 389–92 (2000) (criticizing the written description requirement).

For the related argument that the biotechnology written description cases are really about enablement and serve to obscure the real purposes of the written description requirement, see Mark D. Janis, On Courts Herding Cats: Contending with the “Written Description” Requirement (and Other Unruly Patent Disclosure Doctrines), 2 Wash. U. J.L. & Pol’y 55 (2000).

¹⁹⁵ See Karen I. Boyd, Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness, 12 Berkeley Tech. L.J. 311, 311–13 (1997).

¹⁹⁶ See, e.g., Rai, *supra* note 120, at 838.

¹⁹⁷ See *id.*, at 838–44.

¹⁹⁸ See Craig R. Miles, Goldilocks Patent Protection for DNA Inventions: Not Too Thick, Not Too Thin, But Just Right, 2 Modern Trends in Intell. Prop. 3 (1998).

the industries in which the calls for specific legislation are loudest.¹⁹⁹ Thus, in a perfect world the patent system might well be tailored to give optimal incentives to each different industry.²⁰⁰

In the real world, however, a number of factors caution against explicitly tailoring the patent system to the needs of particular industries.²⁰¹ The most obvious barrier is legal—the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPs”) prohibits member states from discriminating in the grant of patents based on the type of technology at issue.²⁰² As we have noted elsewhere, however, the United States has not faithfully followed this treaty mandate.²⁰³ Neither has the European Union, which has industry-specific rules for compulsory licensing of pharmaceuticals and for the patentability of software and business methods.²⁰⁴

Even if industry-specific patent legislation is legal, we are not persuaded that it is a good idea for several reasons. First, while economics can make useful policy suggestions as to how patents work in different industries, we are skeptical of the ability of a statute to dictate in detail the right patent rules for each industry.²⁰⁵

¹⁹⁹ See *supra* notes 37–60 and accompanying text.

²⁰⁰ See Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in *Innovation Policy and the Economy*, *supra* note 125, at 51, 53, 71 (arguing that “intellectual property regimes should be designed so that the subject matter of each one has relatively homogenous needs for protection”); Merges & Nelson, *supra* note 100, at 843; cf. Allison & Lemley, *Complexity*, *supra* note 41, at 142–44 (noting that patents are more industry-specific than they used to be and that this is likely to lead to calls for industry-specific patent reform).

²⁰¹ For a discussion of the possible international problems with industry-specific legislation, with specific reference to software, see Rochelle Cooper Dreyfuss, *Information Products: A Challenge to Intellectual Property Theory*, 20 N.Y.U. J. Int’l L. & Pol’y 897, 912–18 (1988).

²⁰² See TRIPs, *supra* note 177, art. 27(1), at 93–94.

²⁰³ See Burk & Lemley, *Technology-Specific*, *supra* note 4, at 1183–85 (describing the different treatment U.S. law gives to different industries).

²⁰⁴ See, e.g., Erwin J. Basinski, *The European Union’s Proposed Directive on Computer-Implemented Inventions: What Price ‘Interoperability’?*, 3 *World eCommerce & IP Report* (Aug. 2003).

²⁰⁵ Some are skeptical of the role of economics more generally in tailoring the patent system, though their discussion has focused on statutory change. See Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1813 (1984) (rejecting as impractical an effort to determine optimal patent length for each industry). But see Frank Partnoy, *Finance and Patent Length* (Nov. 29, 2001) (working paper, on file with the Virginia Law Review Association). Partnoy’s complaint is that the patent term is standard across industries, when in fact it should vary not only within industries but also over time to account for interest rates. Partnoy, *supra*, at 1, 18–22,

Many of the predictions of economic theory are fact-specific—they suggest different factors that should bear on the outcome of particular cases, but that require case-by-case application that cannot easily be captured in a statute.²⁰⁶ Economic theory is more useful in making general suggestions about how the patent system can be adapted to particular factual contexts than as the basis for a whole series of new statutes.

Second, rewriting the patent law for each industry would involve substantial administrative costs and uncertainties. Congress would have to write new statutes not just for biotechnology and software, but for numerous different industries with special characteristics. Semiconductors, pharmaceuticals, chemicals, nanotechnology,²⁰⁷ and other industries, such as telecommunications, would all need separate statutes. District court judges, who already have enough trouble learning the arcane rules of patent law in the relatively few patent cases they hear, would have to learn a host of new statutes. The law supporting these statutes would be slow to develop, since fewer cases would come up involving each statute.²⁰⁸ The resulting uncertainty would perhaps enrich lawyers, but it surely would not be conducive to encouraging innovation. There would also be a great deal of line drawing to be done, as the boundaries between industries are vague and notoriously mutable. Semiconductor manufacturers patent and use software all the time. Drug delivery systems might be thought of as medical devices, pharmaceuticals, or biotechnology; presumably a different law would apply depend-

28–33. This latter argument seems to ignore opportunity costs: While it is true that the absolute value of a patent royalty stream is a function of interest rates, its value relative to other possible investment decisions may not change with interest rates.

²⁰⁶ Industry-specific legislation is part of a broader debate over the appropriateness of general legal rules versus more tailored, fact-specific standards. We discuss that debate in more detail *infra* notes 224–25 and accompanying text.

²⁰⁷ For an exploration of legal issues related to nanotechnology, see Frederick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. Cal. Interdisc. L.J. 593 (1995).

²⁰⁸ Cf. Marcel Kahan & Michael Klausner, *Path Dependence in Corporate Contracting: Increasing Returns, Herd Behavior, and Cognitive Biases*, 74 Wash. U. L.Q. 347, 348 (1996) (arguing that legal terms exhibit network effects because the body of law increases as they are litigated). But see Lemley & McGowan, *Networks*, *supra* note 26, at 570–76 (disputing the significance of these effects); Larry E. Ribstein & Bruce H. Kobayashi, *Choice of Form and Network Externalities*, 43 Wm. & Mary L. Rev. 79, 128 (2001) (same).

ing on how the invention was characterized. Even technologies that seem radically different, like biotechnology and software, may unexpectedly converge, as recent developments in bioinformatics and proteomics have made clear.²⁰⁹ Further, a significant percentage of inventions fall into more than one field.²¹⁰ And new fields arise regularly; imagine trying to fit all modern inventions into categories created fifty or one hundred years ago. As a result, it would prove impossible to carve up innovation into static fields.²¹¹

This last point raises a related one. The history of industry-specific statutes suggests that many fail because they are drafted with current technology in mind and are not sufficiently general to accommodate the inevitable change in technology.²¹² The most notorious example is the Semiconductor Chip Protection Act ("SCPA").²¹³ Passed after six years of debate, the SCPA created a detailed set of rules designed to protect semiconductor mask

²⁰⁹ See, e.g., Symposium on Bioinformatics and Intellectual Property Law, Open Source Genomics, 8 B.U. J. Sci. & Tech. L. 254, 254-62 (2002) (presentation by Dan Burk discussing analytical commonalities of bioinformatics and software production). Bioinformatics involves the regularized use of computer models to identify and predict gene structures. See Ken Howard, The Bioinformatics Gold Rush, 283 Sci. Am. 58, 58 (2000). Proteomics involves the use of computer chips to build and test proteins. See, e.g., Carol Ezzell, Beyond the Human Genome, 283 Sci. Am. 64, 64, 67-69 (2000) (describing proteomics).

²¹⁰ See Allison & Lemley, Who's Patenting What?, *supra* note 20, at 2114 n.45 (stating that, on average, patents in the late 1990s fell into 1.49 different technology areas). This is actually a modest increase from the 1970s, when the number was 1.37. Most of this increase is due to the growth of software and biotechnology patents. See Allison & Lemley, Complexity, *supra* note 41, at 93 tbl.1.

²¹¹ It might seem odd for us to emphasize the administrative costs of industry-specific legislation, given that we ultimately endorse industry-specific judicial interpretation. Our positions are reconcilable because judicial interpretation occurs in a particular factual context. The litigation process will provide judges with the information they need to decide cases. So while there is an administrative cost to judicial as well as legislative determination of industry-specific factors, it is largely a cost society would be paying anyway to resolve the lawsuit. Cf. Gordon Tullock, Trials on Trial: The Pure Theory of Legal Procedure 28-30, 199 (1980) (discussing litigation as a social mechanism to encourage private expenditures toward public information).

²¹² This general problem with legislative responses was identified in detail by Guido Calabresi more than twenty years ago. See Guido Calabresi, A Common Law for the Age of Statutes (1982) (articulating problems with obsolete statutes and legislative responses).

²¹³ 17 U.S.C. §§ 901-914 (2000).

works. Significantly, the statute has virtually never been used.²¹⁴ The most likely reason is that the particular focus of the SCPA—duplication of mask works—is obsolete because of changes in the way semiconductor chips are made. Industry-specific patent statutes risk a similar fate.²¹⁵

Finally, and most troubling, both public choice theory²¹⁶ and practical experience warn that each new amendment to the patent statute represents an opportunity for counterproductive special interest lobbying.²¹⁷ Technology-specific patent legislation will encourage rent-seeking by those who stand to benefit from favorable legislation. Patent law has some balance today in part because different industries have different interests, making it difficult for one interest group to push through changes to the statute. Industry-specific legislation is much more vulnerable to industry capture. It is no accident that the industry-specific portions of the patent law are among the most complex and confusing sections,²¹⁸ and that they have had some pernicious consequences.²¹⁹ The copyright

²¹⁴ There is only one reported case interpreting the SCPA. See *Brooktree Corp. v. Advanced Micro Devices*, 977 F.2d 1555 (Fed. Cir. 1992).

²¹⁵ Cf. 35 U.S.C. § 103(b) (2000) (detailing special nonobviousness standard for biotechnological innovations), which is irrelevant today largely because general patent standards reach the same result. See *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995).

²¹⁶ See Daniel A. Farber & Philip P. Frickey, *The Jurisprudence of Public Choice*, 65 *Tex. L. Rev.* 873 (1987).

²¹⁷ See, e.g., John R. Allison & Emerson H. Tiller, *The Business Patent Myth*, 18 *Berkeley Tech. L.J.* (forthcoming Dec. 2003) (warning against “the definitional gerrymandering of patent lawyers” in designing industry-specific statutes).

²¹⁸ In particular, 35 U.S.C. § 103(b) (2000) (biotechnological processes), *id.* § 155A (2000) (private patent relief), *id.* § 156 (2000) (pharmaceutical patent term extension), and *id.* § 287 (2000) (medical process patents).

²¹⁹ The Hatch-Waxman provisions in particular have been used on numerous occasions to violate the antitrust laws. *Id.* § 156 (2000). Pharmaceutical patent owners have colluded with putative generic entrants to prevent that company or any other from entering the market. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *Andrx Pharm., Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 535 U.S. 931 (2002). On the legality of such collusion, compare Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 *Antitrust Bull.* 491, 532–38 (2002) (arguing for treatment under the rule of reason or alternatively for a “quick look” rule of reason), with Herbert Hovenkamp et al., *Anticompetitive Settlements of Intellectual Property Disputes*, 87 *Minn. L. Rev.* 1719, 1728–29 (2003) (arguing that per se illegality is appropriate in some cases) [hereinafter Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellec-*

model—in which industry-specific rules and exceptions have led to a bloated, impenetrable statute that reads like the tax code²²⁰—is hardly one patent law should emulate.²²¹

B. Policy Levers in Patent Law

The difficulties with industry-specific legislation, however, do not mean that we must abandon the idea of tailoring patent law to the needs of specific technologies. Statutes differ in the specificity with which they dictate the rules for judicial decision. They exist on a continuum between detailed rules such as the tax code capable of rote application on one end, and rules like antitrust law delegating broad authority to judges to make correct decisions on the other.²²² On this continuum, the Patent Act is closer to antitrust law than to the tax code. While the statute sets the basic parameters for patentability and infringement, it does not specify in detail how those basic principles are to be applied. Further, in many instances, such as application of the doctrine of equivalents or of unenforceability, judicially created doctrines play a major role in defining the scope of patent protection.²²³

Such tailoring activity necessarily vests a fair degree of discretion in the judiciary in order to adapt the general statute to the particular circumstance. The discussion of patent tailoring thus partakes to some extent in the long-running debate over the comparative

tual Property Law § 33.9 (Supp. 2003) [hereinafter 2 Hovenkamp et al., IP and Antitrust].

²²⁰ On the unnecessary complexity of the copyright laws, see Jessica Litman, Digital Copyright 25, 29 (2001); Jessica Litman, The Exclusive Right to Read, 13 Cardozo Arts & Ent. L.J. 29, 34 (1994); Jessica Litman, Revising Copyright Law for the Information Age, 75 Or. L. Rev. 19, 22–23 (1996).

²²¹ Indeed, scholars have suggested the opposite—that copyright law should learn from patent. See Mark A. Lemley, The Economics of Improvement in Intellectual Property Law, 75 Tex. L. Rev. 989, 992 (1997); Wiley, Jr., *supra* note 62, at 119–21, 137–44.

²²² The antitrust laws are an obvious example of the latter. The few sentences of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1–2 (2000), have spawned a vast set of judicially created standards for identifying and punishing anticompetitive behavior.

²²³ See, e.g., Richard Gilbert & Carl Shapiro, Optimal Patent Length and Breadth, 21 RAND J. Econ. 106, 106 (1990) (emphasizing the importance of patent scope to incentives); Merges & Nelson, *supra* note 100, at 839, 916 (same).

merits of rules versus standards.²²⁴ Within this debate, “rules” have been characterized as bright-line and definite decisional criteria. Rules are cheap to administer because they are simple and straightforward, but due to their inflexibility they may lead to costly outcomes if they fit a given situation poorly. Standards, by contrast, are characterized as flexible case-by-case decisional criteria that can take situational variance into account. But standards are typically and intentionally stated indeterminately. As a result, they offer little guidance to expected behavior and so may impose costs associated with this uncertainty. Standards typically imbue courts or decisionmakers with greater discretion than would a rigid decisional rule, and so standards are favored where greater discretion is needed.

The need to allow courts flexibility to accommodate different technologies within the general framework of patent law militates in favor of a standards-based patent statute. The rules and standards debate, however, is only part of the patent specificity story. Adaptation of the patent statute to specific industries requires allowance for judicial discretion, but the adaptation process will not necessarily be standards-based. Where commonalities within an industry can be identified, tailoring may sometimes be best accomplished via judicial application of a bright-line rule. At other times it may be best accomplished case-by-case, via application of a flexible standard. Additionally, the definitional line between rules and standards is not always pristine, and the distinction largely depends on the level of abstraction at which decisional discretion is viewed. Standards operationalize case-by-case determinations, but only by laying down a broad decisional criterion. The choice to de-

²²⁴ The body of literature on this topic is extensive. See, e.g., Frederick Schauer, *Playing by the Rules: A Philosophical Examination of Rule-Based Decision-Making in Law and in Life* (1991); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 *Duke L.J.* 557 (1992); Duncan Kennedy, *Form and Substance in Private Law Adjudication*, 89 *Harv. L. Rev.* 1685 (1976); Russell B. Korobkin, *Behavioral Analysis and Legal Form: Rules vs. Standards Revisited*, 79 *Or. L. Rev.* 23 (2000); Eric A. Posner, *Standards, Rules, and Social Norms*, 21 *Harv. J.L. & Pub. Pol’y* 101 (1997); Pierre Schlag, *Rules and Standards*, 33 *UCLA L. Rev.* 379 (1985); Cass R. Sunstein, *Problems With Rules*, 83 *Cal. L. Rev.* 953 (1995).

For a debate on the merits of rules and standards in patent law, see Robert P. Merges & John Fitzgerald Duffy, *Patent Law and Policy* 805–06 (3d ed. 2002); Thomas, *Formalism*, *supra* note 56; R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of *Festo**, 151 *U. Pa. L. Rev.* 159, 234–37 (2002).

cide certain types of cases under a standards regime is itself an establishment of directive precedent that channels the discretion of future courts.

The need for industry-specific statutory tailoring implicates the broader question of legal generalization versus particularization, of which the issue of rule-based or standards-based decisionmaking is, perhaps paradoxically, a particular instance.²²⁵ Law necessarily contains general prescriptions for governing behavior, prescriptions that may fit particular instances well or poorly. Where the fit is poor, it may be sensible to equip decisionmakers with discretion to tailor the general prescription.²²⁶ The patent statute equips courts with precisely such discretion via a series of doctrinal policy levers.

²²⁵ See Frederick Schauer, *Generality and Justice* (forthcoming 2003) (on file with the Virginia Law Review Association) (exploring various examples of generalization in law). Another version of this problem appears in the literature on "default rules" where some law is characterized as inflexible and mandatory, and other law is characterized as a permissive default that can be waived or varied by private contract adapted to the situation of particular contracting parties. For discussion of this paradigm of default rules, see Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 *Yale L.J.* 87 (1989); Ian Ayres & Robert Gertner, *Strategic Contractual Inefficiency and the Optimal Choice of Legal Rules*, 101 *Yale L.J.* 729 (1992); Randy E. Barnett, *The Sound of Silence: Default Rules and Contractual Consent*, 78 *Va. L. Rev.* 821, 831-55, 860-73 (1992); Einer Elhauge, *Preference-Eliciting Statutory Default Rules*, 102 *Colum. L. Rev.* 2162 (2002); Einer Elhauge, *Preference-Estimating Statutory Default Rules*, 102 *Colum. L. Rev.* 2027 (2002).

²²⁶ Vesting courts with discretion may worry some. Courts are not immune from the sorts of rent-seeking criticisms that have been leveled against Congress. See Einer Elhauge, *Does Interest Group Theory Justify More Intrusive Judicial Review*, 101 *Yale L.J.* 31, 67-68 (1991); A.C. Pritchard & Todd J. Zywicki, *Finding the Constitution: An Economic Analysis of Tradition's Role in Constitutional Interpretation*, 77 *N.C. L. Rev.* 409, 494 (1999). But there is good reason to believe that courts are less subject to capture than legislatures or agencies: Federal judges have life tenure; they are not compensated based on anything litigants (and certainly not patent litigants) do or do not do; they have no supervisors; and they are less likely to engage in logrolling than large legislative bodies.

In the patent context, capture could take the more subtle form of influence by parties who appear repeatedly before the courts. This seems less of a problem in patent law, however, because companies tend to be both plaintiffs and defendants in patent cases. Cf. Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 *N.Y.U. L. Rev.* 1, 14-15 (1989) (finding that the Federal Circuit has done well in understanding and responding to the needs of innovation). Certainly the PTO is far more subject to influence of this sort.

1. Existing Policy Levers

The great flexibility in the patent statute presents an opportunity for courts to take account of the needs and characteristics of different industries. Courts can, and should, apply the general rules of patent law with sensitivity to the characteristics of particular industries. In this Section, we identify a number of policy levers that already exist in patent jurisprudence, and explain how they are or can be used to tailor the unitary patent system to the more complex realities of the world, while avoiding the problems of industry-specific legislation. The levers we identify are not, by any means, the only sources of judicial discretion in patent law. Indeed, we do not discuss two of the largest judicially created doctrines in patent law—the doctrine of equivalents and inequitable conduct.²²⁷ Rather, we concentrate on policy levers that seem to us to require, or at least permit, systematic variation in patent rules by industry. Some of these policy levers operate on a “macro” level—that is, they expressly treat different industries differently.²²⁸ As a result, they may require courts to differentiate among industries in order to invoke a particular rule. For example, creating special rules for biotechnology requires courts to define certain inventions as “biotechnological.” Other policy levers operate on a “micro” level: They treat different inventions differently, without express regard to industry, but in ways that have disproportionate impacts on different industries. While they are not as obviously technology-specific, micro policy levers are just as important as macro policy levers in industry-specific tailoring because they permit the law to build up industry-specific treatment through case-by-case application.²²⁹

²²⁷ Among the other sources we do not discuss is the multi-factor test for reasonable royalty damages.

²²⁸ For example, the rules for obviousness and written description have been applied differently to biotechnology and software. See *infra* notes 277–93 and accompanying text; see also Burk & Lemley, *Technology-Specific*, *supra* note 4, at 1160–83 (supporting this claim in detail).

²²⁹ For example, the utility rule announced in *Brenner v. Manson*, 383 U.S. 519 (1966), tends to be applied only in biotechnology and chemical cases, and the experimental use doctrine only in pharmaceutical cases. The pioneer patents doctrine will affect industries with major new inventions more than industries in which invention is cumulative. See *infra* notes 244–55 and accompanying text.

The following paragraphs describe nine industry-specific policy levers already present in patent law. These doctrines are evidence of the substantial discretion already built into patent jurisprudence. Courts have not used all of these doctrines to achieve policy goals expressly, though they have sometimes done so accidentally or implicitly. The doctrines all implicate the technology-specific potential of patent law, however, and they are all capable of being used to bring patent law in line with optimal patent policy.

a. Abstract Ideas

Section 101 of the Patent Act defines the range of subject matter that is potentially patentable.²³⁰ Patentable subject matter has been defined quite broadly, as encompassing “anything under the sun that is made by man.”²³¹ There are, however, a few judicially-created exemptions from the scope of patent protection.²³² Of these, the most significant remaining exception is the rule against the patenting of abstract ideas. The rule originated in the case of *O'Reilly v. Morse*, which involved Samuel Morse's patent on the telegraph.²³³ Morse, of “Morse code” fame, was allowed a broad patent for a process using electromagnetism to produce discernable signals over telegraph wires.²³⁴ The Court in *O'Reilly* denied Morse's eighth claim, in which Morse claimed the use of “electromagnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances.”²³⁵

The rule against patenting abstract ideas, while couched in terms of patentable subject matter, is really a judicial effort to restrict the permissible scope of patents and to channel patent protection towards finished products. Patenting an abstract idea or concept,

²³⁰ 35 U.S.C. § 101 (2000).

²³¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 82-1979, at 5 (1952) and H.R. Rep. No. 82-1923, at 6 (1952)).

²³² One of these—the rule against patenting business methods—was recently abolished by the Federal Circuit. See further discussion of this *infra* note 368 and accompanying text.

²³³ 56 U.S. (15 How.) 62 (1853).

²³⁴ *Id.* at 112.

²³⁵ *Id.* Although Morse's application has become the poster child for improper attempts to claim abstractions, it may better illustrate the need for parity between disclosure and claims: Morse could not claim all uses of electromagnetism for printing intelligible characters because he had disclosed how to make all such uses.

rather than the particular device or process used to implement that concept, would permit the patentee to “engross a vast, unknown, and perhaps unknowable area.”²³⁶ The abstract ideas rule is a micro policy lever: It applies to inventions in all industries, but has particular significance for certain industries. This policy lever has two potential effects. First, it prevents patents from covering entire concepts, limiting them instead to particular implementations. This provides room for subsequent innovators to work out new implementations of the abstract idea without fear of patent liability.²³⁷ To borrow from the language of copyright, the abstract ideas rule limits the control an initial inventor has over derivative works. This is particularly significant in software and telecommunications, where it would be unwise to give the first person to think of an idea the exclusive right to control all implementations of the idea. Second, the abstract ideas doctrine prevents those who discover abstract ideas or natural rules— $E=mc^2$ is the example most commonly cited—from asserting control over the entire idea, rather than concrete implementations of that idea. It therefore forces patents downstream, away from unfinished research and toward completed products or processes more suitable for the market. In Schumpeter’s taxonomy, it channels patents toward innovations rather than merely inventions.²³⁸ This result may have particular impor-

²³⁶ *Brenner v. Manson*, 383 U.S. 519, 534 (1966). Likewise, the Court, in disallowing the patent claim in *O’Reilly*, said:

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.

56 U.S. (15 How.) at 113.

²³⁷ Indeed, the Court in *O’Reilly* was prescient in suggesting that the development of the telegraph did not justify giving Morse a patent on any use of electricity to communicate information: Much modern communication relies on the non-telegraphic use of electricity.

²³⁸ See Nelson and Winter, *supra* note 128, at 263 (attributing the distinction between invention and innovation to Schumpeter); William Kingston, *Direct Protection of Innovation* 13 (William Kingston ed., 1987). For more on the invention-innovation distinction, see *infra* note 321 and accompanying text.

tance in biotechnology, where the patenting of upstream research ideas and tools threatens to stifle downstream innovation.²³⁹

b. Utility

Proof that the invention is useful has long been required for patent protection.²⁴⁰ In the last several decades, however, the utility requirement has lost much of its force. The courts have all but abandoned the requirement that an invention be morally beneficial,²⁴¹ permitting patents even on inventions that seem calculated to deceive.²⁴² The PTO has permitted patents on a wide variety of seemingly frivolous inventions.²⁴³ The only exceptions are biology and chemistry. Beginning with *Brenner v. Manson*,²⁴⁴ the courts have required proof that a new chemical molecule or chemical process display some concrete and terminal application before it can be patented.²⁴⁵ In the case of pharmaceuticals, the PTO subsequently elevated this holding to require proof of therapeutic effi-

²³⁹ But see Mark D. Janis & Jay P. Kesan, *Weed-Free I.P.: The Supreme Court, Intellectual Property Interfaces, and the Problem of Plants* 33 (Ill. Pub. Law and Legal Theory Research Papers Series, Working Paper No. 00-07, 2001) ("[S]ubject matter eligibility doctrines are among the least effective policy instruments in all of intellectual property law.").

²⁴⁰ The statutory basis for this requirement is in 35 U.S.C. § 101 (2000), which permits the patenting of "new and useful" inventions, as well as 35 U.S.C. § 112 (2000), which requires disclosure of how to "make and use" the invention. Naturally, no use can be disclosed unless the invention has one.

²⁴¹ See, e.g., *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367 (Fed. Cir. 1999) (declining to follow old cases requiring proof of moral utility); *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Tex. 1988) (holding that a radar detector patent satisfied the utility requirement despite potential use for illegal purposes); *Ex parte Murphy*, 200 U.S.P.Q. (BNA) 801, 802 (Bd. Pat. App. & Inter. 1977) (rejecting the proposition that an immoral gambling invention lacked utility). For an argument that the moral utility doctrine should be revived specifically in the field of biotechnology, making it a macro policy lever, see Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 Wm. & Mary L. Rev. (forthcoming Feb. 2004).

²⁴² See, e.g., *Juicy Whip*, 185 F.3d at 1365-67 (finding a deceptively designed drink dispenser to have utility even though it was designed to deceive).

²⁴³ See, e.g., U.S. Patent No. 4,998,724 (issued Mar. 12, 1991) ("Thumb-Wrestling Game Apparatus With Stabilizing Handle"); U.S. Patent No. 5,031,161 (issued July 9, 1991) ("Life Expectancy Timepiece"); U.S. Patent No. 5,076,262 (issued Dec. 31, 1991) ("Ear-Flattening Device").

²⁴⁴ 383 U.S. 519 (1966).

²⁴⁵ *Id.* at 534-35.

cacy before a patent could issue.²⁴⁶ The Federal Circuit has weakened this rule somewhat, holding that indicators of therapeutic efficacy, such as animal modeling or *in vitro* data, can satisfy the utility requirement.²⁴⁷ While the Federal Circuit has not been as systematic in applying utility to inorganic chemistry, the requirement still has some force there as well.²⁴⁸

Under these cases, the standard for utility in the life sciences is different—and substantially higher—than the standard in any other industry. This higher standard is similarly apparent in a related life sciences manifestation of the *Brenner* legacy regarding patents on DNA molecules, especially short or partial gene sequences such as ESTs.²⁴⁹ The PTO's Utility Guidelines for such patents require a showing of "specific," "substantial," and "credible" applications not found in examination of other technologies.²⁵⁰ Since the PTO's rules have no independent legal force,²⁵¹ these rules must rely on either the agency's reading of *Brenner* or on some future judicial ratification of the standard. In either case, this variance from other

²⁴⁶ Request for Comments on Proposed Utility Examination Guidelines, 60 Fed. Reg. 97, 98 (Jan. 3, 1995).

²⁴⁷ See *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995).

²⁴⁸ See, e.g., *In re Ziegler*, 992 F.2d 1197, 1203 (Fed. Cir. 1993) (rejecting a claim to be the first inventor of polypropylene because the patentee had not yet discovered utility for polypropylene).

²⁴⁹ ESTs are fragments of genes that do not themselves produce a functional protein, but can be used as markers to identify a particular DNA sequence on a chromosome. The proper showing of utility necessary for ESTs has been the subject of considerable academic debate. See Julian David Forman, A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications, 12 Alb. L.J. Sci. & Tech. 647, 679–81 (2002) (arguing that the Utility Guidelines force patents too far downstream); Merges & Eisenberg, *supra* note 164, at 20 (concluding that ESTs do not satisfy the utility requirement).

²⁵⁰ Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001).

²⁵¹ The Guidelines purport only to interpret the law, something over which the courts have the ultimate say. See *id.* at 1097–98 (stating that the Guidelines "do not constitute substantive rulemaking and hence do not have the force and effect of law"); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996). After the decision in *Dickinson v. Zurko*, 527 U.S. 150, 161–62 (1999), however, the courts owe deference to PTO factfinding under the Administrative Procedures Act, and under the same statute may owe some deference to PTO rulemaking on substantive issues of patent law. See Craig Allen Nard, Deference, Defiance, and the Useful Arts, 56 Ohio St. L.J. 1415, 1509 (1995) (arguing that the PTO is entitled to deference on legal issues under the APA); see also Arti K. Rai, Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials, 2 Wash. U. J.L. & Pol'y 199, 201–02 (2000) (advocating deference to PTO factfinding).

fields is not reflected in the statute but derives ultimately from judicial interpretation.

Thus, the utility doctrine constitutes an example of a macro policy lever: It creates a blanket rule for one set of cases that differs from the rule in others.²⁵² This rule is expressly framed in policy terms. The Court in *Brenner* worried that if a patentee could patent a product before discovering its function, “a vast, unknown, and perhaps unknowable area” might fall within the patentee’s control.²⁵³ By giving patent protection too early—before the actual use of the product has been identified—patent law might deter research by others on the use of the product.²⁵⁴ As we noted in Part II, the concern about upstream patenting is particularly significant in the context of biotechnology. The courts have indeed applied the utility doctrine more strictly in biotechnology cases than in others, though the application to pharmaceuticals and other chemical cases may be more problematic.²⁵⁵

c. Experimental Use

Patent law has two different doctrines of experimental use, one entirely non-statutory and the other partially so. Experimental use first arises as an exception to the rule that an invention cannot be patented if it was on sale or in public use more than one year prior to the filing of a patent application.²⁵⁶ While the statute seems to brook no exception for public uses made for some legitimate pur-

²⁵² See, e.g., *In re Kirk*, 376 F.2d 936, 961 (C.C.P.A. 1967) (Rich, J., dissenting) (*Brenner*’s utility requirement would never be “indulged in with respect to other scientific ‘tools’ or a mechanical or optical or electronic sort.”). Forman endorses the use of utility as a technology-specific policy lever, though he believes the doctrine as applied to biotechnology is currently too powerful. Forman, *supra* note 249, at 650.

²⁵³ *Brenner*, 383 U.S. at 534.

²⁵⁴ *Id.*; cf. Lemley, *Economics of Improvement*, *supra* note 69, at 1048–72 (discussing the concern that centralized control of downstream innovation would reduce innovation by third parties).

²⁵⁵ See, e.g., Eric Mirabel, *Practical Utility is a Useless Concept*, 36 *Am. U. L. Rev.* 811 (1987) (criticizing judicial construction of “useful” in the chemical field); A. Samuel Oddi, *Beyond Obviousness: Invention Protection in the Twenty-First Century*, 38 *Am. U. L. Rev.* 1097, 1127 (1989) (arguing that utility requirements have an adverse effect on innovation); Charles E. Smith, *Comment, Requirements for Patenting Chemical Intermediates: Do They Accomplish the Statutory Goals?*, 29 *St. Louis U. L.J.* 191, 202–04 (1984) (suggesting an alternative to the restrictive “use” requirement).

²⁵⁶ 35 U.S.C. § 102(b) (2000).

pose, a long line of cases beginning with *City of Elizabeth v. Pavement Co.*²⁵⁷ has held that patent applicants do not trigger the one-year statutory bar if their use or sale is part of a bona fide experiment.²⁵⁸ The courts have looked to a variety of factors to determine whether a patentee's use is experimental, including whether the goods were sold, whether the patentee kept control over them, whether the patentee sought feedback, and whether the final product changed as a result.²⁵⁹ The basic inquiry, however, is focused on the patentee's purpose in releasing the product.

The second doctrine of experimental use arises as a defense to a claim of infringement. In an early opinion, Justice Story wrote that "it could never have been the intention of the legislature to punish a man, who constructed such a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."²⁶⁰ The Federal Circuit has construed this defense to infringement quite narrowly, holding that any intent to make commercial use of the resulting product precludes reliance on the defense.²⁶¹ The defense was not always so narrow, however, and commentators have suggested that it could play an expanded role in permitting legitimate efforts to improve on or design around a patent.²⁶²

²⁵⁷ 97 U.S. 126 (1877).

²⁵⁸ See, e.g., *Pfaff v. Wells Elecs.*, 525 U.S. 55, 64 (1998) (holding that "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").

²⁵⁹ See, e.g., *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 (Fed. Cir. 1996) (enumerating factors bearing on experimental use).

²⁶⁰ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

²⁶¹ See, e.g., *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002); *Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 862–63 (Fed. Cir. 1984). There is also a separate statutory experimental use defense which is limited to uses by generic drug makers of patented products during preparations for FDA approval of abbreviated new drug applications ("ANDAs"). 35 U.S.C. § 271(e)(1) (2000). That statutory doctrine was construed narrowly by the Federal Circuit in *Integra LifeSciences Inc. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003).

²⁶² See, e.g., Eisenberg, *supra* note 65, at 1021 (analyzing scope of experimental use exemption by comparing exclusive rights and free access regimes); Suzanne T. Michel, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 High Tech. L.J. 369, 372 (1992) (advocating a customized experimental use exception); Janice Mueller, *No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1 (2001) (endorsing a broadened experimental use defense akin to the European sys-

Both judicially created experimental use doctrines are micro policy levers.²⁶³ They do not expressly differ by industry, but for obvious reasons they are more likely to be applied in industries where reproduction and testing of products are necessary parts of the product development process. Experimental use as a defense to infringement is likely to be particularly important where it is difficult or impossible to evaluate a product or design around a patent without reproducing the product itself. Cohen and Lemley have argued that this is true in computer software but not in most other industries.²⁶⁴ Similarly, the experimental use exception to the Section 102(b) statutory bar benefits inventions whose design requires testing by a large segment of the public or inventions whose durability over a substantial period is at issue. Software is a good example of the former. Software companies tend to engage in extensive “beta-testing” of their products with consumers before—indeed even after—releasing the first commercial version. The pavement at issue in *City of Elizabeth* is a good example of durability.²⁶⁵ By contrast, pharmaceuticals and chemical process inventions may be tested in laboratories for years without release to the public. The experimental use doctrines accommodate the general rules of patent law to the needs of iterative industries in which copying or open use of prototypes is a practical necessity.

d. The Level of Skill in the Art

A number of factual questions in patent law are answered from the perspective of the person having ordinary skill in the art (the “PHOSITA”). Much of the case law concerning the PHOSITA arises out of the consideration of the obviousness standard found in Section 103 of the patent statute. Although originally developed as a common law doctrine, the nonobviousness criterion was codi-

tem). Most of the rest of the world interprets experimental use more broadly than the Federal Circuit does. See, e.g., Rebecca S. Eisenberg, Patent Swords and Shields 1 (2003) (working paper, on file with the Virginia Law Review Association) (noting the broader approach to experimental use in Europe) [hereinafter Eisenberg, Swords].

²⁶³ The statutory experimental use defense, by contrast, is a macro lever because it applies only to products that require FDA approval. We do not consider it further in this Article, however, because it is a statutory, rather than a judicial, creation.

²⁶⁴ Cohen & Lemley, *supra* note 140, at 16–21.

²⁶⁵ *City of Elizabeth*, 97 U.S. 126.

fied in the 1952 Patent Act as a requirement that the claimed invention taken as a whole not be obvious to one of ordinary skill in the art at the time the invention was made.²⁶⁶ The PHOSITA is equally central to calibrating the legal standard for patent disclosure. In return for a period of exclusive rights over an invention, the inventor must fully disclose the invention to the public. The first paragraph of Section 112 requires that this disclosure enable "any person skilled in the art" to make and use the claimed invention.²⁶⁷ This same standard controls several related disclosure doctrines as well. First, the definition of enablement affects the patentability requirement of specific utility, as the invention must operate as described in the specification if the inventor is to enable one of ordinary skill to use it.²⁶⁸ Additionally, compliance with the independent requirements of adequate written description and best mode disclosure is measured with reference to the understanding of a person skilled in the art. Finally, the definiteness of patent claims, which must be written so as to warn members of the public what is covered by the patent, has traditionally been assessed with regard to the knowledge of one having ordinary skill in the art. If the terms of the claims would not be comprehensible to such a person, they fail the requirements of Section 112.²⁶⁹

The PHOSITA also shows up as a convenient metric in other unexpected areas, including judicially created patent doctrines. Claim construction requires reference to how the PHOSITA would understand terms in the patent claims.²⁷⁰ The PHOSITA reappears in some formulations of the standard for infringement by equivalents. In its germinal opinion on the doctrine of equivalents, *Graver Tank Manufacturing Co. v. Linde Air Products Co.*, the Supreme Court indicated that the equivalence between elements of an alleg-

²⁶⁶ 35 U.S.C. § 103 (2000).

²⁶⁷ Id. § 112 ¶ 1 (2000).

²⁶⁸ See *Newman v. Quigg*, 877 F.2d 1575, 1581–82 (Fed. Cir. 1989).

²⁶⁹ The Federal Circuit's recent decision in *Exxon Research & Engineering Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001), however, holds that indefiniteness is a pure question of law. How the court will resolve the understanding of the PHOSITA as a legal matter is not entirely clear, though it nominally undertakes a similar burden in construing patent claims. See *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1454–55 (Fed. Cir. 1998) (en banc).

²⁷⁰ See Craig Allen Nard, A Theory of Claim Interpretation, 14 Harv. J.L. & Tech. 1, 6 (2000) [hereinafter Nard, Claim Interpretation].

edly infringing device and those of a claimed invention might be tested by determining whether the elements were known in the art to be substitutes for one another.²⁷¹ The Federal Circuit strengthened this use of the PHOSITA by making the “known interchangeability” of elements—judged from the perspective of one of ordinary skill in the art—a fundamental test for equivalence.²⁷² A great deal of patent doctrine therefore rests upon the measurement of some legal parameter against the skill and knowledge of the PHOSITA. In many of these instances, the role of the PHOSITA is a judicial, rather than a statutory, creation.

As the name suggests, PHOSITA-based analysis is specific to the particular art in which the invention is made. Courts measure most significant patent law doctrines against a benchmark that varies by industry. If the court concludes that an art is uncertain and its practitioners not particularly skilled, it will be inclined to find even relatively modest improvements nonobvious to the PHOSITA. At the same time, the court will be inclined to require greater disclosure to satisfy the requirements of Section 112, and correspondingly to narrow the scope of claims permissible from any given disclosure. If the art is predictable and the PHOSITA quite skilled, the reverse is true.²⁷³ The result is to make the PHOSITA a potentially significant macro policy lever.

Overwhelming evidence indicates that the application of the PHOSITA standard varies by industry, leading for example to fewer, but broader, software patents and more, but narrower, biotechnology patents.²⁷⁴ It is less clear that the court is in fact using the PHOSITA explicitly as a policy lever, responding to the characteristics of particular industries, rather than merely trying to predict what those of skill in the art would think.²⁷⁵ But as we have observed elsewhere, if the court is trying to apply the PHOSITA standard neutrally, it is not doing a very good job.²⁷⁶ In any event, because application of the PHOSITA standard causes nominally

²⁷¹ *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.* 339 U.S. 605, 609 (1950).

²⁷² See *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995) (en banc), rev'd on other grounds, 520 U.S. 17 (1997).

²⁷³ See *Burk & Lemley, Technology-Specific*, supra note 4, at 1190–94.

²⁷⁴ *Id.*

²⁷⁵ *Id.* at 1193–96 (considering both alternatives).

²⁷⁶ *Id.* at 1196.

unitary patent rules to be applied very differently—indeed in directly contradictory ways—in different industries, we have included it among the ways in which patent law can accommodate the characteristics of particular industries.

e. Secondary Considerations of Nonobviousness

Section 103 of the Patent Act provides that obviousness shall be tested by reference to the differences between the invention and the prior art.²⁷⁷ In *Graham v. John Deere Co.*,²⁷⁸ the Court introduced a series of nonstatutory factors, called “secondary considerations” of nonobviousness, which the Court said “may have relevancy.”²⁷⁹ The Federal Circuit has elevated these secondary considerations to a required element of any obviousness analysis.²⁸⁰ The considerations the court has endorsed include the commercial success of the invention, the failure of others to make the invention, the existence of a long-felt need for the invention, unexpected results, efforts by others to copy the invention, licensing or other acquiescence by the market treating the patentee as the inventor, and (in some but not all circumstances) simultaneous invention by others.²⁸¹ With the exception of simultaneous invention, all of these factors favor a finding of patentability, while their absence is not evidence that an invention is obvious.²⁸² These secondary considerations are policy based; they result from the court’s belief that the reaction of the market will show that certain inventions are more deserving of protection than others.

The standard secondary considerations of nonobviousness are micro policy levers. They nominally apply to every case in any in-

²⁷⁷ 35 U.S.C. § 103(a) (2000).

²⁷⁸ 383 U.S. 1 (1966).

²⁷⁹ *Id.* at 17–18.

²⁸⁰ See, e.g., *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662–63 (Fed. Cir. 2000) (“In order to determine obviousness as a legal matter, four factual inquiries must be made . . .”).

²⁸¹ See *Brown & Williamson Tobacco Co. v. Philip Morris Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000) (enumerating factors). In *Hybritech, Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1380 n.4 (Fed. Cir. 1986), the court held that simultaneous invention—the only secondary consideration that can favor the accused infringer—need not always be considered.

²⁸² Courts say that secondary considerations are relevant only when evidence of nonobviousness is present. See *Custom Accessories v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 (Fed. Cir. 1986).

dustry. In fact, however, the secondary considerations are actually weighted toward inventions that are embodied in actual products, patents that cover entire products, and significant "leaps," rather than toward components of a product or incremental inventions. Commercial success, long-felt need, licensing, and copying all work best for actual products that are sold, rather than for upstream research tools or intermediary products. Commercial success depends on the connection between the patent and a product on the open market,²⁸³ so it is more likely to be evident in products like pharmaceuticals than in one of the myriad components of a semiconductor chip. Factors like commercial success, long-felt need, and acquiescence tend to favor inventions that are significant advances over what came before, rather than incremental improvements. Accordingly, these factors are more likely to apply in a pharmaceutical or biotechnology case than in a software case. While secondary considerations are nominally neutral, their application in fact favors inventions in certain industries.²⁸⁴

f. Written Description

One of the disclosure requirements in Section 112 of the Patent Act is that the patentee provide an adequate "written description" of the invention.²⁸⁵ Section 112 separately provides that the patent specification must teach the PHOSITA how to make and use the invention;²⁸⁶ this is related to, but distinct from, the written description requirement.²⁸⁷ The doctrine traces its origin to older versions

²⁸³ See, e.g., Dreyfuss, *supra* note 226, at 9–10 (commending the Federal Circuit for incorporating limiting considerations in its commercial success analysis); Edmund Kitch, *Graham v. John Deere Co.*: New Standards for Patents, 1966 Sup. Ct. Rev. 293, 330–35 (criticizing the role commercial success plays in proving nonobviousness); Robert P. Merges, *Economic Perspectives on Innovation: Patent Standards and Commercial Success*, 76 Cal. L. Rev. 803, 823–27 (1988) ("Today the patent applicant must show her products sales or market share in relation to other products in the market, and demonstrate its comparative success to the court.").

²⁸⁴ Cf. Robert M. Hunt, *Patentability, Industry Structure, and Innovation* (Fed. Reserve Bank of Phila., Working Paper No. 01–13/R, 2001) (arguing that a uniform obviousness standard will encourage innovation in some industries but discourage it in others).

²⁸⁵ 35 U.S.C. § 112 ¶ 1 (2000).

²⁸⁶ *Id.* This is the "enablement" requirement.

²⁸⁷ See *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998); *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (holding that to fulfill the written de-

of the patent statute that lacked a requirement for the inventor to provide claims. Thus, the written description once served the purpose now served by claims: to define the technology protected under the patent, and to put the public on notice of the boundaries that would define infringement.

Because these purposes are now served by the claims, the written description criterion has evolved to serve a new purpose. The modern written description requirement is designed to ensure that at the time the patentee files a patent application, she actually has conceptual possession of the invention she is now claiming. In its modern incarnation, written description evolved as a highly technology-specific doctrine centered in the chemical arts. After remaining dormant for many years,²⁸⁸ the doctrine has more recently been applied primarily to bar patentees from changing their claims during prosecution to track a competitor's product that they did not themselves conceive of, even though their specification might have enabled one of skill in the art to make it.²⁸⁹ In biotechnology, however, the doctrine has been applied as a sort of "super-enablement" requirement, forcing biotech patentees to list particular gene sequences in order to obtain a patent covering those sequences.²⁹⁰

The written description doctrine as currently applied is a macro policy lever. The Federal Circuit has applied the doctrine to bio-

scription requirement the specification must allow a PHOSITA to recognize that the inventor invented what is claimed).

²⁸⁸ On the history of the doctrine, see Merges et al., *supra* note 28, at 208–09.

²⁸⁹ See, e.g., *Gentry Gallery*, 134 F.3d at 1479–80 (holding that patentee's disclosure of reclining sofa invention did not extend to the placement of the sofa controls outside the console, where patentee considered the new location only after his competitors began such placement); *Hyatt v. Boone*, 47 U.S.P.Q.2d (BNA) 1128, 1131 (Fed. Cir. 1998) ("It is insufficient as written description, for purposes of establishing priority of invention, to provide a specification that does not unambiguously describe all limitations of the count."); *In re DiLeone*, 436 F.2d 1404, 1405 (C.C.P.A. 1971) ("[T]he statutory requirement that the specification describe the invention might not be met even where the specification satisfies the related statutory requirement that it enable any person skilled in the art 'to make and use the same.'") (citation omitted).

²⁹⁰ *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (holding that proof of conception of a DNA invention requires disclosure of the actual DNA sequence). But cf. *Singh v. Brake*, 317 F.3d 1334, 1343–44 (Fed. Cir. 2003) (holding that disclosure of the only two meaningful embodiments in a genus of DNA sequences was sufficient to describe that genus).

technology cases in a way that would be inconceivable in other industries, such as software.²⁹¹ The effect is to narrow the scope of biotechnology patents—or at least DNA patents²⁹²—rather dramatically. The same may be said of the application of the enablement requirement through the intermediary of the PHOSITA. In certain industries, such as software, the enablement requirement is easily satisfied and therefore plays virtually no role in limiting the scope of claims. In other industries, such as biotechnology, the doctrine has been applied with much more vigor.²⁹³

g. Reasonable Interchangeability

The doctrine of equivalents in patent law permits a court to find infringement in some circumstances even though the accused product does not fall within the literal scope of the patent claims. For the doctrine of equivalents to apply, the differences between a particular claim limitation and the accused product must be “insubstantial.”²⁹⁴ Courts have formulated a variety of tests to determine whether the differences in question are substantial. One major test—adopted by the Supreme Court in *Graver Tank*—asks whether the accused element performs substantially the same function in substantially the same way to achieve substantially the same result.²⁹⁵ This tripartite test has been criticized on the grounds that it doesn’t work well in all circumstances, particularly for composition of matter claims.²⁹⁶ The most significant alternative is the “known interchangeability” test, which asks whether one of ordinary skill in the art would consider the accused element to be rea-

²⁹¹ For much more detail on this point, see Burk & Lemley, *Technology-Specific*, supra note 4, at 1173–78.

²⁹² The court has proven less willing to apply the written description doctrine to other biotechnology inventions, such as monoclonal antibodies, at least in the absence of some effort to change the claims in prosecution. *Enzo Biochem v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324–25 (Fed. Cir. 2002).

²⁹³ See Burk & Lemley, *Technology-Specific*, supra note 4, at 1183–85.

²⁹⁴ *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995) (en banc), rev’d on other grounds, 520 U.S. 17 (1997).

²⁹⁵ *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.* 339 U.S. 605, 609 (1950).

²⁹⁶ See, e.g., *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39–40 (1997) (noting that “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”).

sonably interchangeable with the limitation described in the patent.²⁹⁷

It is not clear how the two tests interact, or what a court would do if it found one test, but not the other, satisfied. We believe the better view is that function-way-result is the dominant test in cases in which it can be applied, and that reasonable interchangeability is merely evidence shedding light on application of the tripartite test. In other words, if two elements work in a substantially different way,²⁹⁸ a court would likely find them not equivalent even if those of skill in the art would find them reasonably interchangeable for most purposes. Nonetheless, reasonable interchangeability is still important as evidence bearing on the tripartite test and in the many cases when the tripartite test simply will not work.

Reasonable interchangeability is a micro policy lever in two different senses. First, the tripartite test works well for inventions in certain industries, such as mechanics and, arguably, software—industries in which patents tend to cover devices or processes. It works far less well for industries—such as organic chemistry, pharmaceuticals, and biotechnology—in which patents tend to cover compositions of matter. As a result, reasonable interchangeability is likely to take on greater importance as a test in some industries than others. Second, because reasonable interchangeability relies on the PHOSITA, it is technology-specific for the same reasons that the obviousness and enablement PHOSITAs are technology-specific.²⁹⁹ The less certain the court perceives a field to be, the less scope will be given to patents under the doctrine of equivalents. These two principles reinforce each other. The court has concluded that chemistry, pharmaceutical research, and biotechnology are inherently uncertain disciplines,³⁰⁰ meaning that in those disciplines—the very ones in which the reasonable interchangeability test will be most important—the test is likely to lead to narrow interpretations of the doctrine of equivalents. Finally, commentators have argued that reasonable in-

²⁹⁷ See *Hilton Davis*, 62 F.3d at 1519.

²⁹⁸ A separate question is how function, way, and result are to be tested. To the extent that they are measured by reference to the knowledge of a PHOSITA, the test may collapse into reasonable interchangeability.

²⁹⁹ See *supra* notes 266–76 and accompanying text.

³⁰⁰ See, e.g., *Amgen, Inc. v. Chugai Pharm. Co.* 927 F.2d 1200, 1208–09 (Fed. Cir. 1991) (finding that biotechnology is an uncertain discipline); Burk & Lemley, *Uncertainty Principle*, *supra* note 160.

terchangeability should be adopted as the explicit rule in biotechnology,³⁰¹ suggesting that it could serve as a macro policy lever as well.

h. Pioneering Patents

It is a venerable principle of patent law that pioneering patents—important patents that open up a new field—should be entitled to a broader range of protection than more modest inventions or improvements on existing ideas.³⁰² To some extent broadened claim scope follows naturally from the situation of a pioneering patent: There is little prior art in a newly opened field that would prevent the inventor from claiming broadly. Broad literal claims may not anticipate later-invented technologies that could be substituted for elements of the claim; however, such substitutions may instead be captured under the doctrine of equivalents, if applied broadly. The pioneer patent rule has not been invoked by the Federal Circuit in recent years, leading some to consider it moribund,³⁰³ but it provides at least one factor to consider in deciding how broadly to apply the doctrine of equivalents.³⁰⁴

³⁰¹ Antony L. Ryan & Roger G. Brooks, *Innovation vs. Evasion: Clarifying Patent Rights in Second-Generation Genes and Proteins*, 17 *Berkeley Tech. L.J.* 1265, 1265 (2002).

³⁰² See, e.g., *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 207 (1894) (“If the invention is broad or primary in its character, the range of equivalents will be correspondingly broad, under the liberal construction which the courts give to such inventions.”); *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed. Cir. 1987) (“A pioneer invention is entitled to a broad range of equivalents.”); John R. Thomas, *The Question Concerning Patent Law and Pioneer Inventions*, 10 *High Tech. L.J.* 35, 37 (1995) (“Courts construe pioneer patent claims . . . to encompass a broader range of so-called ‘equivalents’ during an infringement determination.”). The Federal Circuit rejected a different argument—that pioneering patents should be entitled to a lower enablement standard—in *Plant Genetic Systems v. Dekalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003).

³⁰³ Compare *Augustine Med., Inc. v. Gayman Indus.*, 181 F.3d 1291, 1301 (Fed. Cir. 1999) (relying on “pioneering” standard), with *Sun Studs Inc. v. ATA Equip. Leasing*, 872 F.2d 978, 987 (Fed. Cir. 1989) (referring to the pioneer patents rule as “ancient jurisprudence”).

³⁰⁴ For an argument that would apply pioneer status in the determination of nonobviousness, see Samson Vermont, *A New Way to Determine Obviousness: Applying the Pioneer Doctrine to 35 U.S.C. § 103(a)*, 29 *AIPLA Q.J.* 375 (2001). We think Vermont’s proposal is not likely to affect the outcome of cases significantly; pioneering inventions are not generally the ones at risk of being declared obvious.

The pioneering patent rule is a micro policy lever. The rationale for the rule is expressly policy-based: If we do not give broad equivalents protection to pioneers in new fields, they will be unable to capture adequate returns from their invention as subsequent improvers figure out commercial applications of the new idea that avoid the literal scope of the patent.³⁰⁵ The power of the doctrine is tied to the nature of innovation in a particular industry. In some industries, like pharmaceuticals, innovation is likely to take the form of discrete new inventions that in many cases open up entire fields of inquiry.³⁰⁶ By contrast, industries such as software and most semiconductor inventions are characterized by more incremental improvements. These incremental improvements will not be entitled to a broader range of equivalents under the pioneering patents rule. Thus, application of the rule, while nominally neutral, is likely to result in broader protection under the doctrine of equivalents in some industries more than others.

i. Reverse Doctrine of Equivalents

The reverse doctrine of equivalents is in some sense the contrapositive of the pioneer patents rule. The reverse doctrine of equivalents permits an accused infringer to escape literal infringement by demonstrating that the device, while falling literally within the scope of the claims, is so far changed in principle from the patented invention that it would be inequitable to hold the infringer liable.³⁰⁷ The doctrine is rarely applied, and a recent Federal Circuit decision casts its future in doubt.³⁰⁸ In theory, however, it serves as

³⁰⁵ See Oddi, *supra* note 255, at 1127.

³⁰⁶ Not all pharmaceutical inventions will take this form, of course. Pharmaceutical companies sometimes engage in the creation of safer, "copycat" drugs. Those inventions would be less likely to qualify for pioneer status.

³⁰⁷ See *Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 562 (1898).

³⁰⁸ In *Tate Access Floors v. Interface Architectural Resources*, 279 F.3d 1357, 1368 (Fed. Cir. 2002), the court suggested that the doctrine had no continued meaning after the passage of the 1952 Patent Act, and (wrongly) stated that the Federal Circuit had never applied the doctrine. *Contra Scripps Clinic & Research Found. v. Genentech*, 927 F.2d 1565, 1581 (Fed. Cir. 1991) (applying the doctrine). See *Amgen, Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1351 (Fed. Cir. 2003) (implying that the doctrine had continuing force, although it did not apply the doctrine in this case).

a vital release valve, preventing patent owners from stifling radical improvements.³⁰⁹

The reverse doctrine of equivalents is a micro policy lever. The doctrine can apply to radical improvements in any area of technology, and it has indeed been used to cover technological paradigm shifts within an industry.³¹⁰ Radical improvements are more likely in some industries than others. Software, for example, tends to progress through iterative steps, and software inventions are therefore less likely to be the sort of radical improvements that qualify under the reverse doctrine of equivalents.

2. Potential Policy Levers

In all of the instances we have just discussed, courts not only have discretion granted to them in the patent statute (or assumed as part of the common law process), but they have also used that discretion (wittingly or not) to tailor patent law to individualized circumstances in different industries. The discretion granted to courts in patent law, however, does not end there. Various other doctrines *could* be used as policy levers within the discretion granted in the statute. The Sections that follow consider several such potential policy levers.

a. Presumption of Validity

The patent statute provides that issued patents are presumed valid.³¹¹ The Federal Circuit has interpreted this provision to require an accused infringer to prove by clear and convincing evidence that a patent is invalid.³¹² Lemley and others have argued that such a strong presumption of validity is unwarranted, given the minuscule amount of time that the PTO spends actually examining

³⁰⁹ See Lemley, *Economics of Improvement*, supra note 69, at 1023–24 (suggesting that the reverse doctrine of equivalents protects radical improvers in patent law more effectively than it does in copyright law); Robert P. Merges, *A Brief Note on Blocking Patents and the Reverse Doctrine of Equivalents in Biotechnology Cases*, 73 J. Pat. & Trademark Off. Soc'y 878, 883 (1991).

³¹⁰ See, e.g., *Scripps Clinic*, 927 F.2d at 1581 (suggesting application of the reverse doctrine of equivalents on remand where the defendant produced similar biological materials by a radically new biotechnological process).

³¹¹ 35 U.S.C. § 282 (2000).

³¹² *Al-Site Corp. v. VSI Int'l*, 174 F.3d 1308, 1323 (Fed. Cir. 1999).

patents and the number of bad patents that slip through the system.³¹³ The arguments against a strong presumption of validity are compounded by the rather startling fact that the patentee never has the burden of proving to the PTO that it should be entitled to a patent; rather, it is the PTO that carries the burden of showing that an application is not deserving of a patent.³¹⁴ While abolishing the presumption of validity outright would require legislative change, the Federal Circuit has substantial control over the strength of the presumption and the cases in which it applies. It could, if it wished, make the presumption one that could be overcome by preponderance of the evidence, rather than by clear and convincing evidence. Alternatively, the Federal Circuit could change its rule so that the presumption did not apply to prior art that was not considered by the PTO. Indeed, before the Federal Circuit was created, a majority of circuits applied precisely this rule.³¹⁵ The Federal Circuit expanded the presumption of validity to encompass prior art the examiner did not consider,³¹⁶ a rule that makes little sense. Yet another approach would be to presume valid only patents whose owners had conducted a diligent prior art search during the application process.³¹⁷

³¹³ See Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 *Berkeley Tech. L.J.* 763, 765–66 (2002); Lemley, *Rational Ignorance*, *supra* note 48, at 1527–29 (2001).

³¹⁴ See *In re Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002); *In re Oetiker*, 977 F.2d 1443, 1449 (Fed. Cir. 1992) (Plager, J., concurring); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 *U. Ill. L. Rev.* 305, 325.

³¹⁵ See, e.g., *Mfg. Research Corp. v. Graybar Elec. Co.*, 679 F.2d 1355, 1360–61 (11th Cir. 1982) (adopting the “considered art only” rule); *NDM Corp. v. Hayes Prods.*, 641 F.2d 1274, 1277 (9th Cir. 1981) (same); *Lee Blacksmith Inc. v. Lindsey Bros.*, 605 F.2d 341, 342–43 (7th Cir. 1979) (same).

³¹⁶ See, e.g., *Kahn v. Gen. Motors*, 135 F.3d 1472, 1480 (Fed. Cir. 1998) (“The presentation of evidence that was not before the examiner does not change the presumption of validity . . .”); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996) (“The presentation at trial of additional evidence that was not before the PTO does not change the presumption of validity or the standard of proof, although the burden may be more or less easily carried because of the additional evidence.”).

³¹⁷ There is no such requirement now; see *FMC Corp. v. Hennessy Indus.*, 836 F.2d 521, 526 n.6 (Fed. Cir. 1987) (“As a general rule, there is no duty to conduct a prior art search.”). Indeed, many sophisticated entities refuse to search for prior art, out of concern over what they might find. Lemley, *Rational Ignorance*, *supra* note 48, at 1510 n.63. For discussion of how to encourage prior art searches, see Kesan, *supra*

The Federal Circuit could use the presumption of validity as a policy lever. While it is possible to envision it as a macro policy lever, granting stronger presumptions in some industries than others based on either historical experience with patents or the policies favoring stronger or weaker patent protection,³¹⁸ a more plausible approach would be to use the presumption of validity as a micro policy lever. If the Federal Circuit were to apply the presumption only to cited prior art, for example, the effect would be to give stronger protection to patents that cite more prior art. Because the empirical evidence is clear that patents in some industries, notably pharmaceuticals, biotechnology, and chemistry, cite more prior art than patents in industries such as electronics,³¹⁹ the effect of such a general rule would be to strengthen patent protection in those industries.

b. New Secondary Considerations

The classic economic framework pioneered primarily by Robert Merges views obviousness as a function of uncertainty.³²⁰ Where uncertainty is higher, the theory goes, courts should lower the standard of patentability to compensate for the risk of failure and therefore compensate for the attendant lower expected reward per dollar invested. Although courts have traditionally focused on uncertainty, and hence obviousness, as a function of invention, invention is rewarded in the marketplace only to the extent it is embod-

note 313, at 770; Jay P. Kesan & Mark Banik, Patents as Incomplete Contracts: Aligning Incentives for R&D Investment With Incentives to Disclose Prior Art, 2 Wash. U. J.L. & Pol'y 23, 26 (2000).

³¹⁸ For example, commentators have long criticized the quality of patents that issue in the software industry. See, e.g., Cohen, *supra* note 190, at 1178-79. A court that agreed with this assessment might conclude that software patents were less deserving of the presumption of validity than other types of patents. At the other extreme, the PTO provides a special two-step review to business method patents, and the result has been that the office rejects more business method patent applications. Allison & Tiller, *supra* note 217 (arguing that Internet business method patents appear to be no worse than the average patent). A court might take this fact into account in strengthening the presumption of validity for business method patents.

³¹⁹ See, e.g., Allison & Lemley, Who's Patenting What?, *supra* note 20, at 2130-31 & tbl.13.

³²⁰ For a detailed elucidation of the ideas in this paragraph, see Robert P. Merges, Uncertainty and the Standard of Patentability, 7 High Tech. L.J. 1 (1992) [hereinafter Merges, Uncertainty].

ied in a successful commercial product that can be sold at a price above marginal cost. Getting from an invention to a successful product requires many more steps: developing the product, testing it, producing it, marketing it, and in many cases developing complementary products or even whole new industries that can take advantage of the invention in the most efficient way. The entire process of research, development, and turning an idea into a finished product can be described as innovation. Invention is thus a subset of innovation.³²¹

Under Merges's theory of technological development, uncertain and high-cost innovation—not just invention—should more likely be entitled to a determination of nonobviousness.³²² Intellectual property law assumes that absent legal protection, the costs and risks of innovating are systematically higher than the costs of imitation. As a result, no one will invest in R&D if the costs of R&D fall exclusively on the innovator, but the benefits of that research can be freely appropriated by all. Where R&D costs are especially high relative to the costs of imitation, lowering the standard for patentability may increase the incentive to invest in innovation by increasing the likelihood of financial reward. High costs will tend to correlate with higher risks, as the larger investment increases the opportunity for loss at any probability of success. The greater variance in outcomes might be expected to deter the rational entrepreneur from investing in such high cost projects unless the expected reward is correspondingly greater. On this approach, the Federal Circuit could take account of the cost and uncertainty of post-invention development in the same way it takes account of other economic indicia of the importance of an invention: by creating a new secondary consideration of nonobviousness that measures the cost of innovation.

We have already suggested that secondary considerations are typically micro policy levers. Cost and uncertainty of innovation, however, incorporated into a new secondary consideration, could be conceived either as a macro or a micro policy lever. Courts could inquire into the cost and uncertainty of each given innova-

³²¹ In using this typology, we follow Joseph Schumpeter. See Nelson and Winter, *supra* note 128, at 263 (attributing the distinction between invention and innovation to Schumpeter).

³²² For a similar argument, see Vermont, *supra* note 304, at 386.

tion, in which case the rule would be facially neutral, though it would apply more often in industries such as pharmaceuticals than in industries where the path to profitability was more clearly defined. A more efficient approach would be to inquire more generally into the cost and uncertainty of innovation in an industry as a whole, and to set rules that apply to a given industry. Uncertainty is difficult to measure with respect to a specific invention.³²³ It is uncertainty across many inventions—the number of inventions that do not pan out and consequently do not result in patent applications—that the test is designed to measure. That measurement can only be done in the aggregate, rather than in individual terms. On this more general approach, uncertainty of innovation as a nonobviousness factor would be a macro policy lever.

c. Patent Misuse

Under a long-standing common law doctrine, patents are unenforceable if they have been misused by their owner.³²⁴ Patent misuse can take one of two basic forms. First and most commonly, a patent is misused if it is employed to violate the antitrust laws.³²⁵ Because the patent laws themselves permit certain types of anti-competitive conduct that might otherwise be illegal,³²⁶ the test is normally stated as whether a patentee seeks to expand the patent beyond its scope with anticompetitive effect.³²⁷ Second, even absent anticompetitive effect, a patentee may commit misuse by expanding the patent beyond its lawful scope in certain ways that are deemed illegal on their face. Most notable among these is a license

³²³ Indeed, it may not make sense to measure uncertainty only in the subset of inventions that are successful enough to be the subject of patent protection, without considering the R&D efforts that did not produce patentable inventions.

³²⁴ For a general discussion of patent misuse, see 1 Hovenkamp et al., *IP and Antitrust*, supra note 87, at ch. 3. The patent misuse doctrine was first recognized in *Motion Picture Patents Co. v. Universal Film Manufacturing Co.*, 243 U.S. 502 (1917), and has long been a part of patent jurisprudence. *Morton Salt Co. v. G.S. Suppiger*, 314 U.S. 488 (1942). It is a common law doctrine; Congress has codified only limits on the doctrine (thus implicitly recognizing its legitimacy), not the doctrine itself. See 35 U.S.C. § 271(d) (2000); see also Mark A. Lemley, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 Cal. L. Rev. 1599, 1610 (1990) (discussing this negative codification) [hereinafter Lemley, *Economic Irrationality*].

³²⁵ 1 Hovenkamp et al., *IP & Antitrust*, supra note 87, § 3.2b-c.

³²⁶ See 35 U.S.C. § 261 (2000) (permitting territorially restricted patent licenses).

³²⁷ See *B. Braun Med. Co. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997).

agreement that purports to extend the patent beyond its expiration.³²⁸

While misuse claims have been on the wane in patent law, they have experienced something of a renaissance in the context of copyright. This employment of misuse may be instructive for patent law, for in copyright the doctrine has been applied primarily in cases relating to computer software where the copyright holder has in some fashion attempted to suppress competition. Most significantly, misuse has been employed by courts to preserve a right of reverse engineering access by competitors seeking to create interoperable products.³²⁹ As we have noted above, reverse engineering is critically important to progress in the software industry, but patent law lacks any explicit reverse engineering provision. If patent misuse were to develop in a parallel fashion to misuse in the software copyright cases, it might provide a basis for reverse engineering of patented software.

Patent misuse similarly has the potential to serve as a powerful micro policy lever in a variety of contexts.³³⁰ The concept of misuse necessarily contains within it an implicit definition of the scope of permissible control over an invention; it is only the expansion beyond that lawful scope that can trigger misuse.³³¹ Thus, in one sense, the content of misuse will necessarily vary from patent to

³²⁸ See *Brulotte v. Thys*, 379 U.S. 29, 32 (1964); 1 *Hovenkamp et al.*, IP and Antitrust, supra note 87, at ch. 3. But cf. *Scheiber v. Dolby Labs.*, 293 F.3d 1014, 1017–19 (7th Cir. 2002) (following *Brulotte*, but criticizing its reasoning).

³²⁹ See *Alcatel USA v. DGI Techs.*, 166 F.3d 772, 792–94 (5th Cir. 1999); *DSC Communications Corp. v. DGI Techs.*, 81 F.3d 597, 601 (5th Cir. 1996).

³³⁰ Copyright misuse provides an excellent example. Misuse claims are unknown in most copyright industries. Successful misuse claims have been made mostly with respect to computer software. 1 *Hovenkamp et al.*, IP and Antitrust, supra note 87, § 3.4a. In addition, digital music and movie cases are increasingly fertile ground for copyright misuse. See *In re Napster Inc. Copyright Litig.*, 191 F. Supp. 2d 1087 (N.D. Cal. 2002).

³³¹ Thus, the Fifth Circuit found misuse in *DGI* and *Alcatel* where the copyright owner argued that the defendant committed copyright infringement by testing the compatibility of its product with the copyrighted one, because such testing necessarily made a temporary copy of the plaintiff's work in RAM memory. *Alcatel*, 166 F.3d at 792–94; *DGI*, 81 F.3d at 601. The court concluded that the plaintiff had attempted to extend the copyright beyond its scope. In so doing, it necessarily concluded that plaintiff's copyright claim failed on the merits, as otherwise it would not have extended the copyright beyond its proper scope. See Mark A. Lemley et al., *Software and Internet Law* 198 (2d ed. 2003).

patent. More generally, whether conduct gives rise to misuse is likely to vary from industry to industry, depending on a number of factors. First, the concentration of market power in an industry will determine whether certain licensing practices, such as exclusive deals, have anticompetitive effect. Highly concentrated industries or those dominated by a single firm are more amenable to patent misuse claims. Second, the importance of interconnection between different products and the need to cross-license different patents will determine the prevalence of potentially anticompetitive practices like tying, patent pooling, and cross-licensing. Industries with overlapping and conflicting patents, like software and semiconductors, are more likely to see efforts to use a patent to gain control of an adjacent product market. Third, the rate of change in an industry will determine whether patentees have much to gain by seeking to extend patents beyond their temporal scope. Pharmaceutical companies have strong incentives to extend the life of their patents, which are most valuable years after the invention.³³² Software companies, by contrast, have no similar incentive. More generally, the courts could use patent misuse to enforce a conception of the proper scope of a patent in a given industry in the face of efforts by patentees in different industries to change that scope.

While patent misuse has the potential to serve as a policy lever, its use by the Federal Circuit to date has been minimal, and seems to have diminished over time. The court has seemed more concerned with strictly cabining patent misuse and its cousin antitrust within strict limits than it has with engaging in detailed determinations of the facts and characteristics of given industries.³³³ The anti-trust/misuse inquiry into competitive effects is necessarily industry-

³³² For a discussion of efforts by pharmaceutical companies to extend the temporal scope of their patents with anticompetitive effect, see 2 Hovenkamp et al., *IP and Antitrust*, supra note 219, § 33.9; Hovenkamp et al., *Anticompetitive Settlements*, supra note 219, at 1739.

³³³ See *C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998) (finding no general concept of "wrongful use" outside of specified categories); *B. Braun Med. Co. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997) (categorizing patent misuse claims). For similar formalist readings of antitrust cases involving patents, see *CSU v. Xerox*, 203 F.3d 1322, 1325 (Fed. Cir. 2000); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999).

specific, however, and could serve as a policy lever designed to ensure that patents are given no more than their appropriate scope.³³⁴

d. Injunctions

Patent rights are exclusive rights that fit the classic formulation of a "property rule."³³⁵ Indeed, the patent right to exclude has been regarded as a nearly absolute property rule, and the assumption that a finding of patent infringement will be accompanied by an injunction is almost universal.³³⁶ In fact, however, the patent statute provides only that courts may grant injunctive relief, not that they must.³³⁷ The legal standard for *preliminary* injunctive relief has vacillated over time. Preliminary injunctions were virtually impossible to obtain before the creation of the Federal Circuit.³³⁸ The Federal Circuit substantially liberalized the standard for granting such injunctions in the 1980s,³³⁹ but then tightened up the standard considerably in the 1990s, to the point where today preliminary injunctions are quite rare.³⁴⁰ It could do something similar with permanent injunctive relief. Indeed, in copyright, as opposed to patent cases, the Supreme Court has on several recent occasions encouraged the lower courts not to grant injunctive relief as a matter of course.³⁴¹

³³⁴ We do not intend to suggest that it necessarily should do so. Patent misuse has other problems, including an irrational set of rules for standing and remedy. See Lemley, *Economic Irrationality*, *supra* note 324, at 1614–20.

³³⁵ For the classic formulation of such a rule, see Calabresi & Melamed, *supra* note 78, at 1092.

³³⁶ See Merges et al., *supra* note 28, at 302.

³³⁷ 35 U.S.C. § 283 (2000).

³³⁸ See Edward J. Kessler et al., *Preliminary Injunctions in Patent and Trademark Cases*, 80 *Trademark Rep.* 451 (1990) (discussing historical treatment and current criteria).

³³⁹ See, e.g., *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987) (holding that there is a rebuttable presumption of irreparable harm for the purposes of granting preliminary injunctions in patent cases).

³⁴⁰ See, e.g., *Amazon.com v. Barnesandnoble.com*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001) (rejecting a preliminary injunction where there are any serious questions about the merits of the case).

³⁴¹ See *N.Y. Times v. Tasini*, 533 U.S. 483, 505 (2001); *Campbell v. Acuff Rose Music, Inc.*, 510 U.S. 569, 578 n.10 (1994); see also *Abend v. MCA*, 863 F.2d 1465 (9th Cir. 1988) (refusing to grant injunctive relief), *aff'd* on other grounds *sub nom.* *Stewart v. Abend*, 495 U.S. 207 (1990). It is true that the copyright statute contemplates

On rare occasions, courts in patent cases have refused to grant permanent injunctive relief. The most significant examples are *Foster v. American Machine & Foundry Co.*,³⁴² in which the court was influenced by the fact that the patentee did not practice the invention,³⁴³ and *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*,³⁴⁴ in which the court was swayed by the health-related nature of the invention, finding a strong public policy interest in continued access to the invention.³⁴⁵ Most recently, Judge Posner, sitting by designation in the district court in *SmithKline Beecham v. Apotex*, found that SmithKline's patent on Paxil was not infringed and that, even if it were infringed, injunctive relief would be improper.³⁴⁶ Beyond these cases, most refusals to grant injunctive relief involve compulsory licensing of patents as a remedy for antitrust violations.³⁴⁷

Injunctive relief can serve as a policy lever at either the macro or micro level. This doesn't mean it necessarily should. As a general matter, courts are correct to treat patents as a property rule regime. The difficulty of valuing the unique assets common in patent cases and the possible variation in the licenses that might be granted make compulsory licensing unwise as a general matter.³⁴⁸ Injunctive relief may be inappropriate in certain circumstances, however. First, if patents are being used to violate the antitrust laws, compulsory licensing of those patents is often a legitimate an-

compulsory licensing to a much greater extent than the patent statute does. See 17 U.S.C. § 111 (2000).

³⁴² 492 F.2d 1317 (2d Cir. 1974).

³⁴³ *Id.* at 1324; see also *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987) (refusing to grant an injunction to a patentee that was exiting the industry because it would not suffer irreparable harm).

³⁴⁴ 146 F.2d 941, 945 (9th Cir. 1944); see also *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir. 1934) (refusing to enjoin an infringement where the result would create public health problems).

³⁴⁵ *Vitamin Technologists*, 146 F.2d at 945.

³⁴⁶ 247 F. Supp. 2d 1011, 1045-46 (N.D. Ill. 2003).

³⁴⁷ See 1 Hovenkamp et al., *IP and Antitrust*, supra note 87, § 6.5c; F.M. Scherer, *The Economic Effects of Compulsory Patent Licensing* (1977).

³⁴⁸ Richard Epstein, *Steady the Course: Property Rights in Genetic Material* 37 (John M. Olin Law & Econ., Working Paper No. 152, Mar. 2003) (on file with the Virginia Law Review Association); Merges et al., supra note 28, at 299-302. For a non-traditional argument against injunctive relief, see Ayres & Klemperer, supra note 72, at 1020-23; cf. Dan L. Burk, *Muddy Rules for Cyberspace*, 21 Cardozo L. Rev. 121 (1999) (favoring unclear or muddy rules for online entitlements).

titrust remedy designed to open a market to competition. For reasons noted above, these antitrust issues are likely to arise in some industries with more frequency than in others,³⁴⁹ so denying injunctive relief on antitrust grounds should similarly be industry-specific in effect. Second, injunctive relief may be inappropriate where patent rights are asserted primarily as holdups rather than as part of an effort to protect a legitimate invention. Some commentators have suggested that injunctive relief may not be appropriate where the patentee does not practice the invention,³⁵⁰ just as lost profits damages are unavailable in such a case.³⁵¹ Alternatively, injunctive relief may be problematic in industries characterized by anticommons problems, because individual patentees may have an incentive to hold out for a disproportionately high royalty, making it impossible to clear the rights necessary to sell products downstream.³⁵² Such an industry may benefit from compulsory licensing. Finally, some have suggested that patents covering products important to society, such as pharmaceuticals and perhaps some food products, should be available at less than the price a patentee could command—in effect a subsidized, compulsory license.³⁵³ All of these po-

³⁴⁹ See *supra* notes 330–34 and accompanying text.

³⁵⁰ See Turner, *supra* note 69 (making this argument); Armond, *supra* note 68, at 122 (making a similar argument limited to denial of preliminary injunctive relief); see also *Foster v. Am. Mach. & Foundry Co.*, 492 F.2d 1317, 1324 (2d Cir. 1974) (taking into consideration whether party practiced welding system patent).

³⁵¹ See, e.g., *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 671 (Fed. Cir. 1988) (“[A] lost profits award is appropriate only if [the patentee] proved that it would have made sales of its . . . product,” but for infringement). Nonmanufacturing patentees, of course, cannot meet this burden.

³⁵² Indeed, the anticommons itself was originally defined with reference to this problem. Michael Heller observed that valuable property was going unused in Moscow because too many people held conflicting rights to the property and would not release them to a single user. Heller, *supra* note 112, at 623. For an argument in favor of compulsory licensing of DNA to solve the anticommons problem, see Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exception*, 76 N.Y.U. L. Rev. 1623, 1628 (2001).

³⁵³ See, e.g., Andrew Beckerman-Rodau, *Patent Law—Balancing Profit Maximization and Public Access to Technology*, 4 Colum. Sci. & Tech. L. Rev. 1 (2002) (arguing for a compulsory licensing scheme to correct the failure of the free market to deliver drugs to developing nations); Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 Wis. Int’l L.J. 481, 504–05 (2002) (endorsing compulsory licensing and stressing the importance of greater access to medicine by the developing world); Ellen t’ Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 U. Chi. J. Int’l L. 27, 45–46 (2002) (discussing the need

tential rules represent possible industry-specific policy levers that courts should consider carefully, either by singling out particular industries for different treatment or by applying standards that would disproportionately affect patents in certain fields.

C. Using Policy Levers

1. Theoretical Objections to Policy Levers

Courts, then, have substantial freedom to tailor the general legal standards of patent law to the needs of particular industries. They should use this discretion. We are aware that legislatures are traditionally considered to have an institutional advantage in detailed fact-finding, that litigation is not cost free, and that appellate courts in particular are not entirely immune from problems of public choice.³⁵⁴ However, all advantages are comparative, and the question is not whether courts are the perfect policy tailors, but whether, given the evils of industry-specific statutes we have described, courts are better situated to engage in tailoring than the legislature. Courts have substantial ability to profile an industry and adapt innovation policy according to the profile, within a reasonable time frame and at reasonable cost.³⁵⁵ Society routinely expects courts to fill this function in areas such as antitrust. We believe that courts can fulfill a similar role in patent law and that they have indeed been doing so without acknowledging it.

We are also aware that our approach runs at least somewhat contrary to a current scholarly fashion advocating judicial minimal-

to reconcile TRIPS with the need to address health concerns in developing countries); cf. Alan O. Sykes, TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution," 3 U. Chi. J. Int'l L. 47, 49 (2002) (questioning the Doha Declaration in light of what it may do to the TRIPS agreement).

Judge Posner's decision in *SmithKline Beecham v. Apotex*, 247 F. Supp. 2d 1011 (N.D. Ill. 2003) is specific to pharmaceuticals, but for a different reason: He concluded that the patentee was trying to extend its proprietary rights beyond their lawful term by asserting a new patent. In any event, he found that permanent injunctive relief was inappropriate even if the patent was infringed.

³⁵⁴ See *supra* notes 216, 226.

³⁵⁵ Suzanna Sherry has made a similar point with regard to Internet policies. See Suzanna Sherry, *Haste Makes Waste: Congress and the Common Law in Cyberspace*, 55 Vand. L. Rev. 309 (2002).

ism.³⁵⁶ The minimalist stance teaches that judges should eschew whenever possible comprehensive decisions that set broad policy or precedent, holding instead to a case-by-case approach that decides only that which is necessary to resolve a particular dispute.³⁵⁷ Under a minimalist approach, narrow, “incompletely theorized” decisions are preferable to decisions that articulate comprehensive theoretical frameworks.³⁵⁸ Minimalist opinions leave as much as possible undecided in order to avoid burdening the discretion of future courts.

We have some sympathy for the general proposition that courts should exercise restraint in declaring far-reaching decisional rules, lest those decisional rules ultimately prove to be misguided. When considering innovation policy, it seems clear to us that considerable damage may be done when courts misconceive the nature of the innovative process and craft such misconceptions into their decisional rules. We have elsewhere specifically criticized the Federal Circuit for adopting counterproductive decisional rules for software and for biotechnology patents, and we have suggested reasons why courts may be prone to get such determinations wrong.

Nevertheless, we think the solution is for the courts to get their decisions right, rather than for them to wash their hands of involvement in the calibration of policy. The failure to articulate policy on an issue is itself a policy decision on that issue. Innovation policy issues do not disappear simply because judges ignore them. Rather, resolution of the issue proceeds on some fortuitous or inadvertent trajectory that is likely to be as damaging as any affirmative judicial mismanagement. Unconscious policymaking is still policymaking—it is just more likely to result in bad policies. Indeed, “policy decisions” made through inadvertence may actually be worse for innovation than trying to make policy and getting it wrong. At least in the latter case the policy in question will be con-

³⁵⁶ See, e.g., Cass R. Sunstein, *One Case at a Time: Judicial Minimalism on the Supreme Court* (1999) (endorsing “judicial minimalism”) [hereinafter Sunstein, *Judicial Minimalism*]; Cass R. Sunstein, *Incompletely Theorized Agreements*, 108 Harv. L. Rev. 1733, 1735 (1995) (“[W]ell-functioning legal systems often tend to adopt a special strategy for producing agreement amidst pluralism. *Participants in legal controversies try to produce incompletely theorized agreements on particular outcomes.*”) [hereinafter Sunstein, *Incompletely Theorized*].

³⁵⁷ See, e.g., Sunstein, *Judicial Minimalism*, *supra* note 356.

³⁵⁸ Cf. Sunstein, *Incompletely Theorized*, *supra* note 356.

sistent. Our previous critique of the current state of patent policy in biotechnology and in software stems as much from the court's failure to act as it stems from any affirmative judicial errors.

This is poor practice where innovation is concerned. Even the foremost academic proponent of minimalism concedes that "[w]hen planning is necessary, minimalism may be a large mistake."³⁵⁹ Innovation policy, it seems to us, is precisely such an environment, where planning is critical for investors and developers of new inventions to bring their technologies to market. While we recognize the appeal of minimal and incomplete judicial theorization for other areas, such as the abstruse conjectures of constitutional law, we do not believe that innovation policy can afford the luxury of ongoing judicial uncertainty.³⁶⁰

Judicial use of policy levers is consistent with minimalism in at least one respect: The policy levers courts have at their disposal are context-specific standards rather than hard-and-fast legal rules of the kind a legislature is more likely to promulgate. The law and economics literature is replete with debates over the wisdom of bright-line rules versus more flexible standards.³⁶¹ We think it unwise for courts to set bright-line rules in areas where their effect on innovation may be uncertain. Rather, policy levers are properly understood as standards: legal principles that can be applied with sensitivity to the industry and the factual context of the cases before the court.

³⁵⁹ Cass R. Sunstein, Foreword—The Supreme Court, 1995 Term: Leaving Things Undecided, 110 Harv. L. Rev. 6, 29 (1996).

³⁶⁰ Rules, as opposed to standards, have their own problems. If a rule is not set correctly, it may encourage undesirable behavior that has not been prohibited expressly. See Thomas, Formalism, *supra* note 56, at 774.

³⁶¹ See, e.g., Louis Kaplow, A Model of the Optimal Complexity of Legal Rules, 11 J.L. Econ. & Org. 150 (1995); Louis Kaplow, Rules vs. Standards: An Economic Analysis, 42 Duke L.J. 557 (1992); Edward Lee, Rules and Standards for Cyberspace, 77 Notre Dame L. Rev. 1275 (2002). Other articles discuss patent law particularly. See Thomas K. Landry, Certainty and Discretion in Patent Law: The On Sale Bar, the Doctrine of Equivalents, and Judicial Power in the Federal Circuit, 67 S. Cal. L. Rev. 1151 (1994); William Macomber, Judicial Discretion in Patent Causes, 24 Yale L.J. 99 (1914); Craig Allen Nard, Certainty, Fence Building, and the Useful Arts, 74 Ind. L.J. 759, 762 (1999) (arguing that rules are preferable to standards in patent law because certainty is needed before litigation can provide it); Thomas, Formalism, *supra* note 56, at 22 (endorsing industry-specific tailoring). Richard Epstein is the best-known proponent of bright-line rules. See, e.g., Richard Epstein, Simple Rules for a Complex World (1995) (endorsing rules over standards).

2. *The Federal Circuit's Treatment of Policy Levers*

The Federal Circuit has proven particularly resistant to considering patent policy in making its decisions. Arti Rai has observed that the Federal Circuit shies away from its role in setting patent policy standards, favoring instead a sort of appellate fact-finding that leads to more intrusive appellate review than is typical in other circuits.³⁶² The tendency to focus closely on the facts of each case may be understandable in a court that generally possesses more technical expertise than the district courts it reviews.³⁶³ As Rai points out, however, the court has focused on factual issues to the exclusion of its natural role as a policy leader.³⁶⁴ Some evidence of the court's reluctance to take on the mantle of policy leadership can be found in Craig Nard's recent study demonstrating that the Federal Circuit pays far less attention to legal and economic scholarship than other circuit courts.³⁶⁵

³⁶² Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 Colum. L. Rev. 1035, 1103–10 (2003); see also William C. Rooklidge & Matthew F. Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort With Its Appellate Role*, 15 Berkeley Tech. L.J. 725, 726 (2000) (“[T]he court from time to time appears to lose track of the important distinction between trial and appellate roles . . .”). Empirical evidence of claim construction demonstrates that at least in that particular area, the Federal Circuit is more likely to reverse district court decisions than appellate courts generally. See Christian A. Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 Berkeley Tech. L.J. 1075, 1097–1106 (2001); Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 Harv. J.L. & Tech. 1 (2001). But see Mark A. Lemley & Colleen Chien, *Are the U.S. Patent Priority Rules Really Necessary*, 54 Hastings L.J. (forthcoming July 2003) (on file with the Virginia Law Review Association) (conducting an empirical study finding significant deference by the Federal Circuit to district court decisions involving patent priority).

³⁶³ See Burk & Lemley, *Technology-Specific*, supra note 4, at 1196–97 (discussing the relative technical competence of district and Federal Circuit judges). We should note, however, that most Federal Circuit judges have neither a technical background nor patent experience when they are appointed to the bench. See John R. Allison & Mark A. Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 Fla. St. U. L. Rev. 745, 751–52 (2000).

³⁶⁴ Rai, supra note 362, at 1103–10. This role is a particularly logical one for the Federal Circuit, since it was created at least in part to provide specialized expertise in patent law. It is this legal expertise, not its factual knowledge, that the court should emphasize.

³⁶⁵ Craig Allen Nard, *Toward a Cautious Approach to Obeisance: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, 39 Hous. L. Rev. 667, 673–74 (2002); accord Rochelle Cooper Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization* 6–8 (2002) (working paper, on file with the Virginia Law

The court's resistance to the use of policy levers is consistent with its distaste for its policy role. Jay Thomas observes in the Federal Circuit a "drift towards simple rules" and away from the complexities of industry-specific analysis.³⁶⁶ Several recent opinions either eliminate policy levers entirely or express a desire to do so.³⁶⁷ The Federal Circuit eliminated the long-standing rule against patenting business methods in 1998,³⁶⁸ and the related "printed matter" doctrine is on uncertain footing as well.³⁶⁹ The court effectively rejected the reverse doctrine of equivalents in 2002.³⁷⁰ The court refused to read the experimental use exception broadly, claiming that

Review Association). Jamie Boyle is more blunt: "The [Federal Circuit] also appears gratifyingly indifferent to academic opinion Being ignored like this is clearly good for the otherwise non-existent humility of legal academics, but . . . one wonders whether it is also a prescription for a good patent law jurisprudence." James Boyle, *Fencing Off the Genome: The Second Enclosure Movement* 7 n.11 (2002) (working paper, on file with the Virginia Law Review Association). Nard's study shows that the Federal Circuit cites less scholarship than other courts with significant responsibility for intellectual property matters. Nard, *supra*, at 678-83. While it is conceivable that the court relies on scholarship and simply doesn't cite it, there is no reason to believe it is more likely to do so than any other circuit.

The notable exception to this rule is Judge Pauline Newman, whose opinions frequently show great familiarity with the economic literature on patent law and its legal implications. See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 639-41 (Fed. Cir. 2000) (en banc) (Newman, J., dissenting) (citing a lengthy set of scholarly authority for her discussion of innovation and competition policy).

³⁶⁶ Thomas, *Formalism*, *supra* note 56, at 2, 3; see also Nard, *Claim Interpretation*, *supra* note 270, at 4-11 (arguing that the Federal Circuit is too formalist in claim construction).

³⁶⁷ One important move in the other direction—the judicial creation of a new discretionary rule—is the newly-minted doctrine of prosecution history laches. See *In re Bogese*, 303 F.3d 1362, 1367 (Fed. Cir. 2002); *Symbol Techs. v. Lemelson Med.*, 277 F.3d 1361, 1364 (Fed. Cir. 2002). Because prosecution history laches is not an industry-specific policy lever, however, we do not discuss it further here.

³⁶⁸ *State St. Bank & Trust v. Signature Fin. Servs.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998). The court claimed that the rule never had actual support in the case law, *id.* at 1375-77, but it was certainly universally acknowledged as an exception prior to 1998.

³⁶⁹ On the doctrine, see *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). The court has not applied the doctrine to computer programs, see *In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994), but it did apply it to a cinematic work in an unpublished decision. See *Bloomstein v. Paramount Pictures Corp.*, 215 F.3d 1351 (Fed. Cir. 1999). For a detailed discussion of the doctrine, see Richard S. Gruner, *Intangible Inventions: Patentable Subject Matter for an Information Age*, 35 Loy. L.A. L. Rev. 355 (2002).

³⁷⁰ *Tate Access Floors v. Interface Architectural Res.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002). But see *Amgen, Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313 (Fed. Cir. 2003) (discussing the doctrine as a continued part of patent law, albeit in dictum).

policy justifications for the doctrine were a matter for Congress,³⁷¹ and Judge Rader's concurrence in *Embrex, Inc. v. Service Engineering Corp.* later suggested doing away with the experimental use exception altogether.³⁷² In each case, the court pointed not to changes in policy that rendered the rule obsolete, but to the absence of any specific authorization for the long-standing judicial rule in the Patent Act.³⁷³ The court has sought to confine other policy levers, such as patent misuse³⁷⁴ and the rule of prosecution history estoppel within the doctrine of equivalents,³⁷⁵ by imposing narrow and specific rules on them, in effect cabining its own discretion. Still other policy levers, such as the pioneering patents doctrine, have not been eliminated so much as neglected.³⁷⁶ Jay Thomas reviewed these developments and concluded that the unifying theme in Federal Circuit jurisprudence over the last ten years is a shift toward simple rules and legal formalism.³⁷⁷

In part, this resistance to setting patent policy may stem from a laudable, though here misguided, sense of judicial restraint that in-

³⁷¹ *Roche Prods. v. Bolar Pharms.*, 733 F.2d 858, 864–65 (Fed. Cir. 1984). It is ironic that in *Roche* the Federal Circuit changed existing law, yet refused to consider policy arguments in support of continuing a doctrine that had long existed.

³⁷² 216 F.3d 1343 (Fed. Cir. 2000) (Rader, J., concurring); cf. *Mayed v. Duke Univ.*, 307 F.3d 1351, 1360–61 (Fed. Cir. 2002) (refusing invitation to eliminate the doctrine altogether, but interpreting it so narrowly that it will likely never be applied).

³⁷³ See Eisenberg, *Swords*, supra note 262, at 5 (“The Federal Circuit has also consistently taken a restrictive view of judge-made, common law rules not incorporated into the language of the statute . . .”). Indeed, *State Street* is a particularly notable example for its faintly ludicrous suggestion that the business method exception had in fact been overruled by Congress forty-six years before, and it was just that no one had noticed. *State St.*, 149 F.3d at 1375.

³⁷⁴ See supra note 324 (discussing limits on the patent misuse doctrine).

³⁷⁵ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc). The Supreme Court reversed, requiring a somewhat more open-ended inquiry. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

³⁷⁶ See supra note 303 (discussing the disuse of the pioneer patents rule).

³⁷⁷ Thomas, *Formalism* supra note 56, at 3; cf. Boyle, supra note 365, at 7 n.11 (“[T]he CAFC lurches from formalism to utilitarian analysis and back again, guided by some muse of its own.”). Wagner, by contrast, defends the Federal Circuit’s shift to formal rules on the grounds that they provide greater certainty. Wagner, supra note 224, at 234–37. For the reasons we explain in the text, we do not agree with Wagner that the certainty that will be gained by eliminating policy levers is worth the cost to innovation that poorly tailored incentives will impose.

stantiates the philosophy of minimalist commentators.³⁷⁸ Judges on any court properly resist rewriting or twisting the rules laid down by Congress in an effort to promote their own policy preferences. That principle has little applicability here, however. The policy levers that we have identified are not methods for avoiding or subverting the statute. Rather, they are examples of the broad judicial discretion intentionally built into the statute. That discretion is an inherent part of the patent system. It resides in such fundamental doctrines as obviousness, the doctrine of equivalents, inequitable conduct, patent misuse, and patentable subject matter, all of which are judicial constructs. Patent law is fundamentally a statute that contains more standards than rules. Even if it wanted to, the Federal Circuit could not eliminate the resulting discretion without fundamentally rewriting the rules of patent law—itsself a form of activism.

The inherent nature of discretion in patent law provides a compelling reason to use that discretion wisely. The Federal Circuit cannot avoid making policy judgments in its decisions. What we fear has already happened in some instances is that it has made those policy judgments inadvertently, setting rules that affect patent owners and accused infringers without considering the policy consequences those rules will have.³⁷⁹ It is important not just to make patent policy intelligently, but to tailor it to specific industries. As we discussed in detail in Parts I and II, innovation differs from industry to industry, and the patent system affects different industries in different ways. These differences are so stark that it may not even be meaningful to speak of the “right rule” in a particular area of patent law without reference to the characteristics of the industry or innovation in question. Ignoring such differences is counterproductive.

For example, intentionally or not, the Federal Circuit has interpreted the obviousness and Section 112 disclosure standards differ-

³⁷⁸ On judicial restraint, see Abner J. Mikva, *Why Judges Should Not Be Advice Givers*, 50 *Stan. L. Rev.* 1825 (1998); Richard A. Posner, *Against Constitutional Theory*, 73 *N.Y.U. L. Rev.* 1 (1998).

³⁷⁹ See Thomas, *Formalism*, *supra* note 56, at 774 (“The drive to formalism may also distance the patent law from innovation policy. When deciding whether inventions from a particular sphere of endeavor should be patented, for example, the Federal Circuit does not query into that field’s pace of innovation, need for interoperability, industrial structure.”).

ently in software and biotechnology.³⁸⁰ We suggest elsewhere that the rules the Federal Circuit actually set for those industries are exactly backwards from a policy standpoint.³⁸¹ Setting a uniform rule would not solve the problem; the industries have different characteristics, and a nominally uniform rule will affect them differently. If the court is to make intelligent policy, it must take the needs of those industries into account.³⁸² The policy levers we have identified in this Section provide a way for the court to accomplish such nuanced decisionmaking. In the Part that follows, we offer some ideas as to how those policy levers should be employed in certain industries with particular needs.

IV. PROPER LEVERS FOR SPECIFIC INDUSTRIES

We offer in this final Part a detailed discussion of the use of policy levers in industries that provide compelling examples of the need for patent tailoring. We have employed each of these industries as examples above to illustrate innovation models. These industries have also, to varying degrees, already been the subjects of patent tailoring, so we have also employed them above as illustrative of certain policy levers. We suggest here how tailoring might be better fitted to these industries, focusing primarily on the levers that courts are already using. For example, we discuss use of obviousness and disclosure doctrines to modulate the scope and frequency of patents, as might be necessary where anticommons or patent thicket theories are applicable. These levers may also be employed to structure temporal sequencing of patent rights, such as might occur in industries where cumulative or follow-on innovation is present. We also suggest some cases where the use of less familiar levers might be appropriate.

³⁸⁰ See Burk & Lemley, *Technology-Specific*, *supra* note 4, at 1183–85.

³⁸¹ See *infra* notes 383–405, 419–44 and accompanying text.

³⁸² For an important recognition of this by a Federal Circuit judge, see Arthur J. Gajarsa, *Quo Vadis?*, 6 Marq. Intell. Prop. L. Rev. 1, 6–7 (2002); cf. Kenneth D. Crews, *Looking Ahead and Shaping the Future: Provoking Change in Copyright Law*, 49 J. Copyright Soc'y 549, 564 (2002) (criticizing a one-size-fits-all approach); David McGowan, *Innovation, Uncertainty, and Stability in Antitrust Law*, 16 Berkeley Tech. L.J. 729, 731 (2001) (arguing that no uniform patent scope will be optimal for all industries).

A. Biotechnology

We begin with biotechnology, an industry that we have touched upon several times already and that we have shown to have been the subject of some technological tailoring in patent law. Biotechnology is in part about pharmaceuticals—and therefore prospect theory—and in part about DNA research—and therefore anti-commons theory.

If any technology fits the criteria of high-cost, high-risk innovation, it is certainly biotechnology. Development of biotechnology products, particularly in the pharmaceutical sector, has been characterized by extremely long development times and high development costs. Such delays are due in part to the stringent regulatory oversight exercised over the safety of new drugs, foods, biologics, and the environmental release of new organisms.³⁸³ Yet the onerous regulatory requirements to which biotechnology is subject may obscure a more fundamental uncertainty that justifies such oversight. Biotechnology products arise out of living systems and are typically intended to interact with other human or nonhuman living systems. Such interactions, whether physiological or ecological, are enormously complex and the systems involved are poorly characterized. As a consequence, the functionality of biotechnology products is always unforeseeable and always involves a high degree of uncertainty and risk.³⁸⁴ Thus, while we have argued that the Federal Circuit has been wrong to suggest that identifying and making biotechnological products—*invention*—is always difficult and

³⁸³ The Pharmaceutical Research and Manufacturers of America estimate that the total time spent from the beginning of a research project to the marketing of a successful drug is twelve to fifteen years, 1.8 years of which is due to the FDA approval process. See Pharm. Research and Mfrs. of Am., *Why Do Prescription Drugs Cost So Much . . .* (June 2000), <http://www.phrma.org/publications/publications/brochure/questions/> (on file with the Virginia Law Review Association). Estimates of the average cost of drug development and testing range from \$150 million to \$500 million; the latter is the industry's figure. Compare id. with Public Citizen, *Rebuttals to PhRMA Responses to the Public Citizen Report, "Rx R&D Myths: The Case Against the Drug Industry's R&D 'Scare Card,'" at* http://www.citizen.org/congress/reform/drug_industry/corporate/articles.cfm?ID=6514 (Nov. 28, 2001) (on file with the Virginia Law Review Association). A recent estimate is even higher—over \$800 million per drug. See Gardiner Harris, *Cost of Developing Drugs Found to Rise*, *Wall St. J.*, Dec. 3, 2001, at B14.

³⁸⁴ For example, the Centocor sepsis antibody, a highly promising biotechnology treatment, succeeded in passing many years of costly trials, but failed in the last phase of FDA approval. Burk & Lemley, *Uncertainty Principle*, *supra* note 160, at n.172.

uncertain, it is also true that turning those research tools into medicines that can be sold in the market—*innovation*—is time-consuming, complex and risky.

At the same time, imitators, such as generic manufacturers, who wish to imitate an innovator's drug face substantially lower costs and uncertainty than do innovators in the industry. While the FDA does impose regulatory hurdles on second comers, the process is substantially more streamlined than it is for innovators. Indeed, the primary regulatory hurdle a generic company faces is to show that its drug is bioequivalent to the innovator's drug.³⁸⁵ Assuming bioequivalency, the FDA allows the generic to rely on the innovator's regulatory efforts. The uncertainty associated with developing and testing a new drug is completely absent for generic competitors; they need only replicate the drug the innovator has identified and tested. Similarly, the hard work involved in producing a cDNA sequence coding for a human protein is in identifying and isolating the right sequence; once the sequence is known, a follow-on competitor can easily replicate it.

Consistent with these characteristics and Merges's standard economic model, the current Federal Circuit jurisprudence lowers the obviousness barrier for biotechnology.³⁸⁶ This lower barrier seems at odds with the modern science of biotechnology. The availability of research tools has made the isolation and characterization of biological macromolecules routine. As a result, considerable criticism has been directed against the Federal Circuit's biotechnology obviousness cases.³⁸⁷ Given such tools, the outcome of a search for

³⁸⁵ 21 U.S.C. § 355(j)(2)(A)(i) (2000).

³⁸⁶ See Burk & Lemley, *Technology-Specific*, supra note 4, at 1178–79.

³⁸⁷ See, e.g., Kenneth J. Burchfiel, *Biotechnology and the Federal Circuit* § 6.2, at 84–85 (1995) (objecting on numerous grounds to the Federal Circuit's treatment of the obviousness requirement); Philippe Ducor, *New Drug Discovery Technologies and Patents*, 22 *Rutgers Computer & Tech. L.J.* 369, 371 (1996) (calling the obviousness criteria "little more than a legal translation of the notion of serendipity"); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 *Wake Forest L. Rev.* 827 (1999) (arguing that patent protection is simultaneously too strong and too weak); cf. Jonathan M. Barnett, *Cultivating the Genetic Commons: Imperfect Patent Protection and the Network Model of Innovation*, 37 *San Diego L. Rev.* 987, 1028 (2000) (arguing for "imperfect" patent protection for biotechnology). See generally John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 *Emory L.J.* 101 (2001).

a particular nucleotide or protein seems relatively certain and hence obvious. If patents are to drive innovation in biotechnology, rather than merely invention, however, courts must take account of the cost and uncertainty of post-invention testing and development.³⁸⁸ The availability or unavailability of a patent is expected to have little effect on the incentive to engage in preliminary research, for instance, to use the available tools to secure a macromolecule of interest.³⁸⁹ The ready availability of tools for finding a new biotechnology product does not change the high cost and uncertainty entailed in developing a marketable product using that macromolecule, however. Hence, under Merges's framework, a lowered standard of obviousness might seem to make sense from a policy standpoint not so much to encourage invention as to encourage the development of marketable products.³⁹⁰

Yet, in its current jurisprudence, what the Federal Circuit gives biotechnology with one hand, it takes away with the other. Although biotechnology patents are relatively easy to obtain under the obviousness standard, the accompanying enablement and written description standards dramatically narrow the scope of the resulting patents. By requiring disclosure of the particular structure or sequence in order to claim biological macromolecules, the Federal Circuit effectively limits the scope of a patent on those mole-

(arguing that in the realm of biotechnology, patent law slows innovation without increasing incentives for potential inventors).

³⁸⁸ See Boyd, *supra* note 195; Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900–2000*, 88 Cal. L. Rev. 2187, 2225–27 (2000) [hereinafter Merges, *Solicitude*]; Merges, *Uncertainty*, *supra* note 320, at 4.

³⁸⁹ See, e.g., Robert P. Merges, *Patent Law and Policy* 519 (2d ed. 1997).

³⁹⁰ See Robert P. Merges & John Fitzgerald Duffy, *Patent Law and Policy* 727–28 (3d ed. 2002) (“[S]ection 103 actually has a bigger effect on decisions regarding which technologies to develop than regarding which research projects to pursue in the first place.”); see also Giorgio Sirilli, *Patents and Inventors: An Empirical Study*, 16 Res. Pol’y 157, 164–66 (1987) (finding that patents give most inventors more incentive to commercialize than incentive to invent). One way to think of this is to conceive of patents as a financing mechanism: By providing definable rights, patents enable companies to obtain the funding they need to turn an invention into a product. See *Picard v. United Aircraft Corp.*, 128 F.2d 632, 642–43 (2d Cir. 1942) (Frank, J., concurring) (arguing that patents may serve as a “lure to investors”); Fritz Machlup, *Patents*, 11 Int’l Encyclopedia of the Social Sciences 461, 467 (David L. Sills ed., 1968); Golden, *supra* note 387, at 167–72; Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. Small & Emerging Bus. L. 137 (2000).

cules to the structure or sequence disclosed.³⁹¹ This standard dictates that the inventor have the molecule "in hand" (so to speak) before being able to claim it. In other words, the inventor can have patent protection for any given molecule only after a substantial investment has already been made in isolating and characterizing the molecule. The result is that everyone who invests in discovering a new molecule will receive a patent, but one that is trivial to avoid infringing, at least literally. Under this standard, no one is likely to receive a patent broad enough to support the further costs of development.³⁹² Indeed, some promising lines of inquiry, such as the

³⁹¹ See, e.g., *Plant Genetic Sys. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003) (holding a patent claim to a class of genetically engineered plants invalid for lack of enablement because only certain types of plants within the class were described, notwithstanding the pioneering nature of the invention); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567–68 (Fed. Cir. 1997) (holding that description of rat insulin DNA did not justify claims to insulin DNA for any other mammals). But see *Amgen, Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1332 (Fed. Cir. 2003) (finding the written description requirement satisfied by a broad claim to cells used to produce EPO, where host cells, unlike DNA, were well known in the art; the written description requirement "may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure"). While *Amgen* reads the written description requirement more loosely than *Lilly*, it appears to have limited its holding to cases in which those of skill in the art already know of a correspondence between function and structure before the invention. *Amgen*, 314 F.3d at 1332, something that will not be true in the DNA patent cases.

³⁹² See Kenneth G. Chahine, *Enabling DNA and Protein Composition Claims: Why Claiming Biological Equivalents Encourages Innovation*, 25 *AIPLA Q.J.* 333 (1997) (arguing for a broader scope of biotechnology patents, extending to proteins with comparable biological activity).

Curiously, Merges doesn't see this as a major problem, suggesting that in general "the Federal Circuit has overall been quite successful at integrating biotechnology cases into the fabric of patent law." Merges, *Solicitude*, supra note 388, at 2228. We think the written description cases and the correspondingly narrow scope afforded biotechnology patents are a more serious problem than Merges acknowledges.

One might question why, if the written description requirement is producing such narrow DNA patents, the biomedical industries consistently cite patent protection as extremely important to them. See, e.g., Cohen et al., supra note 37 (reporting the results of a survey in which biomedical companies rated patents more important than did companies in any other industry); Levin et al., supra note 22 (same). We think there are two answers. First, the industries that count patents as extremely valuable tend to be chemistry and pharmaceuticals, not biotechnology per se, and certainly not those in the business of discovering and using DNA sequences. Second, the biotechnology written description cases are relatively new, and the industry-specific studies are somewhat older, so their understanding of the value of patents may not reflect modern realities.

development of drugs custom-tailored to individual DNA, may be foreclosed entirely if a biotechnology patent is not broad enough to cover the small structural variations that inhere in custom drugs.

Unfortunately, this proliferation of narrow biotechnology patents may be nearly impossible to avoid under the reciprocal structure of obviousness and enablement in current PHOSITA patent doctrine.³⁹³ In order for the invention to avoid obviousness, it must be deemed beyond the skill of the PHOSITA to construct given the level of disclosure in the prior art. Yet this means that in disclosing the invention, the inventor must tell those of ordinary skill a good deal more about how to make and use it, effectively raising the standard for enablement and written description. The Federal Circuit's insistence that the results of biotechnology research are unforeseeable or unpredictable avoids the problem of obviousness but results in an extremely stringent standard for disclosure and description. Once again, the result is not optimal from the perspective of economic policy. We have suggested elsewhere a doctrinal solution to this particular problem, namely, treating the PHOSITA standards in obviousness and disclosure as separate policy based questions, rather than as a common standard.³⁹⁴

Even given such doctrinal tools, however, courts must confront the policy question of the proper scope of patents in the biotechnology industry. The proper focus of biotechnology patent policy is a matter of some dispute. Merges's classic economic framework suggests that the standard of nonobviousness should be low to compensate for the high cost of innovation in the industry.³⁹⁵ Both the need for effective protection and the anticommons literature suggest that the disclosure requirement should be less strict than it currently is, lest property rights be too disintegrated to permit effective licensing.³⁹⁶ Yet if both the nonobviousness and disclosure

³⁹³ See, e.g., Mark J. Stewart, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After Regents of the University of California v. Eli Lilly & Co.*, 32 Ind. L. Rev. 537, 557–58 (1999) (noting the linkage between the Federal Circuit's view of biotechnology as an uncertain art and the narrowness of the patents that result).

³⁹⁴ Burk & Lemley, *Technology-Specific*, supra note 4, at 1202–05.

³⁹⁵ Merges, *Uncertainty*, supra note 320.

³⁹⁶ See Heller & Eisenberg, supra note 113; Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289 (2002).

requirements are lessened, the result will be more patents with broader scope. This increase, in turn, will produce a large number of blocking patents, potentially giving rise to a patent thicket.³⁹⁷ Blocking patents are not necessarily bad, particularly when they are coupled with mechanisms like the reverse doctrine of equivalents that will relieve bargaining pressures in extreme cases.³⁹⁸ They will certainly give biotechnology companies incentives to innovate, at least initially. But blocking patents do raise the specter of overlapping first-generation patents choking out innovation, particularly where those first-generation patents are granted on upstream research tools.³⁹⁹

We suggest instead that courts should modify Merges's classic theory. Lowering the obviousness threshold is only one way to encourage investment in uncertain technologies. An alternative is to broaden the scope of the patents that do issue by reducing the disclosure requirement or by strengthening the doctrine of equivalents for a particular industry. Doing either will encourage innovation in uncertain industries not by increasing the chance of getting a patent, but by increasing the value of the patent once it is granted. In fact, we believe that while Merges is correct to suggest that the standard of patentability should be responsive to the cost and uncertainty of innovation, obviousness is the wrong lever to use in biotechnology.⁴⁰⁰ Lowering the obviousness threshold makes

³⁹⁷ For example, suppose a patentee isolates the DNA sequence for human beta-interferon, but because of the lowered disclosure requirement is entitled to claim all mammalian beta-interferon. The lowered obviousness requirement may mean that future inventors can patent rat, bat, and cat beta-interferon respectively if they discover those particular sequences; it is well established that a patent on a genus does not necessarily render obvious claims to a previously undisclosed species within that genus. See *Corning Glass Works v. Sumitomo Elec. U.S.A.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989). Those later patents will be subservient to, but block, the original broad patent to mammalian beta-interferon.

³⁹⁸ For detailed discussions, see Lemley, *Economics of Improvement*, supra note 69; Merges, supra note 104, at 75. There is some evidence that the reverse doctrine of equivalents may play a greater role in the biotechnology arena than elsewhere. See, e.g., *Scripps Clinic & Research Found. v. Genentech*, 927 F.2d 1565, 1581 (Fed. Cir. 1991) (invoking the doctrine in an infringement case regarding a patent for the purification of a blood-clotting factor using monoclonal antibodies).

³⁹⁹ See Eisenberg & Merges, supra note 164 (discussing patents on Expressed Sequence Tags); Heller & Eisenberg, supra note 113 (discussing the anticommons).

⁴⁰⁰ See also Eisenberg, supra note 162, at 26 (arguing that the Federal Circuit's low obviousness standard for biotechnology has aggravated the anticommons problem).

it more likely that marginal inventions will be patented, but does nothing to encourage inventions that would have met the (already rather modest) obviousness standard anyway. If getting from invention to market is the costly and uncertain part of the endeavor, it is these more significant inventions that we need to worry about rewarding.⁴⁰¹

This alternative approach—a fairly high obviousness threshold coupled with a fairly low disclosure requirement—will produce a few very powerful patents in uncertain industries. It will therefore solve the anticommons problem often identified with biotechnology while at the same time boosting incentives to innovate.⁴⁰² Because there will be relatively few patents, the problem of patent thickets should not arise. This calibration of patent frequency and scope seems to be the proper response to the anticommons concern found in much of the biotechnology literature. We worry that the alternate solution—favoring greater governmental control of inventions supported by public funds over unfettered intellectual property rights⁴⁰³—might unacceptably reduce the incentive for biotechnology companies to move beyond invention to innovation and product development.

Recalibrating patent scope through disclosure would seem to require a much more fundamental rethinking of the Federal Circuit's Section 112 jurisprudence. The court currently requires *more* disclosure from patentees in uncertain arts, while our proposal would require *less*. The key to understanding this seeming puzzle is the difference between uncertainty about invention *ex ante* and the uncertainty about innovation (getting the product to market) *ex post*. The court repeatedly intones the maxim that biotechnology is

Merges himself notes that increasing the scope of patents is an alternative to lowering the obviousness threshold. See Merges, *Uncertainty*, supra note 320, at 47. He does not pursue that alternative in his paper, however.

⁴⁰¹ Indeed, Hunt suggests that lowering the nonobviousness threshold actually creates a tradeoff, increasing the probability of acquiring a patent but reducing the value of any given patent, thus possibly weakening the incentive to innovate. Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform* (Working Paper No. 99-3, Mar. 1999).

⁴⁰² See Heller & Eisenberg, supra note 113; Rai & Eisenberg, supra note 396, at 289.

⁴⁰³ Rai and Eisenberg take this approach. See Rai & Eisenberg, supra note 396, at 291.

an “uncertain art.”⁴⁰⁴ We think, however, that it is not so much invention as product development, production, and regulatory approval that are uncertain in the biotechnology industry. From a policy perspective, the result is the same: Biotechnological inventions need more incentive than other types of inventions if they are actually to make it to market. From a disclosure perspective, however, the difference is quite significant: There is no reason to require heightened disclosure of an invention—and correspondingly narrow its scope—if invention itself is not uncertain in the art.

Biotechnology, then, is properly described in part by the anti-commons theory (too many narrow patents must be aggregated to produce a viable product), and in part by prospect theory (a long and uncertain post-invention development process justifies strong control over inventions). A rational patent policy for DNA would seek to minimize the anticommons problems and give inventors sufficient control to induce them to walk the uncertain path towards commercial development. A variety of policy levers might be employed to this end. The utility and abstract ideas doctrines can restrict the anticommons problem in a few cases by preventing unnecessary upstream patents (for example on ESTs) that threaten to hold up downstream innovation. The written description and enablement doctrines need to be recalibrated to permit broader claiming of inventions. The doctrine of equivalents can play a similar role, perhaps by rejuvenating the doctrine of pioneer patents or by applying the notion of known interchangeability with an eye towards function instead of structure. Experimental use may also play a role by ensuring that the long development time necessary in the biotechnology industry does not interfere with an inventor’s ability to patent the ultimate product.⁴⁰⁵

⁴⁰⁴ See, e.g., *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (calling biotechnology less “predictable” than mechanics or electronics).

⁴⁰⁵ Other policy levers may also be relevant to biotechnology. For example, arguments against injunctive relief may be stronger in biomedical cases than in the cases of other sorts of inventions due to the strong public health interest. The levers we discuss in the text are the most important for fashioning the incentive to innovate, however.

B. Chemistry/Pharmaceutical

The uncertainty principle that courts have applied in biotechnology may have pernicious effects in other industries as well. For example, small-molecule chemistry has long had its own discrete set of patentability doctrines, developed in a long line of cases that attempt to accommodate the level of skill in that particular technology.⁴⁰⁶ The rules articulated in this line of cases represent something of a compromise between the predictable similarities in the characteristics of molecular families and the difficulty in predicting the effect of structure in three dimensions. As a first approximation, structural relatedness between molecules disclosed in the prior art and a novel molecule claimed in a patent gives rise to a *prima facie* case of obviousness.⁴⁰⁷ However, chemical structures depicted two-dimensionally on paper may not accurately reflect the properties of a physical structure that exists in three dimensions. Molecules react with one another in three dimensions, and the three-dimensional configuration dictates the chemical characteristics of the molecule.

Thus, even in small molecules, the three-dimensional complexity arising from what appear on paper to be slight changes in structure may give rise to radically different properties in apparently related molecules. Even with three-dimensional modeling the effects of such complexity have long been difficult to predict. Such unpredicted characteristics occurred with enough frequency that a rule developed allowing a *prima facie* case of obviousness in small molecules to be rebutted by evidence of unpredictable or unexpected properties in the claimed molecule.⁴⁰⁸ The technological assumption built into such a rule appears to be that the PHOSITA in small-molecule chemistry can generally predict the properties of a chemical or group of chemicals or may occasionally be surprised by

⁴⁰⁶ See *In re Dillon*, 919 F.2d 688, 702–15 (Fed. Cir. 1990) (en banc) (Newman, J., dissenting) (recounting the history of chemical obviousness cases).

⁴⁰⁷ See Harold C. Wegner, *Patent Law in Biotechnology, Chemicals & Pharmaceuticals* 156–57, 168 (1992).

⁴⁰⁸ See *In re Papesch*, 315 F.2d 381, 386 (C.C.P.A. 1963); see also Helmuth A. Wegner, *Prima Facie Obviousness of Chemical Compounds*, 6 *Am. Pat. L. Ass'n Q.J.* 271 (1978) (“Sound evaluation of the possibility of *prima facie* obviousness depends mainly on a knowledge of the technical field involved, rather than . . . the precise boundaries of structural differentiations . . .”).

their properties, but in either case, the outcome is based on the molecules' structural depiction.

The rule in these small-molecule cases appears closely related to that announced in the Federal Circuit's biotechnology cases. The Federal Circuit has declared that DNA "is a chemical compound, albeit a complex one,"⁴⁰⁹ and it has articulated a desire to treat the patenting of macromolecules in the same fashion as the patenting of more traditional organic molecules. In focusing upon structural depiction as the linchpin of both obviousness and disclosure, the biotechnology cases rely upon, and appear to extend, the line of chemical cases summarized above. Just as we question the application of these rules to macromolecules, we are similarly uncertain that these special rules for obviousness in small-molecule chemical cases are well suited to accommodate current chemical research practice, especially in light of the rules articulated by the Federal Circuit for macromolecules.

In particular, modern techniques of rational drug design and combinatorial chemistry seem to push against this traditional construction of chemical obviousness in much the same way that the routinization of DNA probing pushes against the rules of patentability in the biotechnology cases. For example, small-molecule chemists now search for useful compounds by first specifying the functions that they hope to find.⁴¹⁰ The characteristics of desirable molecules are represented mathematically in equations depicting functionally equivalent chemical groups and side chains.⁴¹¹ Based on the predictions of such mathematical models, chemists can then

⁴⁰⁹ *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991); see also *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995) (using the example of chemical compounds to clarify the law regarding DNA); *In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993) (drawing an analogy between chemistry and DNA). But see Rai, *supra* note 251, at 203 (arguing against treating biotechnology cases as analogous to earlier chemical cases).

⁴¹⁰ See generally Hugo Kubinyi, *The Quantitative Analysis of Structure-Activity Relationships*, in 1 *Burger's Medicinal Chemistry and Drug Discovery* 497, 497-571 (Manfred E. Wolff ed., 1995) (describing methods for analyzing compounds).

⁴¹¹ See Richard B. Silverman, *The Organic Chemistry of Drug Design and Drug Action* 26-34 (1992) (describing the Hansch equation that correlates biological activity with physicochemical properties of drug candidates).

search through large panels of related molecules, selecting those with the closest match to predicted function.⁴¹²

This methodology closely parallels the type of molecular "search" considered in most of the Federal Circuit macromolecule cases, where large libraries of DNA molecules are probed in order to identify those that correspond to an expected functional characteristic—for example, the propensity to hybridize with probes of a particular nucleotide configuration, and concomitantly the capacity to code for cellular production of particular gene products.⁴¹³ Combinatorial chemistry, much like DNA probing, tends to focus upon the function of the end product, removing much of the uncertainty from the outcome of a search for a desired molecule but not necessarily from predicting the precise structure of the molecule that is ultimately found. Indeed, the role of chemical structure is to some extent marginalized, as dissimilar structures with similar functions may be treated as equivalent in narrowing the search. Just as in biotechnology, a focus on structure rather than function may render chemical patent protection ineffective because modern development tools render structure less important to the invention.

Consequently, the industry-specific patent prescriptions for small-molecule chemistry increasingly resemble those we suggest for biotechnology. To the extent that such research is done in heavily regulated contexts, particularly for pharmaceutical applications, it faces much the same innovation profile as biotechnology. Other stringent regulatory oversight, such as that of the EPA under the Toxic Substances Control Act,⁴¹⁴ may affect innovation outlooks similarly. Chemistry and pharmaceuticals, like biotechnology, seem to fit well into prospect theory. Fewer and broader patents, encouraged by relaxing the disclosure doctrines and strengthening the doctrine of equivalents, are most likely to provide the proper encouragement to innovation. A relatively robust utility doctrine can prevent anticommons problems in chemistry by preventing the

⁴¹² See Joseph C. Hogan, Jr., *Directed Combinatorial Chemistry*, 384 *Nature* 17 (1996); Dinesh V. Patel & Eric M. Gordon, *Applications of Small-Molecule Combinatorial Chemistry to Drug Discovery*, 1 *Drug Discovery Today* 134 (1996); Jan J. Scicinski, *Chemical Libraries in Drug Discovery*, 13 *Trends in Biotechnology* 246 (1995).

⁴¹³ See generally James D. Watson et al., *Recombinant DNA* 104–07 (2d ed. 1992) (describing techniques for probing libraries of cloned genes).

⁴¹⁴ 15 U.S.C. §§ 2601–2692 (2000).

patenting of numerous analogues to a successful chemical by “inventors” who do not know what the chemical can do.⁴¹⁵

One policy lever that will likely take on greater importance in the pharmaceutical industry than in biotechnology is patent misuse. Pharmaceutical companies have gone to great lengths to try to extend the lawful scope of their patents by collusively settling disputes with generic companies,⁴¹⁶ strategically delaying prosecution of patents, and obtaining multiple patents covering the same invention.⁴¹⁷ The patent misuse doctrine can play a powerful role in deterring anticompetitive efforts to extend patent rights beyond the scope a rational pharmaceutical patent policy would give.⁴¹⁸

C. Software

While most biotechnological and chemical inventions require broad patent protection because of their high cost and uncertain development process, the opposite is true in the case of software development. Software inventions tend to have a quick, cheap, and fairly straightforward post-invention development cycle. Most of the work in software development occurs in the initial coding, not in development or production. The lead time to market in the software industry tends to be short. The capital investment re-

⁴¹⁵ Alternatively, Rebecca Eisenberg has suggested that FDA law can serve to encourage innovation in pharmaceuticals, not just to regulate them, by granting industry-specific exclusive rights. The advantage of this industry-specific exclusivity is that it is applied downstream to products as they enter the marketplace and not upstream where anticommons problems are more likely. See Eisenberg, *supra* note 184, at 5–8.

⁴¹⁶ See 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); Hovenkamp et al., Anticompetitive Settlements, *supra* note 219, at 1749–63; Maureen A. O’Rourke & Joseph F. Brodley, An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis, & Lemley, 87 Minn. L. Rev. 1767 (2003).

⁴¹⁷ On these latter strategies, see Glasgow, *supra* note 135, at 248–51.

⁴¹⁸ Alternatively, the problem could be controlled to some extent using policy levers relating to obviousness. Pharmaceutical companies often engage in the practice of “double-patenting”: seeking multiple patents on the same or only slightly different technologies in an effort to extend the effective life of their proprietary right. Strengthening the obviousness standard will make it harder to extend patent life through double-patenting because the doctrine of “obviousness-type double patenting” precludes obtaining two patents that would be obvious in view of one another unless the patentee disclaims the longer patent term. See *Ortho Pharm. Co. v. Smith*, 959 F.2d 936, 940–43 (Fed. Cir. 1992).

quirement for software development is relatively low—mostly consisting of hiring personnel, not building laboratories or manufacturing infrastructure. Debugging and test marketing is tedious and potentially time consuming, but it does not rival the cost of stringent safety testing and agency oversight that is necessary in the biotechnology and pharmaceutical industries.⁴¹⁹

Because innovation is less uncertain in software than in industries like biotechnology, Merges's economic framework suggests that the nonobviousness bar should be rather high.⁴²⁰ A few broad software patents are indeed what the current Federal Circuit jurisprudence will likely produce. By relaxing the enablement requirement and permitting software inventions to be defined in broad terms, supported by very little in the way of detailed disclosure, the Federal Circuit has encouraged software patents to be drafted broadly and to be applied to allegedly infringing devices that are far removed from the original patented invention.⁴²¹ By implication, the Federal Circuit's standard also seems to suggest that many narrower software patents on low-level incremental improvements will be invalid for obviousness in view of earlier, more general disclosures. They may also be invalidated under the on-sale bar, because the Supreme Court's view that a software invention is "ready for patenting"⁴²² when it is the subject of a commercial offer for and when the inventor has described its broad functions, even if it is not clear how the code will be written or that it will work for its intended purpose,⁴²³ means that any patentee who waits until the code is written to file a patent application risks being time-barred for not filing earlier.

Unfortunately, the Federal Circuit's current standard seems to be precisely backwards. Software is an industry characterized, at least to a limited extent, by competition theory⁴²⁴ and, to a greater

⁴¹⁹ See *supra* notes 145–57 and accompanying text (making these points in more detail).

⁴²⁰ See Merges, *Uncertainty*, *supra* note 320, at 29–32.

⁴²¹ See Burk & Lemley, *Technology-Specific*, *supra* note 4, at 1170–73.

⁴²² See *Pfaff v. Wells Elecs.*, 525 U.S. 55, 67–69 (1998).

⁴²³ See *Robotic Vision Sys. v. View Eng'g*, 249 F.3d 1307, 1311–13 (Fed. Cir. 2001) (finding a software invention on sale under § 102(b) more than one year before it was actually made).

⁴²⁴ The success of the open source movement suggests that significant innovation can occur in the software industry in the absence of intellectual property protection,

extent, by cumulative innovation. Cumulative innovation theory suggests that patent protection for incremental software inventions should be relatively easy to acquire in order to reward incremental improvements, implying a somewhat lower obviousness threshold. It also suggests that the resulting patents should be narrow and, in particular, that they should not generally extend across several product generations for fear of stifling subsequent incremental improvements. This in turn means that software patents should be limited in scope.⁴²⁵

Implementing a rational software policy obviously requires some significant changes to existing case law. A number of policy levers might be brought to bear on this problem. First, obviousness doctrine needs to be reformed, preferably by way of a more informed application of the level of skill in the art⁴²⁶ or, alternatively, by application of new secondary considerations of nonobviousness.⁴²⁷ Second, a higher disclosure requirement and restrictions on the doctrine of equivalents will help reduce patent scope.⁴²⁸

Additionally, we think that software patents are the ideal candidate for a new policy lever: reverse engineering. Many commentators have explained the importance of permitting competitors to reverse engineer a product in order to see how it works and to discover ways to design around it.⁴²⁹ In the case of copyright, courts

though it does not follow that we would get as much or the same kinds of innovation were we to abolish intellectual property protection for software outright. For discussions of the open source movement, see Yochai Benkler, *Coase's Penguin, or, Linux and the Nature of the Firm*, 112 Yale L.J. 369 (2002); David McGowan, *Legal Implications of Open-Source Software*, 2001 U. Ill. L. Rev. 241 (2001).

⁴²⁵ Jim Bessen and Robert Hunt find that software patents tend to be issued to manufacturing companies, not software developers, and that they are consistent with strategic "patent thicket" behavior. James Bessen & Robert M. Hunt, *An Empirical Look at Software Patents* (May 2003) (working paper, on file with the Virginia Law Review Association). If they are correct, it is further evidence that the scope of software patents should be reduced to eliminate the overlap problem.

⁴²⁶ For this suggestion, see Burk & Lemley, *Technology-Specific*, *supra* note 4, at 1202-05.

⁴²⁷ See, e.g., Burk & Lemley, *Uncertainty Principle*, *supra* note 160 (suggesting cost and uncertainty of post-invention development as a new secondary consideration supporting nonobviousness).

⁴²⁸ See generally Richard R. Nelson, *Intellectual Property Protection for Cumulative Systems Technology*, 94 Colum. L. Rev. 2674 (1994) (discussing the need to reduce the scope of patents in the software industry).

⁴²⁹ See, e.g., Cohen & Lemley, *supra* note 140 (discussing the policy issues in detail and citing numerous authorities).

have adapted the doctrine of fair use, sometimes together with copyright misuse, to allow competitors to engage in reverse engineering of computer software.⁴³⁰ Patent law includes no express provision allowing reverse engineering, nor is there any judicially developed exception akin to copyright's fair use doctrine that might permit it. Indeed, patent law generally lacks provisions akin to fair use or other exceptions that might readily be pressed into the service of reverse engineering, although commentators have suggested that patent law may need such exceptions for precisely this reason.⁴³¹

This does not mean that reverse engineering a patented product is necessarily illegal under patent law. Some inventions, such as the paper clip, are readily apparent once embodied in a product.⁴³² Improvers do not need to reverse engineer the paper clip and determine how it works in order to improve it; they just need to look at it. Additionally, in many cases, the patentee has done all the work necessary for reverse engineering patented inventions by disclosing how to make and use the claimed invention in the patent specification. In theory, an express provision authorizing reverse engineering would be superfluous if the enabling disclosures required to secure a patent were sufficiently strong—someone who wanted to learn how a patented device worked would only need to read the patent specification.⁴³³

Patentable inventions in software, however, generally do not have these characteristics.⁴³⁴ Software devices typically cannot be

⁴³⁰ See *supra* note 329 and accompanying text.

⁴³¹ Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 *Colum. L. Rev.* 1177 (2000).

⁴³² See, e.g., U.S. Patent No. 5,179,765 (issued Jan. 19, 1993) (for a "Plastic Paper Clip").

⁴³³ 35 U.S.C. § 112 (2000) (requiring patent applicants to describe their invention in such detail as to enable PHOSITAs to make and use it).

⁴³⁴ Samuelson and her colleagues argue that certain features of computer programs are readily apparent to competitors and are therefore vulnerable to copying. Samuelson et al., *supra* note 21, at 2333. Their argument, however, depends not only on the vulnerability of programming innovations to casual inspection, but also on the ability of competitors to reverse engineer and analyze the design know-how lying "near the surface" of a program. *Id.* at 2335–37. If patent law precludes reverse engineering, it also precludes this sort of knowledge. It is true that certain types of computer program innovations, particularly user interfaces, are necessarily available to even the casual user, at least in part. It is unlikely, however, that these innovations are the most significant parts of a new computer program or the parts most likely to be

readily understood by casual inspection, and particularly not without access to human-readable source code or other documentation. Examination of the patent itself is unlikely to yield information equivalent to a reverse engineering inspection because the Federal Circuit does not require would-be patentees of software inventions to disclose the implementing source code or, for that matter, very much at all about their inventions.⁴³⁵ Accordingly, software patents present unique obstacles to consummation of the patent law's traditional rights-for-disclosure bargain with the public.

The specific reverse engineering techniques commonly used for software, in turn, may raise some infringement problems that are unique to software. The definition of infringement in the patent statute is extremely broad, encompassing anyone who "makes, uses, offers to sell, . . . sells . . . , or imports" a patented product.⁴³⁶ Reverse engineering a patented computer program by decompiling⁴³⁷ it likely fits within this broad category of prohibited conduct, at least where the program itself is claimed as an apparatus. Reverse engineering clearly constitutes a "use" of the patented software, though owners of a particular copy of the program surely have the right to use it.⁴³⁸ More significantly, decompilation may also constitute "making" the patented program by generating a temporary yet functional copy of it in RAM memory⁴³⁹ and, in cer-

patented. Further, those innovations for which precise understanding is most important (such as application program interfaces) are also those that will not be available to casual inspection.

⁴³⁵ See *supra* note 54 and accompanying text.

⁴³⁶ 35 U.S.C. § 271(a) (2000).

⁴³⁷ We should be clear that we are concerned primarily with reverse engineering by "decompilation"—that is, working backwards from the object code to construct a simulacrum of the source code. Other forms of reverse engineering, such as "black-box" reverse engineering, do not involve making even temporary copies of the program, though they certainly involve "using" it. Our discussion of "reverse engineering" should be understood to refer to decompilation, not to black-box reverse engineering.

⁴³⁸ For further discussion of the implied license and exhaustion doctrines that confer such a right, see Cohen & Lemley, *supra* note 140, at 30–35.

⁴³⁹ It seems clear that generating even temporary instantiations of a patented product "make" that product for purposes of patent infringement. This principle is firmly established in the pharmaceutical context, where courts have held that a patent is infringed when the patented product is generated by metabolization of a different drug within the human body and that chemical intermediates temporarily generated in the course of making a final product may infringe a patent covering those intermediates. See *Hoechst-Roussel Pharm. v. Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997); *Zenith*

tain instances, a longer-term (though still “intermediate”) copy in more permanent memory.⁴⁴⁰ Those copies probably constitute patent infringement unless protected by some defense.⁴⁴¹ The result of all of this is that the nominally neutral patent law rule—no defense for reverse engineering—affects software more than other industries.

The need for a reverse engineering exception in patent law militates in favor of adapting the existing doctrines of exhaustion or experimental use to that end.⁴⁴² Patent misuse might also be adapted, as it has been in the copyright arena, to prevent patent holders from deterring or prohibiting reverse engineering related to their inventions. The exception might even be created by reinterpreting the infringement provisions of Section 271(a). The resulting patent doctrine would constitute a macro policy lever. As Cohen and Lemley observe, in most industries there is either no need to reverse engineer an invention or reverse engineering can be done without infringing the patent.⁴⁴³ Only in software is there a

Labs. v. Bristol-Myers Squibb, 19 F.3d 1418, 1422 (Fed. Cir. 1994); see also Keith E. Witek, *Software Patent Infringement on the Internet and on Modern Computer Systems—Who Is Liable for Damages?*, 14 *Santa Clara Computer & High Tech. L.J.* 303, 323–24 (1998) (arguing that since patent law lacks a fixation requirement, even near-instantaneous duplication of patented software is a prohibited “making” of the patented product).

Anthony Mahajan argues that reverse engineering for valid social purposes (compatibility, competition, or study) may be necessary and likely does not constitute patent infringement. Anthony J. Mahajan, *Intellectual Property, Contracts, and Reverse Engineering After ProCD: A Proposed Compromise for Computer Software*, 67 *Fordham L. Rev.* 3297, 3317–18 (1999). We think, however, that Mahajan has confused the result the law should reach with the result a court likely would reach by applying the statute.

⁴⁴⁰ Thus, an article-of-manufacture claim to a particular program “encoded on a computer hard drive” might be infringed by a reverse engineered copy temporarily stored on a computer hard drive.

⁴⁴¹ One possible argument that the copies are noninfringing is that most copies made during the reverse engineering process are nonfunctional, either because they are only partial or because they are converted to assembly language or source code form. Theoretically, a source code readout of a computer program could be considered a description of the invention, rather than a copy of the invention itself. Nonetheless, decompilation also involves the generation of object code “copies” of the patented program, at least in RAM.

⁴⁴² Cohen and Lemley have explained how the doctrines of exhaustion and experimental use might be modified to create a right to reverse engineer patented software. Cohen & Lemley, *supra* note 140, at 29–35.

⁴⁴³ See *id.* at 23–25.

need for a particular doctrine to protect the right to reverse engineer—and therefore the ability of improvers to innovate. Thus, a judicially created reverse engineering defense would make sense across the board in software cases but not in other patent cases.⁴⁴⁴

D. Semiconductors

As we have outlined above, the semiconductor industry also displays unique characteristics that require incentive tailoring. Design and fabrication of microprocessors has become increasingly complex and expensive as a result of increasing miniaturization. Microprocessor innovation requires the coordinated and extended effort of large teams of skilled engineers, as well as the development and construction of production processes and facilities, at a cost of billions of dollars.⁴⁴⁵ This high R&D cost is matched, however, by a relatively high imitation cost. The days in which an imitator could copy a chip design by copying the “mask works” used in etching the chip and cheaply make identical chips overseas are long gone.⁴⁴⁶ Imitators must build their own fabrication facilities, and much of the innovation in the industry lies in processes that are hard to identify and duplicate.

These characteristics suggest that patents could play an important role in encouraging semiconductor device innovation. Costs of development are extremely high, and patent incentives might serve to attract needed capital.⁴⁴⁷ At the same time, the disclosure function of patents might be important in order to prevent expensive

⁴⁴⁴ This macro lever may nonetheless be tailored, for example, by adopting a rule privileging only reverse engineering done for certain laudable purposes. This case-specific tailoring does not change the character of the policy lever, however, which is still industry-specific.

⁴⁴⁵ See *supra* note 15.

⁴⁴⁶ The Semiconductor Chip Protection Act, 17 U.S.C. §§ 901–914 (2000), was designed to protect semiconductor “mask works” against knock-off copying. The act has virtually never been used, however, arguably because the nature of the semiconductor business changed to make the manufacturing process much more difficult—and, hence, harder to imitate at low cost. See Mark A. Lemley et al., *Software and Internet Law* 274 (2d ed. 2003).

⁴⁴⁷ See John H. Barton, *Antitrust Treatment of Oligopolies with Mutually Blocking Patent Portfolios*, 69 *Antitrust L.J.* 851, 852 (2002) (arguing that patents may support innovation in the semiconductor industry by restricting entry to an oligopoly, permitting a supracompetitive price that supports R&D expenditures).

duplication of effort in wasteful patent "races."⁴⁴⁸ These specific criteria militate in favor of relaxed standards for obtaining patents; as in the case of biotechnology, high development costs might be offset by heightened rewards.

Broadening the scope of patents might satisfy the need for increased patentability in the semiconductor industry, as it does in the pharmaceutical industry, were it not that the proliferation of patents in this setting might quickly develop into an innovation-obstructing patent thicket. Rather than being covered by a single patent, semiconductor chips are composite devices, comprised of multiple inventions, each of which may be covered by a separate patent. Different companies may hold patents to circuit designs, materials, and manufacturing processes that go into fabricating a single chip. Competing companies in the industry, working along parallel research lines to produce faster and smaller chips, will often obtain patents on similar inventions with overlapping claims. Thus, a new microprocessor may need to incorporate technology covered by hundreds of different patents under the control of dozens of different companies.⁴⁴⁹

Thus, despite high development costs, the need in the semiconductor industry is not a "prospect" need for broad rights. Placing broad rights in the hands of a developer might actually hinder creation of a device incorporating many inventions. Optimally, then, semiconductor patents should be calibrated either to avoid, to whatever extent possible, creation of a patent thicket or to facilitate "clearing" of the thicket through quick and easy cross-licensing of overlapping rights. Unlike biotechnology, where broad patents are needed, we believe that the classic Merges analysis favoring a lowered obviousness bar⁴⁵⁰ would work well in this setting. It will do so, however, only if coupled with measures designed to reduce the scope of patents that issue. Patents in the semiconductor industry ought to be narrow, so that overlapping coverage is minimized and potential hindrances can be invented around or

⁴⁴⁸ See Mark F. Grady & Jay I. Alexander, Patent Law and Rent Dissipation, 78 Va. L. Rev. 305, 306-08 (1992); Robert P. Merges, Rent Control in the Patent District: Observations on the Grady-Alexander Thesis, 78 Va. L. Rev. 359, 360 (1992).

⁴⁴⁹ See Hall & Ziedonis, *supra* note 170, at 109-10 (noting the formidable cross-licensing issues in the semiconductor industry).

⁴⁵⁰ Merges, Uncertainty, *supra* note 320, at 47-49.

avoided. The written description and level-of-skill-in-the-art policy levers might be tailored to this end. In addition, application of the doctrine of equivalents to semiconductors must be tightly disciplined. Because a lowered obviousness standard will leave fewer prior art obstacles to a broad range of equivalents, such discipline would need to come from stringent readings of the “function-way-result” and “known interchangeability” tests under the doctrine of equivalents or from the logical converse of the pioneer patents rule.

Alternatively, patent thickets might be cleared by more drastic means. For example, we have identified injunctive power as a policy lever that courts have occasionally used to create a sort of compulsory licensing in compelling cases.⁴⁵¹ Refusing to grant injunctions for the infringement of semiconductor patents could make the patented material more accessible, even in the face of extensive patent overlap, holdout behavior, and bargaining breakdown. This is not a course that we necessarily recommend, as we believe this type of compulsory licensing is a policy lever that should be used sparingly. Historically, courts justifiably have been reluctant to use this lever. Nonetheless, we mention the possibility as an illustration of alternative levers that might accomplish the needed tailoring should “clearing” of the thicket by private means prove unworkable. At a minimum, courts should encourage private ordering mechanisms such as standard-setting organizations and patent pools that seek to clear interfering rights.⁴⁵²

⁴⁵¹ See *supra* notes 335–52 and accompanying text.

⁴⁵² For more on the importance of standard-setting organizations (“SSOs”) to clearing rights in the semiconductor industry, see Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 Cal. L. Rev. 1889 (2002). For more on patent pools as a form of collective rights organization serving similar goals, see *Merges*, *supra* note 121, at 1293; cf. *Lemley*, *supra*, at 1951–54 (suggesting ways SSOs are better suited than patent pools to serving this function).

A recent Federal Circuit decision casts doubt on the deference the court will give to private ordering in the semiconductor industry. See *Rambus, Inc. v. Infineon Tech.*, 318 F.3d 1081, 1096–1105 (Fed. Cir. 2003) (reading narrowly and refusing to apply an SSO’s policy requiring disclosure of patents). Because these issues involve antitrust rather than patent policy, we do not consider them further here.

CONCLUSION

By declaring in *Chakrabarty* that the patent statute covers “anything under the sun,”⁴⁵³ the United States Supreme Court recognized the general applicability of patent law to all technologies. Not all innovation works in the same way, however. The growing complexity of innovation and the patent system itself poses the greatest challenge to patent policy in the history of the Republic. The patent statute has sufficient flexibility to meet the needs of all new and existing technologies, but only if it is applied with sensitivity to the industry-specific nature of innovation. We have identified various existing and possible future policy levers that can be used by courts to meet this demand. We have also integrated into the discussion of such levers theories of the patent system that have previously appeared contradictory or mutually exclusive. In doing so, we hope to have lent some coherence to the growing literature on innovation and patent law and to have helped set patent policy on a firm footing for the twenty-first century.

Developing such a “unified theory” of patents and innovation is an ambitious enterprise, and this Article undertakes only the first step. We have merely begun to outline the ways courts might tailor patent law to the needs of specific industries. There is, for example, much yet to be said regarding institutional competence and authority. We have focused here almost entirely on the role of the courts in tailoring the statute; the policy levers we have identified operate largely as a question of law, and we consider the courts best placed to employ such levers. Administrative agencies may also have a role in shaping statutory applications. In the case of patents, the PTO is an actor to consider, with what may be an expanding role in shaping the application of the statute.⁴⁵⁴ These are questions for another day. We hope merely to have created a solid and coherent framework on which others may build.

⁴⁵³ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).

⁴⁵⁴ For a discussion of the role of the PTO in setting and interpreting legal rules, see *supra* note 251.