

**Rethinking Patents
for Optimal Health Care Innovation**

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ABSTRACT

The patent system as it exists in the United States and throughout the world has been the subject of intense debate in recent years, particularly as it impacts public health. Concern that patents allow their owners to possess supra-optimal control over essential technologies like biomedical research tools and pharmaceuticals has prompted many to question whether society is really coming out ahead. Surprisingly, despite a great deal of attention in the economic and legal literature, the answer remains unclear. A failure to understand the impact of patents precludes optimal structure and use of the system; eventually, it may lead to patents evolving into a barrier to efficient development and dissemination of important, life-saving technologies.

This article suggests that the resolution to the patent cost-benefit question must begin with a more comprehensive analytical approach than the literature has previously entertained. After discussing the narrow purpose of patents, it advances the notion that a patent is not a one-dimensional legal right that is either “strong” or “weak,” but rather a collection of independent variables that have an impact on the incentive to invest in innovation. These variables can be broadly categorized as (1) “legal factors” such as the scope of subject matter and the extent of the right in terms of breadth and length; and (2) “cultural/institutional factors” such as the enforceability of the right and restraints on alienation like price controls. This analysis is used to evaluate current innovation problems and the impact of legal and market revisions to the relevant rules.

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I. Introduction

The individuals and companies that comprise the various segments of the health care industry — medical equipment, pharmaceuticals, biologics as well as the medical arts themselves — have done more than perhaps any other area of the global economy to transform the way we define quality of life. Diseases that once appeared unshakable scourges to humanity like polio, smallpox and leprosy have now been eliminated or controlled to the level that most people give them hardly a second thought.¹ Infant mortality rates in most countries are so low that death is an unexpected asterisk rather than a substantial probability.² We live longer with less chronic illness and pain.³ Even “senility,” once thought to be an inevitable consequence of aging, has been characterized as a specific neurological disorder that could potentially be cured. Advances in health care have truly redefined what it means to live a human life.⁴

However, a number of recent events have shaken public faith in the path of health care innovation, suggesting that it may have turned a corner toward a more uncertain and possibly

¹ See, e.g., WORLD HEALTH ORGANIZATION (“WHO”), WORLD HEALTH REPORT 2004, 85, Ann. Tbl.2 (2004) (hereinafter, “WHO HEALTH REPORT”) (describing the polio eradication programs in the context of collaborative efforts to address the AIDS crisis, and showing in tabular form that polio and leprosy account for an almost immeasurable percentage of the world’s disease burden, with smallpox not evident at all). See also WHO, WHO LEPROSY ELIMINATION PROJECT: STATUS REPORT 2003, 7 (2003) (noting that leprosy was eliminated as a public health problem at the global level in 2000).

² See, e.g., WHO HEALTH REPORT at 156.

³ *Id.* at Ann. Tbl.4 (statistical evidence of Healthy Life Expectancy (HALE), which is dramatically higher in high income countries).

⁴ See, e.g., WHO, WORLD HEALTH REPORT 1999, 1-3 (1999) (“[T]he 20th century health revolution appears to have resulted far more substantially from the generation and application of new knowledge.”)

dangerous future. In one example, recent clinical studies have questioned the safety of a new and highly profitable class of pain-relieving drugs known as Cox-2 inhibitors.⁵ Consumers were outraged to learn of these risks in view of the fact that these vaunted, proprietary drugs, with names like Vioxx and Celebrex, appear to offer little if any benefit for many patients over cheaper alternatives.⁶ Some now question whether our system adequately encourages the discovery of truly innovative treatments or simply the development of high profit, “me too” medications.⁷ Similarly, when a flu epidemic appeared certain to strike the United States in the winter of 2004, the public was surprised to find that the loss of one major flu vaccine supplier left the country in dramatically short supply.⁸ The continued industry-wide reliance on time consuming, mid-twentieth century vaccine technology utilizing chicken eggs prevented any

⁵ See Food & Drug Administration (“FDA”), *FDA Issues Public Health Advisory Recommending Limited Use of Cox-2 Inhibitors*, FDA Talk Paper (Dec. 23, 2004), available at, <http://www.fda.gov/bbs/topics/ANSWERS/2004/ANS01336.html>; Thomas Burton, *Painkillers Fall Under Sharp Review*, WALL ST. J., Dec. 24, 2004, at A.3

⁶ See Barry Meier, et al., *Medicine Fueled by Marketing Intensified Trouble for Pain Pills*, N.Y. TIMES, Dec. 19, 2004, at 1 (“[M]any medical experts now say that Celebrex and Vioxx, selling for \$2 or \$3 a pill, have been too widely prescribed to patients who could safely obtain the same pain benefits from over-the-counter drugs costing pennies apiece.”).

⁷ See, e.g., MARCIA ANGELL, *THE TRUTH ABOUT DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 74-80 (2004).

⁸ See Cici Connolly, *CDC Announces Plan To Ration Flu Vaccine; States to Get Doses Based on Risk*, WASH. POST., Nov. 10, 2004, at A.06.

substitutes from being readily available,⁹ indicating a lack of research and development investment in this critical area. At some level, these innovation problems suggest failures in the way that modern medical discoveries are encouraged. Are they merely ebbs in an otherwise vibrant stream of progress, or indications that something more fundamental is broken in our in our health care innovation system?

To investigate breakdowns in global health care innovation, one necessarily looks to factors that influence the behavior of private industry. Given the inputs required and the impracticality of complete central control, privately funded research and development currently produces a large share of medical products and non-clinical services for the public.¹⁰ The way in which the private sector allocates its resources and marshals its forces determines the direction of a substantial portion of health care innovation. As with any other industry, economic incentives drive research inputs, and pure competition forces are supplemented with mechanisms to ensure risky, groundbreaking research is part of the equation. The most prominently employed supplemental mechanism to encourage private research and development spending is the award of patent property rights for the discovery of truly innovative methods or materials. A system of such rights attempts to provide an incentive for taking the kinds of expensive risks required to make the medical discoveries necessary to battle the world's dread diseases. One can infer,

⁹ See Bruce Japsen, *Anemic profits hurt vaccine supply*, CHI. TRIB., Oct. 24, 2004, at 1 (“Every year, vaccine makers hand-process millions of chicken eggs in their labs It's a tedious, 1940s approach, fraught with commercial risk . . .”).

¹⁰ In the United States, private funding accounts for most R&D spending, and the proportion is increasing. See Peter Neumann & Eileen Sandberg, *Trends in Health Care R&D and Technology Innovation*, 17 HEALTH AFFAIRS 111, 115 (1998) (noting that data from the U.S. “reveal an ongoing and marked shift in the relative amount of R&D conducted in the private sector.”)

therefore, that dissatisfaction with the current state of health care innovation could mean that private industry behavior may not be aligning adequately to patent incentives. Correspondingly, the incentives may be exacting more in terms of social costs than benefits from productive industry behavior. Perhaps it is evidence of a breakdown in the patent system itself.

The optimal functioning of the patent system has frequently been the subject of legal and economic research. In fact, in just the last two years, broad reviews of the U.S. patent system were produced by such prominent sources as the Federal Trade Commission (“FTC”)¹¹ and the National Academies of Science (“NAS”).¹² Surprisingly, despite the scope of these major recent efforts and the great number of smaller theoretical and empirical works in the economic and legal literature,¹³ the degree to which current patent systems promote innovative behavior remains unclear.¹⁴ The NAS concluded in its report that, outside of a handful of industries such

¹¹ FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) (hereinafter “FTC REPORT”). This report is particularly interesting in that it reports the statements of participants in a lengthy information gathering project, but states few conclusions.

¹² NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES OF SCIENCE, A PATENT SYSTEM FOR THE 21ST CENTURY, 41 (Merrill, et al., eds. 2004) (hereinafter “NAS REPORT”).

¹³ For example, noted economists Adam Jaffe and Josh Lerner, both of whom have published extensively on various aspects of patent incentives, also recently delivered a detailed analysis of the problems in the U.S. system. ADAM JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS (2004).

¹⁴ See, e.g., George Priest, *What Economists Can Tell Lawyers About Intellectual Property*, 8 RES. L. & ECON. (1986) (“Economists know almost nothing about the effect on social welfare of the patent system or . . . other intellectual property.”); Roberto Mazzoleni & Richard Nelson, *Economic Theories about the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031, 1031-2 (1998) (“In this paper we discover the answer [as to the benefits and costs of patents] certainly is not simple and currently not well settled.”); Adam Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RES. POL’Y 531 (2000). Economist Robert Hahn

as pharmaceuticals, “One may legitimately question whether the impact of patents on innovation and its consequences for social welfare are, on balance, positive . . .”¹⁵ While admittedly lacking the grounding to establish comprehensive criteria for innovation, the NAS and FTC reports offer suggestions — many quite similar — on how the U.S. system must be reformed.¹⁶

Unfortunately, the persistent uncertainty underlying the essential questions about how patents contribute to innovation casts a shadow of doubt over such reforms, posing a real obstacle to

makes one of the more blunt comments on the lack of consensus on patents and innovation in a recent review of the economic literature: “As a newcomer to the field I thus assumed that basic policy questions, such as whether strengthening patent protection spurs innovation, would more or less been answered. I was wrong.” Robert Hahn, *The Economics of Patent Protection: Policy Implications from the Literature*, Working Paper, AEI-Brookings Joint Center for Regulatory Studies (2003), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=467489.

¹⁵ NAS REPORT, *supra* note 12, at 41.

¹⁶ *E.g., id.* at 81-83 (making seven recommendation for reform, including a post-grant opposition procedure); FTC REPORT, *supra* note 11, at Exec. Sum. 4-17 (making ten recommendations for reform, including a post-grant opposition procedure); AMERICAN INTELLECTUAL PROPERTY LAW ASS’N (“AIPLA”), AIPLA RESPONSE TO THE NATIONAL ACADEMIES REPORT ENTITLED “A PATENT SYSTEM FOR THE 21ST CENTURY” 14-15 (2004), available at http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/2004/NAS092304.pdf. Some of the recommendations are even contradictory. For example, the NAS Report calls for a unitary patent system but subsequently suggests that different obviousness standards should apply to different technologies. NAS REPORT, *supra* note 12, at 85 (“The committee realizes that there may appear to be some contradiction between [our unitary system] position and our belief in the importance of exploiting the mechanisms and doctrines that reflect differences among technologies or allow for some deliberate discrimination among them by the USPTO, by the courts, and by patent holders themselves.”).

meaningful change.¹⁷ Moreover, ill-founded revisions may actually lead to more problems down the road.

The source of the uncertainty regarding patents may lie in the fact that most studies fail to narrow the relevant inquiry by first addressing the more fundamental question of exactly what it is we expect our patent system to do.¹⁸ They consider a variety of goals and how current rules may contribute or detract from them, leading to potentially conflicting solutions. Additionally, existing studies tend to treat patent strength as a one-dimensional right that is either “strong” or “weak,” depending on its legal attributes. Such studies fail to account for the full extent and interrelationship of factors that contribute to the ability of a patent right to act as an incentive for important innovation. Without this detailed background, traditional patent system analysis can actually obscure the most important reasons that individuals and companies either respond to or ignore patent incentives. In the context of health care, it is critical to understand if and how patent rights truly encourage innovation to ensure that the benefits of property rights and access to essential medicines effectively coexist

This article suggests that the resolution to the patent-innovation question must begin with a more comprehensive approach to patent incentives than the literature has previously entertained. It begins in Part II with a preliminary discussion of the proper, narrow goal of a patent system, and reviews evidence that existing systems are meeting these goals. Next, in Part

¹⁷ See Mazzoleni & Nelson, *supra* note 14, at 1051 (“Our lack of knowledge here clearly limits our ability to analyze intelligently the current pressing issues of patent reform.”)

¹⁸ See Edmund Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property Law*, 53 VAND. L. REV. 1727, 1740-42 (“Some literature on intellectual property rights has tended to treat the policy question as one of whether to have or not to have the intellectual property right, without considering the full range of features that can be varied by the law in order to affect the operation of the right.”).

III, the article undertakes a detailed, conceptual analysis of the full scope of independent variables that have an impact on the ability of a patent right to act as an incentive to invest in innovation. These variables can be broadly categorized as (1) “legal factors” and (2) “cultural/institutional factors.” The article argues that the variables are weighted in their effect on innovation, and that weighting may differ depending on the industry. In Part IV, the article demonstrates the application of the more comprehensive approach to characterizing patent incentives, using it to explain the health care innovation failures described above and to evaluate how future legal and market revisions to current patent system rules are likely to affect innovation.

II. Health Care Innovation and Patents: Understanding the Narrow Role for a Powerful Right

The focus of the general literature on patents and innovation has been on determining whether having a particular patent system yields a net positive return or, alternatively, merely locks up important innovations to the benefit of a few property owners for a net societal loss.¹⁹ While this discourse is useful, it may be too expansive.²⁰ Whether patents are beneficial in

¹⁹ See, e.g., WILLIAM LANDES & RICHARD POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 310 (2003) (“The most important economic question about the patent system is whether on balance . . . it increases or reduces economic welfare.”). For an excellent review of the most significant findings on the innovation effect in the relevant literature, consider Bronwyn Hall’s recent work, *Business Method Patents, Innovation, and Policy*, U.C. Berkely/NBER Working Paper, 6-11 (2003) (reviewing both theoretical and empirical literature on the effect of patent and innovation and concluding that it is an exceedingly difficult question to answer).

²⁰ For example, Robert Hahn summarizes the empirical research on five different questions regarding the effect of patents: (1) innovation, (2) information disclosure, (3) technology transfer, (4) commercial development and (5) economic growth. Hahn, *supra* note 14, at 14-37. The NAS Report is particularly striking in this regard, listing such

some respect is a broader issue than whether they fulfill the purpose for which they were designed. The distinction is important in terms of directing patent reform; the law can serve only so many masters. Before assessing the success of current patent regimes in fostering health care innovation, some basic ground rules on the goals of a patent system need to be established. To gauge the success of the patent system, one must determine exactly what outcomes we want to achieve. The astute observer can identify the central themes of the current system from its historical underpinnings and assess the continued viability of the goals the context of the modern global economy.

A. Characteristics of a Successful Patent System

The essential nature of the patent right is the power to exclude others from the invention.²¹ Unlike a real property right that revolves around keeping trespassers from treading on land within certain boundaries, a patent relates to control over a discrete collection of acts

diverse possible patent system goals as promoting economic growth, creating jobs and promoting health. NAS REPORT, *supra* note 12, at 40 (“Ultimately, the test of a patent system is whether it enhances social welfare. . . .”). *See also* Mazzoleni & Nelson, *supra* note 15 at 1033 (reviewing several theories on the purpose of granting patents); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (“First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.”)

²¹ *See* *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996) (“The right to exclude others from a specific market, no matter how large or small that market, is an essential element of the patent right. As we have stated, ‘because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole.’”) (citing *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1456-57 (Fed. Cir. 1988)).

involving the invention. The rights to exclude others from making, using and selling are the essential ones reflected in most international patent regimes.²² It is through the use of these rights of exclusion that the patentee can obtain the monopoly profits that make create the incentive to invest in innovation.²³

The concept of granting an exclusive right to practice an invention in order to encourage innovation certainly did not originate in the United States; it has a long history, particularly in the Western world, which played a strong role in informing the current system. Evidence of rudimentary patent systems extends back at least as far as the Venice in the 1400s wherein the state extended “patents of monopoly” to members of the glassblowing guilds to protect their innovative techniques.²⁴ This practice later spread across the European continent.²⁵

Interestingly, the objective was often to encourage the import of innovative manufacturing

²² See WIPO Intellectual Property Handbook: Policy, Law and Use, WIPO Publication No.489 (E), at p. 17 (2d ed. 2004), available at <http://www.wipo.int/about-ip/en/iprm/pdf/ch2.pdf> [hereinafter “WIPO Handbook”] (“Thus, [the patent owner] is given a statutory right to prevent others from commercially exploiting his invention, which is frequently referred to as a right to exclude others from making, using or selling the invention.”).

²³ See, e.g., WILLIAM NORDHAUS, INVENTION, GROWTH AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE 70 (1969) (patents create incentives by conferring monopoly power for a limited period of time).

²⁴ See Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part I)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 697, 705-709 (1994). The Tyroleans apparently granted similar rights for the superior manufacture of mining equipment. JAFFE & LERNER, *supra* note 13, at 7. There may be some connection in these stories as the Tyroleans may have influenced the Venetians. *Id.*

²⁵ See Frank D. Prager, *A History of Intellectual Property from 1545 to 1787*, 26 J. PAT. OFF. SOC'Y 711, 715 (1944); MARTIN ADELMAN, ET AL., CASES AND MATERIALS ON PATENT LAW (1998) (describing the evolution of the French and English systems as the two major categories of offshoots from the Venetian system).

techniques practiced in foreign lands in addition to promoting invention at home.²⁶ By giving prospective grantees the incentive to seek out ideas that literally would have been otherwise unavailable, development of home industries was thus encouraged.²⁷

By the time the United States Continental Congress met in 1787 to reconsider the Articles of Confederation, the concept of patent monopolies was well known, and particularly well established in England in the form of the Statute of Monopolies.²⁸ Although the historical record surrounding the inclusion of the so-called “intellectual property clause”²⁹ is surprisingly limited, it appears to have been championed primarily by James Madison and Charles Pinckney and modeled closely on European models.³⁰ As to why the delegates settled on the patent right as the mode of “encouraging the progress of . . . the useful arts,” particularly given the general opposition to government-sponsored monopolies among political advocates of the time, the

²⁶ See Walterscheid, *supra* note 24, at 706-07.

²⁷ Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550-1800*, 52 HASTINGS L.J. 1255 (2001).

²⁸ Frank D. Prager, *Historic Background and Foundation of American Patent Law*, 5 AM. J. LEGAL. HIST. 309, 309 (1961); Edward C. Walterscheid, *To Promote the Progress of Science and the Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution*, 2 J. INTELL. PROP. L. 1 10-12 (1994).

²⁹ U.S. CONST., Art. 1, § 8, cl. 8.

³⁰ *Id.* at 46-54. Many perpetuate the myth that Thomas Jefferson was the true intellectual force behind United States patent law, but there is a great deal of evidence that his views were contrary to those who actually promoted and drafted the intellectual property clause. See Edward C. Walterscheid, *The Use and Abuse of History: The Supreme Court’s Interpretation of Thomas Jefferson’s Influence on Patent Law*, 39 IDEA 195, 202-05 (1999) (“[T]o use Jefferson as an exemplar of contemporaneous views on the patent law at the end of the eighteenth century and the first part of the nineteenth century is to materially skew the historical record.”).

answer may boil down to simple economics: granting exclusive rights is free.³¹ In other words, excepting the social costs, patents may have been the only mechanism for encouraging industrial growth that the new United States government could employ without spending a penny. This decision is phenomenally important because it transfers the cost of financing innovation to the private sector. The system chosen by the Continental Congress evidences two important principles: (1) industrial progress is facilitated by recognizing new and innovative technologies as opposed protecting existing businesses,³² and (2) some payment or exchange is necessary to motivate an individual to produce these ideas.³³ There are, of course, other socially-valuable

³¹ Granting exclusive rights is “free” in the sense that there is no need for public financing. Another way of stating this is that it forces individuals to internalize the costs of innovation. See LANDES & POSNER, *supra* note 19, at 294 (“The standard rationale of patent law is that it is an efficient method of enabling the benefits of research and development to be internalized, thus promoting innovation and technological promise.”).

³² JAFFE & LERNER, *supra* note 13, at 8; *Bonito Boats, Inc. v. Thundercraft Boats, Inc.* 489 U.S. 141, 146-48 (1989) (“In addition to novelty, the 1790 Act required that the invention be ‘sufficiently useful and important’ to merit the 14-year right of exclusion.”).

³³ Edward C. Walterscheid, *Charting a Novel Course: The Creation of the Patent Act of 1790*, 25 AIPLA Q.J. 445 (1997). The underlying basis of this exchange is that there will be an underinvestment in risky undertakings without the patent guarantee. See Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Inventions*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 610-614 (1962).

characteristics to modern patent systems,³⁴ but they are better viewed as byproducts rather than an integral part of the innovation mechanism.³⁵

Since the development of a truly modern patent system, the patent rules in the United States and other nations have continued to evolve to become even more stringent. The most prominent change in this regard is the incorporation of a standard that prohibits the patenting of inventions that, even if novel, are obvious in view of existing knowledge.³⁶ Arguably, the reward has also increased over the years in terms of the length of the right of exclusion³⁷ and its

³⁴ For example, many would add the rapid disclosure and dissemination of information as another important patent system characteristic. See FTC REPORT, *supra* note 11, at Ch. 2(I)(A)(3). This is common notion in the patent jurisprudence of the Supreme Court. See, e.g., *Bonito Boats*, 489 U.S. 150-51 (“In consideration of its disclosure and the consequent benefit to the community, the patent is granted.”).

³⁵ In the context of the requirement to disclose enabling information to obtain a patent, the rule actually functions like an incomplete grant of monopoly over the claimed invention (*i.e.*, a grant back). See LANDES & POSNER, *supra* note 19, at 299 (“The requirement of public disclosure creates a situation of *incomplete appropriability* by the patent holder . . .”).

³⁶ See *Graham v. John Deere Co.*, 383 U.S. 1, 13-16 (1966). In other countries, this concept is known as “inventive step.” Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 255 [hereinafter “EPC”] at Art. 56 (“An invention shall be considered as involving an inventive step if... it is not obvious to a person skilled in the art.”); Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994; Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, Legal Instruments--Results of the Uruguay Round Vol. 31, 33 I.L.M. 81 (1994) [hereinafter “TRIPs”], Art. 27(1).

³⁷ Since 1995, U.S. law has been in conformity with the international standard patent term of twenty years from the date an application is filed. 35 U.S.C. §§ 154(a)(2), 271 (2000). The amendments to the Patent Act changed the method of calculating the patent term from seventeen years from issuance of the patent to twenty years from filing of the patent application. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546 (Fed. Cir. 1996).

scope.³⁸ A pattern can be discerned. Such changes represent a systematic push toward the encouragement of a specific type of private sector innovation — one that is so groundbreaking, resource intensive and fortuitous that only a powerful incentive will bring it into being. In other words, we are looking for innovations that are truly the *result* of the patent system, instead of merely developed along side of it.³⁹ Viewed from the converse perspective, one can derive the measure of patent system success: does the patent system encourage the creation of inventions by the private sector that would not have been made in the absence of a property incentive?⁴⁰

³⁸ The firm acceptance of the “doctrine of equivalents” — the rule permitting capture of subject matter broader than the actual claim language -- being the primary example. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002) (Reaffirmation of doctrine in U.S. law, stating, “The language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty.”); EPC, *supra* note 36, at Art. 69(1) (“The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.”); *Tsubakimoto Seiko Co. v. THK K.K.*, 52 Minshu 113 (Sup. Ct. Feb. 24, 1998) (affirming the application of the doctrine of equivalents in Japanese patent law). *See also* John R. Thomas, *Litigation Beyond the Technical Frontier: Comparative Approaches to Multinational Patent Enforcement*, 27 L. & POL’Y INT’L BUS. 277, 286-88 (1996).

³⁹ Obviously, this is not to say that the requirements of the patent system encourage such innovations exclusively. Even non-obvious inventions could be created in the absence of a property right. *See* JAFFE & LERNER, *supra* note 13, at 8 (stating that the economic logic of patent law is that fewer innovations would be developed without it, but not zero).

⁴⁰ *See* FTC REPORT, *supra* note 11, at Ch. 1(C)(1) (“[O]ne could ask whether the claimed invention would have emerged in roughly the same time frame ‘but for’ the prospect of a patent.”). Noted judge and scholar Richard Posner has suggested that this question can be merged with the obviousness inquiry: “[I]f a court thinks an invention for which a patent is being sought would have been made as soon or almost as soon as it was made even if there were no patent laws, it must pronounce the invention obvious and the patent invalid.” *Roberts v. Sears, Roebuck &*

The tautological explanation as to why the patent reward must be the impetus behind patent-protected intellectual progress is straightforward. Simply put, there is no reason to employ an incentive to induce behavior that would occur in its absence. But the complexities of intellectual property benefits and costs suggest that the system is not so clearly binary, and a deeper analysis is required to demonstrate why this truly is the best measure of a patent system.

One can begin by considering innovation and property rights grants in respective isolation. It is likely that most innovative behavior is beneficial at some level, regardless of whether it occurs in response to an incentive. Funding the development of useful products or services — including in production and distribution channels — is useful.⁴¹ Moreover, it has been noted that patent rights can serve other valuable functions apart from innovation incentives. For example, patents can act as a signal to competitors regarding a company's intent to research and market in a particular field.⁴² Additionally, patents can serve as negotiation tools and, if necessary, defensive mechanisms against the practices of competitors.⁴³ They can also provide some breathing room to fully develop technology and products that would otherwise be pounced

Co., 723 F.2d 1324, 1346 (7th Cir. 1983) (Posner, J., dissenting). This view is perhaps an overly stringent interpretation of obviousness/inventive step, but it does have an attractive economic logic to it.

⁴¹ See Bronwyn H. Hall, *The Private and Social Returns to Research and Development*, in *TECHNOLOGY, R&D, AND THE ECONOMY* 140-41 (B. Smith & C. Barnfield eds., 1996) (summarizing positive spillover effects from innovative activity).

⁴² See generally Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625 (2002).

⁴³ See Bronwyn H. Hall & Rosemary H. Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-1975*, 32 RAND J. ECON. 101 (2001).

upon by free riders.⁴⁴ In view of these returns, one could argue that focusing merely on the creation of a narrow type of incentive-aligned invention is too limited. But when the social costs of patents are figured in, the rational for a narrow standard is evident.

A patent allows its owner to extract monopoly rents for the period of exclusivity.⁴⁵ Although this is not to say that a patent owner necessarily has “monopoly power” — that depends on the market in which the invention competes⁴⁶ — he or she does have the ability to exert almost complete control over the availability of that innovation during the patent term.⁴⁷ The public has knowledge of the innovation but cannot make use of it except by permission of

⁴⁴ See Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON 266 (1977). But see John Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 483-85 (2004) (arguing that unchallenged development of patented innovation does not completely underlie patent policy, because rivalries are as important after the grant as before).

⁴⁵ See ROBERT COOTER & THOMAS ULEN, LAW & ECONOMICS 122-23 (4th ed. 2004) (“[A] patent enables the inventor of something valuable to earn profits that exceed the ordinary rate of return on investment.”). The concept that monopolies can be more conducive to innovation than competition is often referred to as “Schumpeterian theory,” in reference to the work of Joseph Schumpeter. See Rebecca Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1038-40 (1989).

⁴⁶ See Kitch, *supra* note 18, at 1729-31; COOTER & ULEN, *supra* note 45, at 122; ROBERT HARMON, PATENTS AND THE FEDERAL CIRCUIT § 1.4(b) at 21 (2000).

⁴⁷ For the most part, patents do not have robust fair use provisions (like copyrights) that would allow others to engage in unauthorized use of the patent for non-commercial purposes. See Daniel R. Cahoy, *Oasis or Mirage: Efficient Breach as a Relief to the Burden of Contractual Recapture of Patent or Copyright Limitations*, 17 HARV. J.L. & TECH. 135, 148-51 (2003).

the patent owner,⁴⁸ who can decide in what way it is used or even if it is used.⁴⁹ While this is constraint enough for the specific subject matter of the patent, various commentators have noted that the patent monopoly may have an even stronger effect on follow-on innovation, which requires access to the pioneering invention.⁵⁰ Progress in industries whose products depend on intellectual property from a number of sources may be restrained.⁵¹

The power of a patent owner to control access is acceptable if one can argue that the innovation would not exist but for the efforts the patentee made in anticipation of the property right. In this case, nothing is being removed from the public domain. Such an invention can hardly be inappropriately “held up” if there is no alternative context where it is more freely

⁴⁸ Patents are published as soon as they are issued, and in most countries the application is published eighteen months after submission. *See, e.g.,* Charles R. McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*, 11 *CARDOZO J. INT'L & COMP. L.* 547, 565 n.85 (2003). While the U.S. allows applicants to “opt out” of the eighteen-month publication rule under certain limited conditions, only a minority of applicants take advantage of the option. *See* Robert A. Clarke, *U.S. Continuity Law and its Impact on the Comparative Patenting Rates of the U.S., Japan and the European Patent Office*, 85 *J. PAT. & TRADEMARK OFF. SOC'Y* 335 (2003).

⁴⁹ *See* Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 *HARV. J.L. & TECH.* 389 (2002).

⁵⁰ *See, e.g.,* Suzanne Scotchmer & Jerry Green, *Novelty and Disclosure in Patent Law*, 21 *RAND J. ECON.* 131 (1990).

⁵¹ One of the more provocative theoretical studies of this phenomenon is the work of James Bessen and Eric Maskin, who argue that in certain industries that depend on sequential innovation like computer-related sectors, patents could actually decrease innovation. *See* James Bessen & Eric Maskin, *Sequential Innovation, Patents and Imitation* (MIT Dept. of Econ., Working Paper No. 00-01, 2000), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=206189.

available.⁵² The benefits gained by eventually having such an invention in the public domain offset the costs of temporary monopoly.⁵³ This rationale should also apply to those innovations that would eventually exist, but are created much sooner due to the property right. Even limited availability during a particular time period is better than none at all.⁵⁴

On the other hand, if a given innovation would have been produced at the same time in the course of normal business operations, the public “deadweight” economic losses may very well exceed the gains.⁵⁵ Despite the fact that the patent owner may personally benefit from the

⁵² It has been noted that a patent for technology necessary to produce a certain type of product could lead to a holdup of that technology, and this situation is more likely to occur if innovation is overproduced and overlaps in a manner that results in a “tragedy of the anticommons.” See Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 689, 699 (1998). However, truly innovative technology — that which would not have been created but for the patent incentive — should not be essential to a product created by others.

⁵³ See Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 250-51 (1994) (describing the concept of economic rents and how the contributions of patent-induced R&D can justify them). Of course, there are broader antitrust implications for the way in which a patentee uses his or her patent grant, as there are with any other type of property. Determining the appropriate degree of antitrust scrutiny is no easy task. See Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813, 1821-1823 (1984).

⁵⁴ Here, one could argue that an innovation created earlier, but locked up by the patentee for a time period beyond that which would have allowed the eventual discovery by competitors is not beneficial.

⁵⁵ See FTC REPORT, *supra* note 11, at Ch.2(I)(B) (“If the promise of patent protection is not necessary [to stimulate invention, disclosure or investment], then the costs — which may include higher prices or retarded follow-on innovation — may cause unjustified injury to consumers.”); Dam, *supra* note 53, at 251 (“[I]f we assume that the innovation were open to all, then all producers would gain the same cost advantage and the economic rent would be competed away; production would rise as cost fell, and in that sense one could say that the patent restricts production and causes a deadweight loss.”).

period of exclusivity to develop and market products incorporating the invention, the public suffers from the exploitation in the context of a protected environment that is less efficient than a fully competitive marketplace. A patent owner free from competition may under-invest or over-invest in an invention with respect to its true value in the marketplace.⁵⁶ Conversely, in an unrestricted environment, other businesses may be able to utilize and further develop the invention while driving down prices through competition.⁵⁷ Without the existence of incentive-aligned behavior, the patent right is more likely to act as a net societal burden.

There are, of course, limits to the extent of property rights that should be provided as incentives, regardless of the ground-breaking nature of the invention. At some point, the incentive for one invention may bleed over and become a disincentive for another.⁵⁸ Additionally, given that it is extremely difficult (if not impossible) to design a patent system that only rewards the inventions made specifically in view of the patent,⁵⁹ some broader category of inventions will necessarily be protected. This is acceptable if minimized. Thus, the object in designing patent rules should be to temper the incentive so that it inspires as many innovations as

⁵⁶ See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY* 609, 619 (1962) (stating that monopolists are less likely to engage in R&D spending for development of inventions they control than competitors).

⁵⁷ See Thomas M. Jorde & David J. Teece, *Innovation and Cooperation: Implications for Competition and Antitrust*, 4 *J. ECON. PERSPECTIVES* 75, 81 (1990).

⁵⁸ See Part III.2, *infra*.

⁵⁹ See, e.g., FTC REPORT, *supra* note 11, at Ch.1(I)(C)(1) (expressing the difficulty of using patent-induced innovation as a patentability criteria by stating “It is usually not possible, however, to use a ‘but for’ approach to analyze whether individual patents should be granted.”)

possible while acting as the smallest barrier to competition in business falling outside of the narrow group of innovations.⁶⁰

B. Empirical Evidence of Innovation from Multiple Studies Yields Equivocal Results

Within the framework of the more limited criteria of patent system success outlined above, one should theoretically be able to assess the current legal environment in the health care field. However, an incentive-aligned definition of innovation — while reasonable in theory — can be extraordinarily difficult to assess in practice.⁶¹ For example, one obviously cannot look at an invention claimed in a patent and determine the motivation for its creation. Over the years, academics have worked to identify the impact of the world’s patent systems through studies of a variety of indirect measures. While none are perfect articulations of the impact of patent incentives, a review of these general approaches can provide some useful insight into the most accurate measures. Additionally, in the context of health care, more informative, technology-specific measures have been discussed. Taken together, the literature indicates that modern patent systems are successful, but less so than most believe (and perhaps less than what is possible).

The closest one can get to a direct measure of patenting motivations is to conduct a survey of patent owners. To date, several surveys have addressed the specific question of whether the companies involved actually undertake a higher level of innovative behavior in

⁶⁰ See, e.g., Robert Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 874-76 (1988) (arguing that the patent system must not employ patentability tests that compromise its primary goal: to identify and reward “significant technical advance.”).

⁶¹ See, e.g., FTC REPORT, *supra* note 11, at Ch.1(I)(C)(1).

response to patents. In 1986, Edwin Mansfield surveyed one hundred firms in twelve distinct industries and found only weak dependency on patents.⁶² According to the survey, four of the twelve industries reported no effect.⁶³ Even for those for those that did, less than 20% of the inventions introduced during a three-year period would not have existed if patent protection was unavailable (except in the pharmaceutical and chemical industries).⁶⁴ More recently, Iain Cockburn and Rebecca Henderson conducted a survey on behalf of the Intellectual Property Owners Association (“IPO”) on respondent attitudes and opinions about their IP practice. Among the results was the indication that losing the protection afforded by the patent system would “strongly affect” or “affect” the R&D spending of 58% of the respondents, while approximately 40% indicated spending would not be affected.⁶⁵ These results are in line with another line of studies indicating that companies rarely regard patents as the most important means of protecting innovation.⁶⁶ While this body of work does not suggest that patents are ineffective, it provides some evidence that the patent system does not benefit all industries

⁶² See Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCIENCE 173, 174-76 (1986).

⁶³ *Id.* at 175 tbl.1.

⁶⁴ *Id.*

⁶⁵ *Id.* at C.4. In response to the question, “My company would spend significantly less on R&D and technology development without patents,” 32% of the respondents strongly “agreed” and 24% “agreed.” *Id.*

⁶⁶ See, e.g., Richard C. Levin, et al., *Appropriating the Returns from Industrial R&D and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 793-98 (1987) (survey results indicating that, apart from a few industries such as chemicals, most business do not rate patents as highly important in protecting investments); Wesley M. Cohen, et. al, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Firms Patent (or Not)*, NBER Working Paper No 7552, pp. 24-27 (2000), available at <http://www.nber.org/papers/w7552> (survey results demonstrating that there are various reasons companies patent other than to protect investments).

equally. Of course, the survey data is not conclusive on this point. As with any measuring device that depends on general questions without evidentiary back up, there is the danger that respondents are providing the answers they believe (or want to believe) are accurate, but are actually different from the corporation's actions.⁶⁷ Additionally, it is difficult to quantitatively assess whether the innovation component of R&D spending is optimally encouraged by the patent system.

Given the difficulties in accurately assessing the motivations for existing patents, the majority of studies simply look for evidence of the effects of intellectual property protection on innovation proxies. Perhaps the most widely used measure of innovation in this context is R&D spending at the firm, industry or country level.⁶⁸ It is particularly useful as a gauge of change over time. Interestingly, for the most part, studies of the effect of patents on R&D spending have demonstrated a weak effect at best. An example of one of the more intriguing works in this area

⁶⁷ For example, with the Cockburn and Henderson study, it is probably fair to say that, in most firms, corporate counsel do not make decisions on how or whether to spend funds on R&D. Conversely, one might expect lawyers to have an ingrained respect for the power of legal protections. Thus, it is plausible that the results are skewed toward finding patents important. Additionally, there is a well-characterized phenomenon known as "hypothetical bias," in which persons tend to provide hypothetical responses that differ from real-life actions simply because there are no consequences. See Ronald Dillehay & Michael Nietzel, *Constructing a Science of Jury Behavior*, in REVIEW OF PERSONALITY AND SOCIAL PSYCHOLOGY 253-54 (L. Wheeler ed., 1980) (discussing the problem in the context of jury simulations). See also Vernon Smith, *Experimental Economics: Induced Value Theory*, 66 AM. ECON. REV. 274, 274-75 (Supp. 1976) (presenting conditions necessary for incentive compatible behavior and noting that when the perceived utility from the experiments reward (if any) do not outweigh the expenditure of effort (or other variables), there is no incentive to participate fully).

⁶⁸ See Hahn, *supra* note 14, at 3 (reviewing several measures of innovation in the literature, and noting "Most commonly, research and development expenditures (R&D) are used as a proxy [for innovation].")

is Park and Ginarte's 1997 study to determine the link between patent "strength" and R&D investment using data from over sixty countries from 1960-1990.⁶⁹ They found a positive association, but only in countries with the highest median incomes, suggesting that other factors must work in concert with legal rights.⁷⁰ On the other hand, a 2002 study by Lerner, using primarily nineteenth century data, found that instituting a patent system or strengthening an existing patent system did not produce more domestic innovation.⁷¹ Similarly, Moser, using evidence of innovations from nineteenth century world's fairs, also finds scant proof that increasing patent rights leads to increasingly innovative behavior.⁷² An interesting reverse perspective is provided in a recent paper by Ashish Arora, et al., wherein the authors attempt to actually gauge the premium effect of obtaining intellectual property (*i.e.*, procuring patents) on the value of an innovation, and then analyzing the effect on R&D spending if that premium is changed.⁷³ The authors did find a positive impact, but it was quite small in all but a few

⁶⁹ Walter Park and Juan Ginarte, *Intellectual Property Rights and Economic Growth*, 15 CONTEMPORARY ECON. POL'y 51 (1997).

⁷⁰ *Id.* at 60 ("The results also show that, while R&D is an important determinant of developed and developing country growth rates, IPRs matter for the R&D activities of the developed economies but not for those of the less developed economies.").

⁷¹ Joshua Lerner, *150 Years of Patent Protection*, 92 AM. ECON. REV. 221 __ (2002) ("Adjusting for the change in overall patenting, the impact of patent protection-enhancing shifts on applications by residents was actually negative")

⁷² Petra Moser, *How do Patent Laws Influence Innovation? Evidence From Nineteenth Century World Fairs*, NBER Working Paper No. w9909, at p. 38-39 (Aug. 2003).

⁷³ Ashish Arora, et al, *R&D and the Patent Premium*, NBER Working Paer 9431 (Jan. 2003).

industries like pharmaceuticals.⁷⁴ Taken as whole, these empirical studies seem at first glance to indicate that the patent system is not tremendously important. But an understanding of the limitations of the data show why the important information for determining the success of patents is likely obscured.⁷⁵

In an attempt to focus only on innovative behavior, a few studies have attempted to gauge the production of a specific type of output over time, such as the number of patents obtained at the industry or country level.⁷⁶ Although there are severe limitations to the most basic form of this analysis that may confuse the results,⁷⁷ a more refined study that differentiates patents by

⁷⁴ *Id.* at 35 (“We find that on average patents provide a positive (greater than unity) expected premium gross of patent application costs in only a few industries, namely drugs, biotech and medical instruments, with machinery, computers, and industrial chemicals close behind.”).

⁷⁵ The greatest problem with using R&D spending as a proxy for innovation is that R&D is a very broad category of firm expense; it is simply too insensitive a measure from which to extrapolate the quantity of incentive-based inventions. Investment in research that may produce pioneering innovation is but one of a number of types of spending companies may group under the umbrella of R&D in making public reports of expenditures, and it is by no means necessarily the largest. See FASB, *Statement of Financial Accounting Standards No. 2 (FAS2)*, at ¶ 8 (Oct. 1974) (definition of “research and development” for accounting purposes, which is the basis for the “R&D” designation in much of the empirical research data). Thus, such studies may not address whether the patent system is productive according to the criteria established above.

⁷⁶ See, e.g., Zvi Griliches, *Patent statistics as economic indicators: a survey*, 28 J. ECON. LIT. 1661, ___ (1990) (“In spite of all of the difficulties, patent statistics remain a unique source for the analysis of the process of technical change.”); Jean O. Lanjouw & Mark Schankerman, *Patent Quality and Research Productivity: Measuring Innovation with Multiple Indicators*, 114 ECON. J. 441, 441-443 (2004).

⁷⁷ Most importantly, all patents are not equivalently valuable, See, e.g., John R. Allison, et al., *Valuable Patents*, 92 GEO. L.J. 435, 460-465 (2004) (arguing that inventions have a determinate value that is known by companies during the process of patent prosecution, and such companies modify prosecution techniques

“impact” or “importance” is informative.⁷⁸ Such weighted patent counts can be related to patent-motivated innovative behavior if one assumes that the most important patents are evidence of the riskiest, most groundbreaking innovations which would be undertaken only if a significant reward was involved. Additionally, an even more sensitive output analysis is

accordingly). Additionally, the absolute number of patents can be the product of patent strategy. *See* LANDES & POSNER, *supra* note 19, at 326-29 (describing the economic forces underlying an inventor’s choice between maintaining trade secrecy and patenting).

⁷⁸ Many studies attempt to weight patent citations with some measure of value. *See, e.g.*, Allison, *supra* note 77, at 439-43 (equating the fact that a patent is litigated to the notion that it is valuable); Manuel Trajtenberg, *A Penny for Your Quotes: Patent Citations and the Value of Innovation*, 21 RAND J. Econ 172 (1990) (assessing innovation by patent counts weighted by forward citations); Mark Schankerman & Ariel Pakes, *Estimates of the Value of Patent Rights in European Countries During the Post-1950 Period*, ECON J., Dec. 1986, at 1052 (patent counts weighted by renewal data). A fairly basic approach to patent weighting is taken by the Organization for Economic Cooperation and Development (“OECD”) Patent Project which counts “triadic” patent families (inventions that are covered by patents in the United States, Europe and Japan) over a given time period. *See* OECD, COMPENDIUM OF PATENT STATISTICS (2004), available at <http://www.oecd.org/dataoecd/60/24/8208325.pdf> [hereinafter “OECD PATENT STAT.”] This project is conducted in collaboration with a number of government entities, including the U.S. National Science Foundation (“NSF”), the World Intellectual Property Organization (“WIPO”), the European Union, and the patent offices of the U.S., Japan and the EU. *Id.* More complex data are produced by Chi Research Inc.’s Patent Scorecard, published yearly by the Massachusetts Institute of Technology’s *Technology Review*. *See* Technology Review, *2004 Technology Review Patent Scorecard*, available at, <http://www.technologyreview.com/articles/downloads/patents0504.xls> (last visited Jan. 3, 2005). The Scorecard compiles a “technological strength” rating for one hundred and fifty companies by multiplying the number of patents in a particular time period by the average number of citations the company’s last five year’s worth of patent receive in the current year (“Current Impact Index”); *See id.* at “Indexing Innovation” notes on “companies” worksheet. Companies that produce a greater number of patents and have a track record of significant patents are deemed more innovative. *Id.*

provided utilizing indicators that are more downstream than patents which can serve as an innovation proxy if their production is deemed sufficiently groundbreaking. This is particularly valuable in the context of health care innovation.⁷⁹ Unfortunately, there is a lack of in-depth investigation in the literature into whether alterations in patent incentives are correlated to changes in these measures. Thus, current studies provide less than conclusive answers on the vitality of the health care innovation environment.

Even if measures are further refined to better reflect patent-inspired innovation, this is only part of the analytical mechanism that must be optimized. An accurate assessment of the

⁷⁹ For example, assessments of the pharmaceutical industry often take into account the number of “new chemical entities” (“NCE”) or “new molecular entities” (“NME”) submitted for regulatory approval or approved that were produced by a given company or country during a particular time period. See Joseph DiMasi, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 154 (2003) (arguing that R&D costs are increasing by calculating adjusted cost per new chemical entity approved over time). New Active Substances (“NAS”) are also used in a similar fashion. IMS Health, *Low NAS numbers highlight the need for new R&D tactics*, (Mar. 23, 2004), available at http://www.ims-global.com/insight/news_story/0403/news_story_040323a.htm (“The trend is still on the decline for first launches of NASs, according to IMS LifeCycle New Product Focus' annual review, which shows only 30 NASs in 2003, versus 36 in 2002. This marks an all-time low since IMS started monitoring NASs in the early 1970s, and the lowest in 25 years since the 32 drugs launched in 1979.”). Similarly, a greater number of primary regulatory approval submissions — such as new drug applications (“NDA”) or priority NDAs, (as opposed to supplemental or abbreviated applications) — may reflect a greater emphasis on pioneering discoveries. For example, the FDA reports separately approvals of priority NDAs due to their indication of important medical breakthroughs. See DEPARTMENT OF HEALTH AND HUMAN SERVICES, FDA CENTER FOR DRUG EVALUATION AND RESEARCH, REPORT TO THE NATION: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 13, available at <http://www.fda.gov/cder/reports/rtn/2003/rtn2003.PDF> [hereinafter “CDER REPORT”] (“These drugs represent significant improvements compared with marketed products.”).

success of an intellectual property regime must incorporate a complete understanding of all of the aspects of the property right that impact innovators, including the institutional and cultural environment in which it exists. Furthermore, going forward, one must understand the contribution of the various property factors in order to make useful recommendations on how to improve the system. Unfortunately, modern assessments of the patent system may suffer from an overly simplistic view of the aspects of the right. In part, this may be due to a desire to fit the available data into the analytical structure; some patent factors may be absent from historical databases or simply difficult to quantify. If we are to make reasonable progress in intelligently reforming the patent system, progress toward a more thorough framework is called for. This can begin with a consideration of all factors that affect the “strength” of patent incentives.

III. An Incentive-Alignment Perspective on Patent Strength

The essential question in assessing patent strength is the degree to which the right encourages *ex ante* investments in innovation.⁸⁰ Perhaps the most important facet of patents as an innovation incentive is the fact that they are treated as a property right under national laws.⁸¹

⁸⁰ See Mark A. Lemley, *Ex Ante vs. Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 148-49 (2004) (arguing that many economic theorists improperly focus on patent rules as a means of controlling already-created innovation, rather than on incentives to produce the innovation).

⁸¹ See, e.g., 35 U.S.C. § 261 (patents have the attributes of personal property under U.S. law); TRIPs, *supra* note 36, at Preamble (“Recognizing that intellectual property rights are private rights”). *But see generally* Mark A. Lemley, *Property, Intellectual Property and Free Riding*, John M. Olin Program in Law and Economics Working Paper No. 291 (Aug. 2004) (arguing that, although intellectual property is generally treated as equivalent to tangible property, fundamental differences in the nature of intellectual property suggest that it should not receive such strong treatment).

They can be created, owned and sold much like tangible items.⁸² There is a degree of certainty in patent rights that provides confidence in the investment,⁸³ particularly in the United States where property rights are given strong constitutional recognition.⁸⁴ Arguably, if patents were a mere regulatory mechanism—a form of government administration of nominally public information—the incentive to invest in patent-protected innovations would be significantly reduced.⁸⁵ However, despite the import of the property designation, there can be a considerable

⁸² See 8 DONALD S. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 22.01 (Rel. 95, Oct. 2004) (“Patents are subject to general legal rules on the ownership and transfer of property.”).

⁸³ COOTER & ULEN, *supra* note 45, at 106-108 (commenting on the nature of private and public goods and why protecting private goods with private property rights encourages efficiency); RICHARD POSNER, ECONOMIC ANALYSIS OF LAW 36-39 (5th ed. 1998) (noting that “The creation of individual (as distinct from collective) ownership rights is a necessity rather than a sufficient condition for the efficient use of resources.”)

⁸⁴ See Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTEL. PROP, MEDIA & ENT. L.J., Part IV.C, D (forthcoming 2005) (on file with the author) (describing how intellectual property rights are protected from uncompensated government infringement by the Fifth and Fourteenth Amendments to the U.S. Constitution).

⁸⁵ For example, air quality is traditionally viewed as a public good, see Abraham Bell & Gideon Parchomovsky, *Of Property and Antiproperty*, 102 MICH. L. REV. 1, 19 (2003) (“[E]x ante, provision of public goods requires government intervention; for example, nonrivalrousness and nonexcludability of air may require government provision of clean air . . .”), and governments have regulated it through environmental protection legislation. However, considerable success in private investment was achieved when the air quality was transformed into a private right that could be bought and sold. See Robert Hahn, et al, *Environmental Regulation in the 1990s: A Retrospective Analysis*, 27 HARV. ENVTL. L. REV. 377, 401-02 (2003) (“A robust market of bilateral SO₂ permit trading emerged in the 1990s, resulting in cost savings on the order of \$1 billion annually, compared with the costs under some command-and-control regulatory alternatives.”).

degree of difference in how property is treated from country to country.⁸⁶ Surprisingly, such important issues are not completely controlled by international convention, but often left to individual countries to manage within their individual frameworks.⁸⁷

To achieve the most complete understanding of how patent rights are likely to impact innovation, one should attempt to capture the broadest conception of property incentives. At the very least, this requires a traditional discussion of the legal boundaries of the right. It also must entail an analysis of the governmental and societal institutions that affect property rights. Finally, one should consider whether and how cultural values regarding property affect the patent incentive. Each is discussed in detail below. To aid in the discussion, and in keeping with the conceptual economic approach of this article, a graphical representation of the impact of each factor is provided. This is merely a broad outline of the proposed contours of innovation; it is not intended to reflect a detailed mathematical theory or collection of empirical data. Although most of these broad categories of potential factors affect all technologies equally, some have greater industry-specific impact; in those cases, health care-related industries are specifically addressed.

⁸⁶ See Jerome Sgard, *Are There Such Things as International Property Rights?*, 27 *WORLD ECON.* 387, 388 (suggesting that variations in national property rights regimes are an obstacle to globalization and stating “A series of empirical elements suggest that the institutions, which define and enforce property rights, tend to remain strongly attached to the legal and judicial framework of each country: their resistance to convergence is apparently strong.”)

⁸⁷ Although both TRIPs, *supra* note 36, and the Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 2, 828 U.N.T.S. 107, refer to either “industrial property” or “intellectual property,” neither define property specifically.

A. Legal Attributes of Patent Property

The boundaries of the patent grant are set by fairly clear legislative guidelines. Even in common law countries that continue to define most aspects of real and personal property through court doctrine, patent rights are primarily creatures of statutory law.⁸⁸ By virtue of several important international agreements,⁸⁹ differences in these rules from country to country — including the lack of certain protections⁹⁰ — are gradually being eliminated in favor of a global set of standards. Although there is no international patent *per se*, it is now true that, on paper at least, basic patent legal rights are quite similar in most nations.

⁸⁸ See, e.g., Srividhya Ragavan, *Can't We All Just Get Along?: The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117, 122-25 (2003) (reviewing the development of patent law in the United Kingdom and stating “The Patents Act of 1949 abolished the common-law grounds, leaving the grant of patents to be governed exclusively by statutory grounds.”)

⁸⁹ The TRIPs agreement, administered jointly by the World Trade Organization (“WTO”) and the World Intellectual Property Organization (“WIPO”), has been the most important in setting comprehensive minimum standards for international intellectual property law (though great differences between nations are still permitted). See Adrian Otten & Hannu Wager, *Compliance With TRIPs: The Emerging World View*, 29 VAND. J. TRANSNAT'L L. 391, 393-94 (1996). Other agreements include the Paris Convention, *supra* note 87 and the Patent Law Treaty, 39 I.L.M. 1047, available at http://www.wipo.int/clea/docs/en/wo/wo038en.htm#P268_43807

⁹⁰ See Rishi Gupta, *TRIPs Compliance: Dealing with the Consequences of Drug Patents in India*, 26 HOUS. J. INT'L L. 599, 602-05 (2004) (“[T]o comply with Trade Related Aspects of Intellectual Property Rights (TRIPS) agreements, India, along with many other developing countries, must adopt an intellectual property regime that mimics the system of much of the developed world, complete with twenty-year patent rights on pharmaceutical products.”).

Alongside the push to harmonize the world's patent regimes⁹¹ is the rather confounding fact that patent law seems to be in a constant state of flux. Unlike the more staid real property doctrine that has permeated Western economies for centuries, patent rights throughout the world have been subject to more frequent periods of revision, some of which have been quite dramatic.⁹² Certain trends can be identified. Most importantly, as the concept of intellectual property has become more accepted and integrated into the international economy — particularly in the Twentieth and Twenty-First Centuries — many believe that a general “strengthening” of these rights has occurred.⁹³ But even if individual patents do in fact convey greater powers to their owners, has the patent right become a stronger force for innovation? It is quite possible that patents powers without limit could act as disincentives for the innovations of others. To determine the extent to which patent legal rights are optimal for innovation, one must consider the individual aspects of the right in terms of their specific goals. These aspects can be broadly categorized as “availability” and “extent.”

⁹¹ There are actually economically rational reasons for countries to resist harmonization. See Suzanne Scotchmer, *The Political Economy of Intellectual Property Treaties*, 20 J.L. ECON. & ORG. 415, 420-422 (2004) (describing the economic advantages of providing national treatment without reciprocity)

⁹² See OECD, PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGES 17-88 (2004), available at <http://www.oecd.org/dataoecd/48/12/24508541.pdf> (summarizing several recent changes in the patent systems of Europe, Japan and the United States in just the last twenty years).

⁹³ See *id.* (“Patent regimes have gone through important changes in the past two decades, most in the direction of strengthening patent rights, in the sense of reinforcing the exclusive rights conferred to patent holders, expanding their coverage and easing their enforcement.”); JAFFE & LERNER, *supra* note 13, at 104-107 (attributing the increase in U.S. patent strength largely to the creation of the Federal Circuit).

1. Greater Availability of Patents has a Linear Relationship to Innovation

The availability of patent coverage for a given technology has received general acceptance as a positive force for innovation. The more encompassing patent laws are with respect to patentable subject matter, the better. United States patent laws in particular have been read quite broadly in this regard. In one of the more expansive declarations of this idea, the U.S. Supreme Court in *Diamond v. Chakrabarty* declared that Congress intended patentable subject matter to be “anything under the sun that is made by man.”⁹⁴ Thus, patents have gradually expanded from their traditional roots in the mechanical arts,⁹⁵ and now impact almost every field of technology from computers to biotechnology.⁹⁶

The rationale for making patent protection available to all fields of technology is reasonable, given certain assumptions. For the most part, it is believed that if an industry sector is sufficiently important to society, it is equally as important to provide incentives for investment in new discoveries in that sector. If patents have at least the potential to create incentives for non-obvious and useful inventions that would not otherwise exist, every industry art should benefit. This is obviously dependant on the ability of other aspects of the patent right and the

⁹⁴ 447 U.S. 303, 309 (1980) (interpreting the Committee Reports accompanying the Patent Act of 1952, the last major revision of U.S. patent law).

⁹⁵ See John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1139-42 (1999) (describing the expansion of patentable subject matter from the tools of the industrial revolution to the almost limitless categories permitted today).

⁹⁶ See Rebecca Eisenberg, *Analyze This: A Law & Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2083-84 (2000) (stating that “A much-noted dimension of the apparent expansion of the patent system in recent years has been the range of patent-eligible subject matter” and recounting several fields into which it has expanded).

environment in which it exists to create the incentives (discussed below). Assuming patents create incentives that result in at least some additional innovation and that they contribute to innovation equally in all fields, the relationship should be straightforward and linear:

Insert Figure 1 Here

Innovation increases directly as the scope of subject matter does. Within a particular technology field, the effect is binary.

There are often disputes when a new area of patentability is recognized.⁹⁷ Indeed, a few areas are so controversial that they are patentable in only some countries.⁹⁸ While this fear of embracing new technology appears inconsistent with the underlying ideals of the patent

⁹⁷ Although the patenting of business methods is the most prominent recent example of controversy over the expansion of patentable subject matter, there have been others throughout history. *See, e.g.,* Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When is it the Best Incentive System?*, in 2 INNOVATION POLICY AND THE ECONOMY 51-52 (Adam Jaffe, et al, eds. 2002) (“[C]ontroversies have swirled around every new technology in the twentieth century.”). Examples include purified chemical compounds, mathematical algorithms and DNA fragments. *See id.*

⁹⁸ The patenting of higher life forms is an example of one such controversy. While the USPTO and the EPO allowed a patent to issue some years ago on a genetically modified mouse that was predisposed to cancerous tumors, the Canadian Supreme Court recently rejected an analogous application from the same inventors. *See* Harvard Coll. v. Canada (Commissioner of Patents), [2002] SCC 76, 219 D.L.R. (4th) 577; Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 519-530 (2003) (relating the outcome of PTO, EPO and Canadian Supreme Court determinations on the patentability of the Harvard “oncomouse”).

system,⁹⁹ a closer inspection reveals that most such disagreements are the result of a concern that an endemic failure of the patent system's innovation incentive structure permeates the narrow technology niche in question. The most common failures are in either the innovation identification framework or the desirability of the reward.

Innovation identification failures occur if a patent system cannot parse true invention — new, nonobvious/inventive step and useful — from common business activity. If patents are allowed for the latter, there is no incentive to invest greater effort and resources in producing the former. The problem arises because the system's ability to differentiate in this manner may not be equivalent across technologies.¹⁰⁰ Similar failures may occur when the reward for

⁹⁹ See NAS REPORT, *supra* note 12, at 84 (“Historically, there has been strong resistance to a differentiated patent system and to subject matter exclusions and fairly consistent adherence to a relatively open-ended unitary system.”)

¹⁰⁰ For example, the initial assessment by a competent patent office staff may be compromised when a technology is so new that few if any examiners have the background to find and apply the prior art. See, e.g., John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 316-321 (2001) (describing among the many failures that can occur in a patent examination system under time and monetary stress: “Overreliance upon patents as indicia of the state of the art works far more mischief in fields long believed to be outside the patent system, however.”). Additionally, in new fields, the prior art necessary for proving a lack of novelty or obviousness may exist only in nontraditional sources like trade magazines. See, e.g., Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 589-91 (1990) (noting the problem of locating prior art for a non-traditional field like business methods, and suggesting that it contributes to poor patent quality). It could even be argued that some new fields are not sufficiently grounded as to demonstrate the application of an idea as opposed to the idea itself. Exactly such arguments were made with respect to business methods following the decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* confirming that they were patentable under U.S. law. 149 F.3d 1368, 1375 (Fed. Cir. 1998) (“Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.”).

patenting is insufficient to increase the level of innovation above the base that would exist in the absence of the system. The benefit of patenting is the limited monopoly over the invention, and although all technologies receive the same property powers under a unitary system, market dynamics may render the powers effectively useless or of little value.¹⁰¹ When additional years of patent protection will end up covering an obsolete product, businesses may not increase investment in innovative R&D in response to the incentive.¹⁰² Additionally, when existing rights — even intellectual property rights — provide sufficient protection without patents, no benefit is obtained by broadening patentable subject matter.¹⁰³

¹⁰¹ One instance in which this is alleged to occur is when technology changes so quickly that the exclusivity a patent adds to that achieved by being simply being first to market is negligible. *See, e.g.,* Hall & Ziedonis, *supra* note 43, at 102 (describing the use of patents in the semiconductor industry and stating “Driven by a rapid pace of technological change and short product life cycles, semiconductor firms tend to rely more heavily on lead time, secrecy, and manufacturing or design capabilities than patents to recoup investments in R&D.”); Mark Schankerman, *How Valuable is Patent Protection?: Estimates by Technology Field*, 29 RAND J. ECON. 77 (1998).

¹⁰² For example, Hall & Ziedonis demonstrate that the number of patents issued to companies in the semiconductor industry increased at a much higher rate than increases in R&D spending. Hall & Ziedonis, *supra* note 43, at 102. This suggests that patenting behavior in this industry became less connected with innovation spending. *See also* FTC Report, *supra* note 11, at Ch. 3(V)(G) (“Panelists consistently stated that competition [as opposed to intellectual property rights] drives innovation in [the software and Internet] industries.”).

¹⁰³ Some would argue that the computer software industry provides such an example, as the benefits from copyright law, trade secret and contract law give equivalent or superior powers to the patent grant. *See* FTC REPORT, *supra* note 11, at Ch. 3(V)(D) (“Some commentators questioned which it was necessary to have patent protection on software given the availability of copyright.”). This was actually the position taken by a presidential commission studying the issue in the United States as far back as the 1960s. *See* Exec. Order No. 11,215, 30 C.F.R. 4661 (1965), “To Promote the Progress of . . . the Useful Arts” In an Age of Exploding Technology, Report of the President’s Comm’n on the Patent System, reprinted in S. Doc. No. 5, 90th Cong., 1st Sess. at 13. *See also* National

While access to patents should support greater innovation absent one of the above market failures, increasing the scope of patentable subject matter can still be controversial, particularly when the technology has a significant impact on public health. The concern is proportional to the importance of the technology — the most groundbreaking treatments for the most dread diseases — due to the general belief that personal property rights should not restrict access to technology that can save lives or alleviate suffering.¹⁰⁴ Despite the fact that patent incentives may lead to better treatments in the future, public policy advocates often attempt to frame the debate to focus on the short term goal of immediate access.¹⁰⁵ One of the broadest of these

Commission on New Technological Uses of Copyrighted Works, Final Report at 1 (1978) (reflecting the same conclusion). Whether copyright should be extended to software source code as far as it has is an open question, and some courts appear to be reconsidering the issue based on software's ultimately utilitarian function. *See* *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 387 F.3d 522, 535-36 (6th Cir. 2004) (merger of idea and expression of software “lock-out” codes precluded copyright protection)

¹⁰⁴ This sentiment is reflected in the WTO's development agenda relating to intellectual property articulated at the recent Doha Ministerial Conference in 2001. The statement makes it very clear that intellectual property rights grounded in TRIPs should yield to national public health emergencies. *See* Declaration on the TRIPs Agreement and Public Health, Adopted on 14 November 2001, WT/MIN(01)DEC/2 [hereinafter “Doha Declaration”], at <http://docsonline.wto.org/DDFDocuments/t/WT/min01/DEC2.doc> (Nov. 20, 2001) (“We agree that the TRIPs Agreement does not and should not prevent members from taking measures to protect public health.”).

¹⁰⁵ *See, e.g.*, Susan K. Sell, *TRIPs and the Access to Medicines Campaign*, 20 WIS. INT'L L.J. 481, 490-91 (2002) (“[I]n the ongoing deliberations over intellectual property rights in the context of the sub-Saharan African HIV/AIDS crisis, ‘public health’ has emerged as an increasingly effective counter-framing to the high-protectionist activists.”); Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, in 4 INNOVATION POLICY AND THE ECONOMY 91-95 (Adam Jaffe, et al, eds. 2002) (describing the efforts of public interest groups to change patent systems to increase access to essential medications).

exclusions is enshrined in the law of the European Patent Convention, the signatories of which recognize patents issued by the governing agency known as the European Patent Office (“EPO”).¹⁰⁶ According to Article 52 of the Convention concerning patentable inventions, among the information not recognized as an invention subject to protection are “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body”¹⁰⁷ This eliminates some of the incentive to invest in uncovering, *inter alia*, new methods of administering pharmaceutical or biotechnology compounds. Such methods have in the past transformed compounds of interest but questionable value into useful medical treatments.¹⁰⁸ To compensate for the reduction in patent incentives, the EPC permits recapturing patent protection over a substance’s “first medical use,” even if the

¹⁰⁶ See EPC, *supra* note 36, at Art. 2 (“The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless otherwise provided in this Convention.”). Interestingly, the EPO is a separate entity from the European Union. See European Commission, The Community Patent - Frequently Asked Questions (Jun. 2000), available at http://europa.eu.int/comm/internal_market/en/indprop/patent/2k-41.htm#9.

¹⁰⁷ See EPC, *supra* note 36, at Art. 52(4) (“Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1.”).

¹⁰⁸ For example, some ground breaking drug treatments actually have patents only on the most effective method of using the compound, rather than the compound itself. See General Accounting Office, *NIH-Private Sector Partnership in the Development of Taxol*, Report to Senator Ron Wyden, 24 (Jun. 2003) (noting that, although the active ingredient of the blockbuster anti-cancer drug, Taxol (paclitaxel), has not been patented, methods of administration of the drug have been patented). In such a case, the core compound may be otherwise freely available.

compound or substance is in the prior art.¹⁰⁹ This is obviously an imperfect solution, particularly if a new method of treatment is possible but some other medical use of the involved pharmaceutical already exists. An additional example is provided by the fact that many countries restrict patent rights on certain medical goods, like pharmaceuticals.¹¹⁰ While such measures may satisfy a moral imperative to subjugate property rights to social policy when emergent conditions dictate, the negative effect of the removal of the patent incentive on innovation is likely result must be acknowledged nonetheless.¹¹¹

2. The Extent of Patent Rights Must be Circumscribed to Promote Innovation

The majority of legal rules that come into play for subject matter deemed patentable address the boundaries of the property right. They dictate a multi-dimensional picture of the property that explains to competitors exactly what is covered and how the right can be enforced. At base, the boundary rules are directed toward capturing every bit of a patentee's true invention, while ensuring that knowledge outside of it is not improperly drawn into the monopoly. This

¹⁰⁹ See EPC, *supra* note 36, at Art. 54(5).

¹¹⁰ See, e.g., Gupta, *supra* note 90, at 602-03 (describing India's current regime that precludes the patenting of pharmaceutical products but not methods of manufacturing them); Frederick M. Abbott, Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework, 22 VAND. J. TRANSNAT'L L. 689, 743 (1989) (detailing the regimes in countries that do not allow the patenting of pharmaceuticals).

¹¹¹ See Lanjouw, *supra* note 104, at 95-96 ("When inventors capture only a part of the benefit to society of their inventions, private returns do not reflect social returns and the result is too little investment in R&D.").

places a limit on the power that should be conveyed to create incentives; stronger patents are not always better.

Three strength factors make up the key components of patent boundaries: (1) the scope or breadth a patentee will be permitted to claim, (2) the type of activities over which the patentee will be able to assert the patent right, and (3) the time period over which the patentee can claim the right. To determine how these factors feed back into innovation, one must step into the shoes of the prospective innovator *before* the investment in innovation has begun. What guarantees are required to solicit investment in innovation that would not be made absent the possibility of a future patent? Additionally, what patent grants to competitors would prevent this investment? Each factor must be addressed separately in view of the manner in which it provides protection and restricts competition.

a) *Claim Scope to Cover Only the Invention*

In theory, designing a set of rules to ensure that a patent right covers only the patentee's true invention is simple and straightforward. It requires a mechanism for assessing the existing prior art — including existing patents — to determine if the invention is novel.¹¹² Of course, if an invention has not been specifically detailed, but can be clearly intuited from a variation on or combination of the existing “prior art”, it can be fairly said to exist. A method for excluding such material is also therefore necessary, and this takes the form of the “nonobviousness”¹¹³ or

¹¹² For example, in the United States, a complex series of novelty bars prevent certain types of inventions from being patented if they were created by others or known to the general public. *See* 35 U.S.C. § 102 (2000).

¹¹³ *See* 35 U.S.C. § 103 (2000).

“inventive step” requirement.¹¹⁴ The application of novelty and nonobviousness is bi-directional. It is rearward looking in that it will prevent a patentee from obtaining a patent if he or she cannot meet this threshold,¹¹⁵ and it is forward looking in that it will prevent an issued patent from being interpreted to cover a competitor’s article or act that would fall within these preclusions (either invalidating the patent¹¹⁶ or narrowing the construction of the claims¹¹⁷).

In addition to avoiding the prior art, a patent system should encourage an applicant to achieve reduction to practice sufficient to demonstrate that the innovation is more than a vague idea, lest property rights be granted to those who are merely making predictions regarding

¹¹⁴ The phrase inventive step in Europe and Japan is equivalent to the U.S. obviousness requirement. *See* EPC, *supra* note 36, at Art. 56. (“An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.”); David J. Abraham, *Shinpo-Sei: Japanese Inventive Step Meets U.S. Non-Obviousness*, 77 J. PAT. & TRADEMARK OFF. SOC’Y 528, 529-30 (1995).

¹¹⁵ *See* *Merges*, *supra* note 60, at 811-12 (“This requirement asks whether an invention is a big enough technical advance; even if an invention is new and useful, it will still not merit a patent if it represents merely a trivial step forward in the art.”). [cal law rev art on commercial success]

¹¹⁶ *See, e.g., Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, ___ F.3d ___, 2004 WL 2861372 (Fed. Cir. Dec. 14, 2004) (in the context of a patent infringement litigation, affirming district court’s determination that asserted claims of a patent for barbell weight plate with handles were obvious in view of the prior art).

¹¹⁷ The Federal Circuit has been clear in stating that patent claims are to be construed to preserve their validity, if possible. *See, e.g., ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed. Cir. 1990). While this does not mean that claims can be rewritten by courts, they can be subject to a reasonable, narrow interpretation if the claim would otherwise be obvious. *See, e.g., Newell Companies, Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 767 (Fed. Cir. 1988) (“The more narrowly a claim is construed, the more likely the claim may be upheld in light of the prior art.”)

inventions that are decades from being available (if ever).¹¹⁸ While nominally an issue of patentable subject matter, the prohibition against protecting abstract ideas is primarily achieved with a requirement that a patentee “enable” those of ordinary skill in the relevant art to practice the invention without undue experimentation.¹¹⁹ In the United States, one is also obligated to provide a “written description” sufficient to demonstrate that the patentee has possession of the

¹¹⁸ See ADELMAN, *supra* note 25, at 83 (“A patent can only issue if an invention achieves a tangible, practical result”); POSNER, *supra* note 83, at 44 (“If granted too early — before the inventor actually knows how to make the product or process embodying the invention — a patent may actually retard innovation . . .”). This is not to say that inventions should be fully marketable when a patent application is filed, but the inventor should have an understanding of the practical application and be able to express it to others of ordinary skill.

¹¹⁹ See 35 U.S.C. § 112 (2000); *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463 (Fed. Cir. 1984) (patent not invalid for non-enablement because undue experimentation was not required to practice the claimed invention). See also EUROPEAN PATENT OFFICE, GUIDELINES FOR SUBSTANTIVE EXAMINATION, part C, ch. IV, § 5.2, available at http://www.european-patent-office.org/legal/gui_lines/e/index.htm [hereinafter “EPO GUIDELINES”] (stating the enablement requirement under the EPO convention); JAPAN PATENT OFFICE, EXAMINATION GUIDELINES FOR PATENT AND UTILITY MODEL IN JAPAN, Part I, p. 19 (Dec. 2000) available at http://www.jpo.go.jp/quick_e/index_tokkyo.htm [hereinafter “JPO GUIDELINES”] (describing enablement requirement under Japanese Patent Law Section 36(4)).

invention at the time the application is filed.¹²⁰ In most cases, enablement probably subsumes written description,¹²¹ but U.S. courts continue to see a distinction.¹²²

The patent that emerges from this system should reflect successful innovative effort. There is an effective prohibition on capturing existing public knowledge and precluding future innovation, while providing a reward for the full extent of the invention. It is, of course, a balance that has negative effects if either side of the scale is too “strong”:

Insert Figure 2 Here

Whether the balance should be altered to encourage “pioneering” inventions is a question that has been advanced from time to time.¹²³ It has been suggested that providing a stronger reward for the successful “prospecting” of truly groundbreaking inventions should be

¹²⁰ See 35 U.S.C. § 112 (2000) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it . . .”). The requirement compels a patent applicant to demonstrate that he or she was “in possession of the ... claimed invention, including all of the elements and limitations.” *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed.Cir.1998).

¹²¹ In other words, how can you teach those of ordinary skill in the art an invention without being in possession of it? This hypothetical scenario probably occurs very rarely, if ever. See *University Of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303, 1312 (Fed. Cir. 2004) (Rader, J. dissenting).

¹²² See *University Of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922 (Fed. Cir. 2004) (“In addition, and most significantly, our precedent clearly recognizes a separate written description requirement.”) (citing *In re Ruschig*, 379 F.2d 990 (CCPA 1967)).

¹²³ See *Kitch*, *supra* note 44, at 268, 276; *POSNER*, *supra* note 83, at 44 (“Patents are granted early--before an invention has been carried to the point of commercial feasibility--in order to head off costly duplication of expensive development work.”).

increased.¹²⁴ A counter to this notion is the fact that it is exactly these groundbreaking inventions that set the stage for most follow on innovation, much of it produced by parties other than the pioneering inventor.¹²⁵ Allowing a supra-potent pioneering right may eliminate some of this innovation which can serve an important role in advancing innovation.¹²⁶ While the latter position could be argued to be relevant only in fields that have a significant amount of follow-on innovation,¹²⁷ it seems equally reasonable to presume that it would therefore not have an incentive effect in those industries in which follow-on innovation does not compete for market share.

Of course, ensuring the patent grant is this perfectly balanced in practice is complex and somewhat slippery. The fact that patents are the product of linguistic interactions between real people — often before the final marketplace application of the invention becomes clear¹²⁸ —

¹²⁴ See Kitch, *supra* note 44, at 266-68.

¹²⁵ See Robert R. Merges & Richard P. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 871-78 (1990) (“Yet we have little faith in the imagination and willingness of a ‘prospect’ holder to develop that prospect as energetically or creatively as she would when engaged in competition.”)

¹²⁶ *Id.*; Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 1048-52 (1997) (“The problem with handing out property rights in advance of invention is the same problem with Kitch’s prospect theory--it is unrealistic to expect that property owners will be uniquely good at identifying potential future inventors or improvers.”).

¹²⁷ See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1620-24 (2003) (“Patent protection for such incremental software inventions should be relatively easy to acquire, but it should be narrow.”); Eisenberg, *supra* note 45, at 1066-69 (central management is least likely to be successful when follow on research is likely to lead down unexpected paths).

¹²⁸ Under U.S. law, there is no requirement that inventions be actually reduced to practice before filing; a patent application itself is considered to be a constructive reduction to practice. See 37 C.F.R. §1.626 (2002); Hyatt v.

provides opportunities for misinterpretations and errors in judgment. The obviousness/inventive step determination in particular is open to interpretation and, to some extent, the possibility of different degrees of restriction depending on how the test is applied.¹²⁹ Some see the raising of the obviousness bar as a useful mechanism to restrict patentability in response to the concern that certain types of patents are issued too readily.¹³⁰ In some cases, courts seeking to achieve predictability in its application may settle on overly formalistic rules.¹³¹ Additionally, the requirement for precise claiming¹³² is complicated by the limitations of the language in which the patent is drafted. Concern that imprecise wording could result in a patentee inadvertently claiming less than he or she was entitled has led U.S. courts to create a rule that extends narrow patent claims to clear “equivalents.”¹³³ As another court-created rule, this “doctrine of

Boone, 146 F.3d 1348, 1352 (Fed. Cir.1998) (“The filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application.”) (citing *Yasuko Kawai v. Metlesics*, 480 F.2d 880, 885 (CCPA 1973)).

¹²⁹ See *Burk & Lemley*, *supra* note 127, at 1651 (noting how secondary considerations of obviousness enable a court to incorporate non-statutory factors at will).

¹³⁰ See, e.g., NAS REPORT, *supra* note 12, at 91-95 (arguing for a more stringent application of obviousness in the context of gene sequence patents).

¹³¹ In the context of chemicals, obviousness can be inferred from the similarity of chemical structures alone. See CHISUM, *supra* note 82, at § 5.04[6] (“A key problem is whether a compound that is ‘chemically obvious’ in the above sense should be viewed as nonobvious for the purposes of the patent laws when the inventor shows that it possesses unexpected properties not in fact possessed by the prior art.”). This arguably means that patentability standards for chemicals are higher than other arts.

¹³² See, e.g., 35 U.S.C. § 112 (2000).

¹³³ *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002) (“Unfortunately, the nature of language makes it impossible to capture the essence of a thing in a patent application.”).

equivalents” suffers from the unpredictability of various — and to some extent conflicting — guidelines that must be derived from the case law.¹³⁴ Attempts to clarify the confusion with more simple, but arbitrary, rules have been rejected.¹³⁵

Similarly, how much reduction to practice is required to support broad claims is another area with many shades of gray. While patents are nominally required to cover inventions that are useful¹³⁶ (or have “industrial application”¹³⁷), one presumes that few would be pursued for creations that are not in fact useful.¹³⁸ Regardless, this requirement has been heightened in some cases, not as a means of preventing useless or inoperable inventions from being patented, but to ensure the applicant knows enough about the potential application of the invention to state a firm, credible utility.¹³⁹ Whether this is a better mechanism than heightened obviousness is

¹³⁴ See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558, 573-75 (Fed. Cir. 2000) (reviewing divergent lines of cases and commentary regarding the application of the prosecution history estoppel to the doctrine of equivalents), *vacated and remanded*, 535 U.S. 722 (2002)/

¹³⁵ See *Festo*, 535 U.S. at 739-40 (rejecting the application of bright line rules to resolve doctrine of equivalents issues due to the impact on existing patent property rights).

¹³⁶ See 35 U.S.C. § 101 (2000).

¹³⁷ See, e.g., EPO GUIDELINES, *supra* note 119, at Part C, IV, 4.2. (“An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”).

¹³⁸ Such guidelines are occasionally used to prevent inventions that violate basic laws of physics, like perpetual motion machines, from being patented. Thankfully, most large companies submit few applications of this type.

¹³⁹ See *Burk & Lemley*, *supra* note 127, at 1644-45 (“The PTO’s Utility Guidelines for such patents require a showing of “specific,” “substantial,” and “credible” applications not found in examination of other technologies.”) (citing Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001)).

unclear, but both attempt to prevent easy, broad innovations from precluding later innovation that may contribute more to progress of the useful arts.

In the end, the task of tweaking the system's patent scope requirements to center may be impossible, but keeping the two sides in mind with any legal revision can minimize social losses.

b) *Patent Rights that Provide Maximum Control of Commercial Uses Support Innovation*

In general, patent rights extend to most commercial uses of (or proposals to use) the invention.¹⁴⁰ This gives a patentee effective control over how the invention impacts the marketplace — or whether to allow it on the market at all¹⁴¹ — during the period of the patent. Adding to this power is the fact that patent infringement is usually classified as a no-intent tort, requiring no knowledge of the patent owner's property right to incur liability.¹⁴² The fact that a patent has been granted in a particular jurisdiction is all the ammunition a patentee needs to control the invention.

On the other hand, there is an interesting limitation in the patentee's ability to reap a reward from the exclusivity due to the fact that patent rights merely exist in the negative; they

¹⁴⁰ For example, the U.S. Patent Act gives patent owners the right to excludes other from making, using, selling, offering to sell the invention in this country, or importing it from another without the authority of the patent owner. 35 U.S.C. 271(a) (2000).

¹⁴¹ See *supra* note 49 and accompanying text.

¹⁴² See, e.g., *Embrex, Inc. v. Service Eng'g Corp*, 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J. concurring) (“Similarly, because intent is irrelevant to patent infringement, an experimental use excuse cannot survive.”); *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (1996).

give the patentee the right to exclude others, but no right to use the invention.¹⁴³ This is in contrast to tangible property rights, which include the right to use the property along with the right to exclude others.¹⁴⁴ The limitation is particularly important if the invention concerns merely an improvement on existing technology, and marketing a product covered by the patent would infringe another's patent property. In this case, a patentee could obtain profits by some licensing arrangement, but the options are certainly narrower. Such a restriction on patent power is necessary given the intangible nature of the right. It also ensures that greater incentives exist for breakthrough innovation that does not depend on the use of another's protected idea.

In addition to commercial uses, one can imagine non-commercial uses of innovation, some of which serve more a general social benefit. Experimental uses to satisfy scientific curiosity may be one type.¹⁴⁵ Limited use to understand the patented technology enough to

¹⁴³ Under U.S. law, while the act of invention itself “vests an inventor with a common law or ‘natural’ right to make, use and sell his or her invention absent conflicting patent rights in others . . .”, *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1578 (Fed. Cir. 1991), a patent conveys the additional right to exclude others from making, using, selling or offering to sell the invention, *Id.* (citing *Six Wheel Corp. v. Sterling Motor Truck Co.*, 50 F.2d 568, 571 (9th Cir. 1931)); WIPO Handbook, *supra* note 22, at 17 (“the owner is not given a statutory right to practice his invention . . .”).

¹⁴⁴ *See, e.g.*, *United States v. Craft*, 535 U.S. 274, 280 (2002) (listing the property rights held by a land owner, even if a tenant in common: “the right to use the property, to exclude third parties from it, and to receive a portion of any income produced from it.”).

¹⁴⁵ *See, e.g.*, *Embrex, Inc. v. Service Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (possible infringement exception for uses that constitute “amusement, idle curiosity, or for strictly philosophical inquiry.”); *see also* *Semitool, Inc. v. Ebara Corp.*, CV 01-873-BR, 2002 U.S. Dist. LEXIS 21939, at *5-*6 (D. Or. Oct. 31, 2002) (recently noting the continued existence of the doctrine). Such uses are narrowly construed under U.S. law. *See* *Duke v. Madey*, 307 F.3d 1351, 361-2 (Fed. Cir. 2002), *cert. denied*, 123 S.Ct. 2639 (2003).

design around may be another.¹⁴⁶ It is perhaps reasonable that giving a patentee control over these uses may incrementally add to the incentive to innovate. However, it is also reasonable to assume that many of these uses could feed back into the innovative efforts of others. Therefore, the benefits of the increasing incentive to a particular inventor could reach an apex, after which broader rights actually decrease the innovate efforts that would have been otherwise made by others:

Insert Figure 3 Here

Occasionally, sticks from the bundle of potential patent rights are excluded for social policy reasons. In fact, such instances are quite common in the context of health care innovation, wherein immediate public health goals often overshadow the protection and preservation of property rights. In the United States, just such a limitation was provided by recent legislation which prohibited the enforcement of patent rights regarding medical procedures against physicians.¹⁴⁷ The law was a clear response to the apparently repugnant notion that a lifesaving medical procedure would be withheld by (or permitted subject to a payment to) the property owner.¹⁴⁸ Of course, to what extent this limitations impact innovation depends on a prospective

¹⁴⁶ See, e.g., Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 21-28 (2001) (describing the rationale for allowing a limited right to use patented software in order to reverse engineer the design).

¹⁴⁷ See *Limitations on Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity*, Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616 (1996).

¹⁴⁸ See Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 789, 798-90 (1996) (reviewing the background behind the adoption of the limitation)..

innovator's view of the commercial nature of those markets *prior* to the investment in innovation.

It is possible for industry-specific quirks to *create* patent powers in addition to those specifically described by statute. In the health care field, one of the most prominent is the tendency of regulatory agency rules to extend the power of patents. For example, in the United States, pharmaceuticals are permitted to be marketed only with the approval of the U.S. Food and Drug Administration ("FDA"). The FDA will not approve certain types of drug applications if a third-party patent covers the substance used in the cited clinical testing.¹⁴⁹ Because the agency has neither the manpower nor expertise to evaluate the legitimacy of alleged patent conflicts, it is left to the party who would be precluded by the patent to either accept the prohibition or challenge the validity, enforceability or scope in federal court.¹⁵⁰ This has the effect of adding the power of "precluding FDA approval of allegedly infringing drugs" to the list of rights.

Whether adjustment is necessary to allow current systems to better support innovation is an open question. Commentators have proposed additional eliminations of patent rights that are alleged to have little or no commercial value except in hold-up costs. The recent NAS report suggested that patent protection over basic research methods should be reduced to better permit

Interestingly, other types of property, such as drugs, surgical instruments, tables, gowns would certainly be withheld without payment. Regardless, the less severe option of a compulsory license was apparently not entertained as a substitute. See Courtenay C. Brinkerhoff, *Medical Method Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking?*, 4 U. BALT. INTELL. PROP. L.J. 147, 154-57 (1996).

¹⁴⁹ This is primarily relevant to abbreviated new drug applications ("ANDA"). See 21 U.S.C. § 355(j)(5)(D)(ii) (2000). It also applies to the lesser used "paper" new drug application. See 21 U.S.C. § 355(c)(3)(D)(ii) (2000).

¹⁵⁰ See DONALD BEERS, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS* § 4.03[A] (1999).

the progress of fundamental science.¹⁵¹ Implicit in this argument is the idea that such uses are of insufficient value to induce significant innovation¹⁵² or are supplemented by non-proprietary incentives,¹⁵³ but have the potential to significantly reduce follow-on research by creating an “anticommons” of conflicting intellectual property rights.¹⁵⁴ Obviously, this is an arguable proposition (with little empirical support)¹⁵⁵ that requires one accept several predicate

¹⁵¹ NAS REPORT, *supra* note 12, at 110-11 (commenting on the *Duke v. Madey* decision and the possible ill effects for biotechnology, stating: “We nevertheless believe that there are three other reasons to consider providing some explicit protection from infringement liability.”).

¹⁵² If the patenting of basic research method could be demonstrated to consistently lead to groundbreaking advancements like the widely used Cohen-Boyer recombinant DNA technique or Kary Mullis’s discovery of the polymerase chain reaction (“PCR”) method of DNA production, *see, e.g.*, Heather Hamme Ramirez, *Comment: Defending the Privatization of Research Tools: An Examination of the Tragedy of the Anticommons in Biotechnology Research and Development*, 53 EMORY L.J. 359, 374-78 (2004) (describing the two techniques and corresponding patents), one might be more willing to accept the loss of some follow-on innovation, assuming that the inventor is rational and uses or otherwise makes the valuable research available. But the literature implicitly suggests that most research tools represent less significant “upstream” innovation that is necessary to achieve more important downstream “highly beneficial and lucrative therapeutic and diagnostic products.” *See* NAS REPORT, *supra* note 12, at 71.

¹⁵³ *See, e.g.*, Eisenberg, *supra* note 45, at 1070-71 (“researchers who are motivated to earn scientific recognition may disclose their discoveries through publication even without patent protection, calling into question the assumption that exclusive patent rights are necessary to prevent secrecy.”).

¹⁵⁴ *See* Heller & Eisenberg, *supra* note 52, at 699.

¹⁵⁵ Due to the lack of empirical evidence, the committee behind the NAS report initiated a study to determine the potential effect of patents in this area. *See* J. Walsh, et al., *Research Toll Patent and Licensing and Biomedical Innovation*, in PATENT IN THE KNOWLEDGE-BASED ECONOMY (W. Cohen, et al, eds. 2003). The study found no

assumptions; it is, however, likely to be favored by large industrial players.¹⁵⁶ Equally intriguing is the debate regarding how the exhaustive effect of sales of patented goods in foreign countries would impact innovation.¹⁵⁷ Should national rules be revised to provide universal exhaustion of patent rights upon the first sale? Arguably, whether adopting an international exhaustion rule would reduce the incentive provided by the expectation of receiving compensation for the use of the patent right in additional countries following the first sale is unclear due to the uncertain state of the current law.¹⁵⁸

Extreme caution must be exercised in excluding aspects of patent rights, especially in an industry-specific manner. One may conclude that little commercial value exists in a particular use at a certain time, however, if there is a future possibility of a market for innovations in that area, eliminating the patent rights may dramatically reduce or eliminate important, incentive-aligned innovation.¹⁵⁹

current impediments (but suggested conditions are appropriate for future problems). *See* NAS REPORT, *supra* note 12, at 72.

¹⁵⁶ *See* FTC REPORT, *supra* note 11, at Ch.3 (III)(D)(4)(a) (describing the issue of royalty stacking due to multiple patents and noting that it could impede the creation of drugs like Embrel).

¹⁵⁷ In a few countries (including the U.S.), a patent owner retains full rights of exclusion for goods sold under the authority of that patentee overseas. *See, e.g.,* *Jazz Photo v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), *cert. denied*, 536 U.S. 950 (2002). Other countries find that the first sale overseas exhausts the rights related to sale, use and importation. *See* Cahoy, *supra* note 84, at Part IV.A (noting that there are a variety of approaches in the international community, including international exhaustion and regional exhaustion rules).

¹⁵⁸ An uncertain right is unlikely to act as an incentive for investment, so eliminating it should have no impact.

¹⁵⁹ This is the primary argument for retaining a unitary patent system. *See, e.g.,* JAFFE & LERNER, *supra* note 13, at 204 (“[T]here is no theoretical or empirical basis for saying specifically how patent treatment should differ across specific technologies.”).

c) ***A Patent Term that Encompasses the Invention's Period of Marketability Best Supports Innovation***

Perhaps the most arbitrary aspect of patent rules is the length of the patent term. By international agreement, most countries have agreed to provide exclusive rights for a period of not less than twenty years measured from the date the patent application is filed.¹⁶⁰ The effective patent life is shorter, as time spent prosecuting the application before the relevant patent examining authority comes off the top of the twenty-year term, leaving most patentees with approximately eighteen years.¹⁶¹ But why twenty/eighteen years as opposed to ten or fifty? As with many time periods in the law (especially common law), it has its basis in historical reasoning that is surprisingly relevant, but no longer factually accurate.

The twenty-year term actually began in the U.S. as a fourteen-year term modeled on the English Statute of Monopolies.¹⁶² The Statute of Monopolies term was neither arbitrary nor random, but based in the approximate time necessary to put the invention into practice throughout the country.¹⁶³ This time reflected the length of two apprenticeships, which lasted

¹⁶⁰ See TRIPS, *supra* note 36, at Art. 33 (“The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

¹⁶¹ For example current PTO statistics show that the average time a patent is pending in the office before it is either issued or abandoned is twenty-eight months. See PTO, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL YEAR 2003, at p. 19, available at <http://www.uspto.gov/web/offices/com/annual/2003/2003annualreport.pdf>

¹⁶² See C. Michael White, *Why a Seventeen Year Patent?*, 38 J. PAT. OFF. SOC'Y 839, 839-41 (1956) (reviewing the historical basis of patent terms in the United States). See also CHISUM, *supra* note 82, at §16.04 [1]; Fritz Machlup, *An Economic Review of the Patent System*, Study No. 15, Subcomm. Pat., Trademark & Copyright, Jud. Comm., 85th Cong., 2d Sess 9 (1958).

¹⁶³ See CHISUM, *supra* note 82, at §16.04 [1].

approximately seven years each.¹⁶⁴ Interestingly, it is not entirely clear that this specific period of time was viewed as an adequate reward for the patentee's effort, but rather was meant to serve the societal goal of technology dissemination.¹⁶⁵ But the impetus for the dissemination was obviously the monopoly profit that could be made (and marketing head start achieved) during the period of exclusivity.¹⁶⁶

For a number of reasons, the patent term in the U.S. was eventually increased to seventeen years from issuance,¹⁶⁷ while other countries used similar time periods.¹⁶⁸ By this point, the connection of patent term to any real world purpose had disappeared.¹⁶⁹ In 1994, the TRIPs agreement mandated a twenty-year patent term that was calculated from filing,¹⁷⁰

¹⁶⁴ See White, *supra* note 162, at 841-42 (“The early English patent length was correlated with the time needed to put the invention into general practice throughout the country--the training period for two sets of apprentices.”).

¹⁶⁵ *Id.*

¹⁶⁶ See NORDHAUS, *supra* note 23, at 76.

¹⁶⁷ See CHISUM, *supra* note 82, at §16.04 [1].

¹⁶⁸ By the 1960s, most countries measured their patent term by twenty years from issuance. See, e.g., PRESIDENT'S COMM'N ON THE PATENT SYS., “TO PROMOTE THE PROGRESS OF ... USEFUL ARTS” IN AN AGE OF EXPLODING TECHNOLOGY 33-35 (1966).

¹⁶⁹ While there was a basis for the original fourteen year term, there is less of a rationale for the particular term extensions enacted over the last 200 years, particularly in view of the fact that copyrights originally had the same term but now may last over five times as long. See generally Edward C. Walterscheid, *The Remarkable — and Irrational — Disparity Between the Patent Term and the Copyright Term*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 233 (2001).

¹⁷⁰ See TRIPS, *supra* note 36, at Art. 33.

producing little change for most patents given the average time period for examination.¹⁷¹ Due to the settled nature of term, modern initiatives to modifying it generally relate to closing loopholes that permit inappropriate extension.

The disconnect between term and any act by the inventor leads one to ask whether the current time period is optimal for producing innovation? Using the modern rationale of patent term — to provide a protected opportunity to profit as a reward for innovative results — one would conclude that it depends on the technology. The type of innovations produced in response to a particular time period would be expected to be the ones able to at least return a profit during that period; inventions requiring less time would of course be produced, but those requiring more would likely not. This suggests that there is no limit to the amount of innovation that could be encouraged with ever-longer patent terms.¹⁷² However, in holding up the public use of some inventions (those with limited life cycles) for a period longer than necessary to create the incentive to produce it, there are potential negative effects. Most prominently, follow-on innovation by others will be delayed,¹⁷³ and in fast-moving technology fields, this could

¹⁷¹ In fact, when Congress changed the term of enforcement for patents in 1995, it created a procedure for electing the old calculation method only for patents then in existence, not future grants. 35 U.S.C. §§ 154(a)(2), 271 (1994 & Supp. V 1999); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546 (Fed. Cir. 1996). This ensured that vested property rights could not be impacted.

¹⁷² It has been suggested that this is actually quite reasonable from an economic perspective. See Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 RAND J. ECON 106, 107 (1990) (“We show that in a homogenous-good market . . . the socially optimal way to reward innovation involves patents of infinite length.”)

¹⁷³ See COOTER & ULEN, *supra* note 45, at 127-28 (“[T]he optimal life of a patent strikes the best balance between encouraging creativity and discouraging dissemination.”). This could also have negative effects in creating inefficient patent races for the inappropriate large incentive. See Duffy, *supra* note 44, at 466-467.

actually reduce overall innovation. Ideally, then, patent term would be tied into the useful life of the invention:

Insert Figure 4 Here

Because the most innovation-friendly patent length has some connection to invention marketability, it seems obvious that the term of a patent should be technology-specific. Conversely, an arbitrary term of twenty years is likely to be too long for some industries such as computer-related inventions, and too short for others such as pharmaceuticals and biotechnology. Economists who have studied the issue have argued that a more effective term is possible.¹⁷⁴ Even some in the corporate world who arguably have benefited from the twenty-year term have suggested modifying the current rules to provide for a more nuanced system.¹⁷⁵ Some countries straddle the issue by providing a tiered patent grant that depends on the type of invention submitted.¹⁷⁶ Such systems tend to convey less protection to incremental improvements than

¹⁷⁴ See, e.g., Gilbert & Shapiro, *supra* note 172, at 107.

¹⁷⁵ Famously, Amazon.com founder and 1-click patent owner, Jeff Bezos, proclaimed that a (then) seventeen year patent term was too long for business method and software patents. Jeff Bezos, An Open Letter from Jeff Bezos on the Subject of Patents (proposing changes to the way that patent law addresses business method and software patents), at http://www.oreilly.com/news/amazon_patents.html (last visited Jan. 5, 2005).

¹⁷⁶ See COOTER & ULEN, *supra* note 45, at 129 (describing Germany’s system of three-year “petty patents” for minor improvements); Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT’L L.J. 151, 160-66 (1999) (describing the German and Australian petty patent models that provide shorter term protection with less rigorous requirements).

pioneering inventions.¹⁷⁷ Additionally, others provide term extensions for unusual delays in the prosecution/examination process¹⁷⁸ or, in rare cases, in a regulatory approval process.¹⁷⁹

While the impetus to revise current regimes seems strong, there are obviously great risks in doing so. Changes to the system going forward could suffer from inaccurate assumptions that are based on current information. Foremost among these, because it is not necessarily true that an industry that has objectively long or short product life cycles will remain that way in the future,¹⁸⁰ applying an inappropriate term could end up cutting off as much or more innovation than it encourages. Moreover, even if the character of an industry as whole does not change, one cannot know for sure that the most significant future innovations will be those that have average marketability time frames. The lack of definite information on the effects of modification tends to create risks that outweigh the benefits of restructuring patent term for the time being. This

¹⁷⁷ See Janis, *supra* note 176, at 188 (“Second tier patent proposals also routinely promise to provide ‘quick’ protection that is effective in securing intellectual property rights for products having life cycles shorter than the average pendency of a regular patent application.”). Additionally, such systems theoretically provide greater access to the patent system for small business entities. *Id.* at 178.

¹⁷⁸ The U.S. system contains one example of a (rather complicated) term extension scheme based on prosecution delay. See 35 U.S.C. § 154(b) (2000). It was instituted as a result of the recent American Inventors Protection Act, Pub. L. No. 106-113, 113 Stat. 1501 (1999) (codified in scattered sections of 35 U.S.C.) (amending the patent law and reorganizing the USPTO).

¹⁷⁹ In the context of certain submissions to the U.S. FDA, up to five year term extensions may be obtained, so long as the effective patent life totals no more than fourteen years from the date of FDA approval. See 35 U.S.C. § 156 (2000); BEERS, *supra* note 150, at § 4.04[D][4].

¹⁸⁰ For example, it is quite possible that, as the biotechnology industry matures, the traditionally long product development time periods (see FTC REPORT, *supra* note 11, at Ch.3(III)(B)) will decline. Assigning a lengthier patent term to this industry based on current R&D statistics could result in an inappropriate incentive structure.

risk, and the fact that the world is struggling to move toward consensus on as many patent rules as possible, it is unlikely that any country will lead the call for substantive change to patent terms in the near future. That suggests patent term will continue to play an important but fixed role in incentive-aligned innovation that must be accounted for by modifications in other patent strength factors.

B. Extra-Legal Attributes of Patent Property

When aspects of the patent system are proposed for adoption in developing countries or simply debated in industrialized countries, the legal rules are the primary focus. Through this dialog and the resulting international agreements, these rules are becoming more and more uniform throughout the world.¹⁸¹ But there remain great differences in the world's intellectual property systems. Data on the aforementioned proxies for innovation, such as R&D dollars¹⁸² and the production of highly innovative end products,¹⁸³ indicate that the incentives to innovate are not the same. It is reasonable to conclude that other factors have a strong influence on innovative behavior, potentially even outweighing or canceling out the effect of legal factors. A

¹⁸¹ See *supra* notes 88-90 and accompanying text.

¹⁸² See, e.g., OECD, RESEARCH AND DEVELOPMENT EXPENDITURE IN INDUSTRY 1987-2001, pp. 32-39 (2003) (indicating disparities in the rise in R&D spending in the U.S. vs. Japan and the EU over the last twenty years.)

¹⁸³ See, e.g., OECD PATENT STAT., *supra* note 78, at 14-15 (showing differences in the rate of growth of triadic patent families between countries and regions); EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS ("EFPIA"), THE PHARMACEUTICAL INDUSTRY IN FIGURES 2004, p. 3 (2004), *available at*, http://www.efpia.org/6_publ/infigure2004a.pdf [hereinafter "EFPIA REPORT"] ("As a whole, Europe remains less attractive for R&D investments than the US. The economic and regulatory framework, the science base, the investment conditions, and societal attitudes towards new technologies all contribute.").

comparison of the business environment of various countries suggests that these additional influences are derived from two broad sources: (1) the legal institutions that provide the framework of property rights ownership and enforcement and (2) cultural biases toward property ownership, and intellectual property ownership in particular. If one is to fully understand how well the patent system is performing, these factors must be taken into account.

In the context of health care, the effect of institutional and cultural factors could be dramatic. Because the impact will tend to be on a region or country-specific basis, it is possible that innovations that require the economic input of those regions or countries will not come to pass if the institutional and cultural factors are suboptimal. This is particularly troublesome when the innovations are in the health care field. For example, countries in Asia or Sub-Saharan Africa have different health care needs than developed nations.¹⁸⁴ A system that does not encourage endogenous innovation will be unlikely to serve those needs, unless they happen to match those of developed nations.¹⁸⁵ Additionally, institutional and cultural factors could stand as a barrier to the importation of foreign technologies, creating a double disincentive for the production of important innovations.

Differences in institutions and cultures are obviously reflective of the varied developmental histories of individual nations. Even among nations of a particular economic status, there can be fundamental distinctions in important elements, such as the common law or

¹⁸⁴ See, e.g., Lanjouw, *supra* note 104, at 93 (“There is a substantial list of ‘neglected diseases’ that are prevalent in poor countries and almost absent in rich countries.”).

¹⁸⁵ See *id.*

civil law nature of the legal system.¹⁸⁶ The characteristics that are integral parts of a property law system have the potential to affect innovation, but in complex ways that must be investigated in detail.

1. Institutions that Support Legitimate Intellectual Property Ownership Have a Positive Influence on Innovation

The value of property ownership is intimately tied to one's ability to enforce that right against infringers and retain that ownership against baseless challenges. However, the most innovation-inducing system is not necessarily that which automatically and strongly favors those who claim property rights. A danger in any property system is the potential for parties to illegitimately claim property ownership or enforcement powers by exploiting the defects in the system. Such tactics may allow illegitimate property claims to preclude future investment in innovation by making the market inaccessible. Thus, some check on property powers must be incorporated, but not one so oppressive that it significantly reduces the property powers that provide the innovation incentive.

This sort of balance is sought in the institutions underlying property ownership and enforcement. How such institutions function under normal conditions and respond to emergent issues like a sudden health care crisis are the basis of this patent strength factor.

¹⁸⁶ See, e.g., Philippe Bruno, *The Common Law from a Civil Lawyer's Perspective*, in INTRODUCTION TO FOREIGN LEGAL SYSTEMS (Richard A. Danner & Marie-Louise H. Bernal eds., 1994) ("There is no doubt that the two systems are very different from linguistic, conceptual, and philosophical points of view").

a) ***Property Ownership with Rational Scrutiny***

All private property systems are concerned to some extent with determining the true owner of the property. Complex deeding requirements, title searches and registration/notice systems are common mechanisms.¹⁸⁷ Tangible property systems have an advantage in this regard in that a particular tangible property right corresponds to a single existing physical space¹⁸⁸; it is rather simple to settle ownership boundaries and especially whether the property exists at all. However, the fact that no patent property exists until it is granted by a government entity means that some procedure must exist for ensuring that the rules for recognizing a creation are followed. Additionally, the intangible nature of intellectual property rights guarantees that overlapping rights are frequent occurrences,¹⁸⁹ and any property award procedure must also

¹⁸⁷ See, e.g., Robert C. Ellickson, *Property in Land*, 102 YALE L.J. 1315, 1328-30 (1993) (describing technologies for marking, defending, and proving boundaries for land, and the economic efficiencies of having private individuals do so).

¹⁸⁸ To describe this concept in economic terms, tangible property is subject to “rivalrous consumption,” as one person’s use precludes another’s. See COOTER & ULEN, *supra* note 45, at 107. It is possible to create new tangible property, but one needs existing tangible property to do so. Thus, ownership of such property may be as simple as transferring rights to the underlying construction compounds.

¹⁸⁹ This is the basis of the contention that multiple patent rights overlapping to cover various aspects of a single product can create a “patent thicket.” See, e.g., Carl Shapiro, *Navigating the Patent Thicket*, in 2 INNOVATION POLICY AND THE ECONOMY 124-26 (Adam Jaffe, et al, eds. 2002) (describing as a basis of the patent thicket, the “holdup” problem when “hundreds if not thousands of patents . . . can potentially read on the same product”); *but see* Ronald J. Mann, *The Myth of the Software Patent Thicket: An Empirical Investigation of the Relationship Between Intellectual Property and Innovation in Software Firms*, Univ. Tex. L & Econ. Working Paper No. 022 (Feb. 2004), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=510103 (presenting survey evidence from industry executives suggesting that patent thickets are not reducing innovative activity). Another reason for the overlap is

carefully account for boundary determination and notice to the public. A complicating factor in the property award system is the fact that no international patent right exists,¹⁹⁰ which conflicts with the increasingly global nature of information.

The complexities of patent ownership create a double-edged relationship to innovation. On one hand, innovation is supported when inventions that meet patentability requirements are awarded patent protection quickly and without undue expense. On the other hand, innovation is potentially reduced when applications that do not disclose patentable inventions are approved in the same way as when patents with an overly broad scope are allowed. Therefore, the system must attempt to balance the costs (both social and monetary) of a meticulous award system with the costs of invalid patents entering the market:

Insert Figure 5 Here

In most countries, patent rights are awarded based on the outcome of a detailed examination of the patentability of a claimed invention.¹⁹¹ Because such a system is expensive to operate, some countries that see a large proportion of secondary filings from foreign entities defer to the determination of a governmental body with a sophisticated examination corps, like

that patent rights include no use rights, but only the right to exclude others (*see supra* notes 21-22 and accompanying text); thus, there is no reason to create an examination mechanism for assessing a patent applicant's freedom to operate.

¹⁹⁰ *See* WIPO Handbook, *supra* note 22, at 17.

¹⁹¹ *See id.* at 24-27 (outlining the generic procedure of a patent examination in most WIPO countries).

the United States or the EPO.¹⁹² International agreements like the Patent Cooperation Treaty (“PCT”) streamline the process somewhat by centralizing as much as possible, but the application is still forwarded to the governments of individual countries for a final determination.¹⁹³ In general, at least part of a patent examination is conducted as a secret, *ex parte* procedure to allow a patent applicant the ability to retain trade secret rights in the innovation if the prosecution is unsuccessful.

The examination process is a frequent source of criticism. Those seeking patents complain about undue delay and the quality of examiners.¹⁹⁴ Those who believe that the quality of issued patents is poor (*i.e.*, that clearly invalid patents are granted) complain about the bureaucratic structure, the funding and lack of oversight.¹⁹⁵ It may be impossible to make an

¹⁹² See Thomas Peterson & John J. Chrystal, *How the Patent Harmonization Treaty Will Co-Exist with the Patent Cooperation Treaty and the Effects and Advantages in Harmonizing the Two Treaties*, 26 J. MARSHALL L. REV. 613, 620 n.36 (1993) (discussing how some countries “piggyback” on the successful patent prosecution in other countries).

¹⁹³ See WIPO, BASIC FACTS ABOUT THE PATENT COOPERATION TREATY 9-10 (2002) (explaining in basic terms how the “international search” can ease the process through the national patent office, but it does not supplant them).

¹⁹⁴ See, e.g., FTC REPORT, *supra* note 11, at Ch.5(II)(A) (“Several panelists from a cross-section of industries indicated that current pendency periods are a significant problem.”).

¹⁹⁵ See, e.g., Thomas, *supra* note 100, at 316-321; JAFFE & LERNER, *supra* note 13, at 130-42 (detailing three major problems that impact U.S. PTO quality: (1) budgetary constraints, (2) maintaining adequate incentives for examiners, and (3) poor management of resources).

examination process perfect, and it has been argued that it would in fact be inefficient to try based on the small number of patents that are ever asserted against others.¹⁹⁶

In addition to an examination process, most countries employ a method of retracting or invalidating patents that were erroneously issued. This is generally accomplished through a government agency in addition to or instead of a court system.¹⁹⁷ The invalidation process can be just as time consuming and resource intensive as the initial examination, if not more.¹⁹⁸ That can add up to a double tax on the patentee and may act as a disincentive to innovation if the procedure is not sufficiently circumscribed. The court model is fairly straightforward, with an invalidation decision generally precluding further enforcement of the patent in a given country.¹⁹⁹ Streamlined agency procedures have the potential to be more efficient and more accurate, but present problems of their own.

¹⁹⁶ See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1508-1511 (2001) (“The strong implication . . . is that society ought to resign itself to the fact that bad patents will issue, and attempt to deal with the problem *ex post*, if the patent is asserted in litigation.”)

¹⁹⁷ See Bronwyn Hall, et al., *Prospects for Improving U.S. Patent Quality via Postgrant Opposition*, in 4 INNOVATION POLICY AND THE ECONOMY 121-29 (Adam Jaffe, et al, eds. 2002) (describing the opposition and litigation proceedings in the U.S. and EU that can be used to address questions of patent validity, and noting substantial differences in structure and efficacy within the same basic forums).

¹⁹⁸ *Id.* at 128 (noting the mean duration of European opposition proceedings is about three years); NAS REPORT, *supra* note 12, at 100 (U.S. reexams and EPO oppositions last at least two years).

¹⁹⁹ In the context of the EU, *see id.* (stating that invalidation of a EPO patent can take place in a national court, but there is no trans-EU court that can invalidate a patent for all EPC signatory countries). In the U.S. the courts have been clear that an invalidation determination has collateral estoppel effect against other potential infringers. *See* *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Foundation*, 402 U.S. 313, 349 (1971).

A comparison of two prominent models, the EPO “opposition” and the U.S. “reexamination”, demonstrates the complexities of creating a system with reasonably succinct procedures that still ensures bad patents can be effectively eliminated. The European system, often praised for its comprehensiveness and degree of use,²⁰⁰ allows a third parties to participate in a detailed inquiry into all major aspects of the patent grant.²⁰¹ Although multiple oppositions may be filed, one of the most significant aspects of this system is that any opposition must be filed *within nine months* of the patent grant; after that, the patent can only be opposed through a national procedure in one of the EPO countries.²⁰² In contrast, a U.S. reexamination may be filed at the U.S. Patent & Trademark Office (“PTO”) by a third party or the patentee, and conducted as an *ex parte* review (really, a second examination)²⁰³ or a third party may request an *inter partes* procedure.²⁰⁴ There is no time limit on requesting reexaminations, but the subject matter

²⁰⁰ See, e.g., Stuart Graham, et al., *Patent Quality Control: A Comparison of U.S. Patent Re-Examination and European Patent Oppositions*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 114 (W. Cohen & S. Merrill, eds., 2003) (noting advantages in the EPO opposition system such as the fact that it handles many more disputes than the U.S. analog).

²⁰¹ See NAS REPORT, *supra* note 12, at 100 (chart comparing issues that may be addressed in EU and PTO oppositions/reexams and demonstrating the much more restricted nature of reexams on issues not related to prior art).

²⁰² See Graham, *supra* note 200, at 87.

²⁰³ See 35 U.S.C. § 302 (2000). See also Graham, *supra* note 226, at 84 (explaining traditional reexamination);

²⁰⁴ See 35 U.S.C. § 311 (2000). See also NAS REPORT, *supra* note 12, at 98 (chart comparing the ability of patent challengers to participate in reexaminations and oppositions, noting third-party participation in the context of *inter partes* reexamination).

is limited to essentially prior art issues,²⁰⁵ which may not be the strongest argument to revoke a patent. The percentage of U.S. patents reexamined pales to the percentage of EPO patents opposed.²⁰⁶ Which system is better for innovation? Most commentators, including associations that include large numbers of intellectual property owners, believe that the European-style system better balances the ability to challenge patents with limits on unnecessary delay in legitimate patent enforcement.²⁰⁷ Many support adopting a similar procedure in the U.S., but only if it replaces rather than simply adds to the existing time and cost of litigation.²⁰⁸

Courts ideally play a cleanup role in the ownership game. Only if the examination and opposition/reexamination processes are unsuccessful will courts be involved. Although court review has the potential to be quite comprehensive — particularly in countries like the U.S. which have very liberal discovery rules²⁰⁹ — it is an inefficient method of disposing of invalid

²⁰⁵ See 35 U.S.C. §§ 301, 311 (2000).

²⁰⁶ See Graham, *supra* note 200, at 90 (reporting that, between 1980 and 1998, there were 33,599 EPO oppositions but only 4,547 U.S. reexaminations).

²⁰⁷ See, e.g., AMERICAN INTELLECTUAL PROPERTY LAW ASS'N (“AIPLA”), AIPLA RESPONSE TO THE NATIONAL ACADEMIES REPORT ENTITLED “A PATENT SYSTEM FOR THE 21ST CENTURY” 14-15 (2004), available at http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/2004/NAS092304.pdf.

²⁰⁸ See, e.g., *id.* at 19 (“[T]o aid in preventing the review proceeding from becoming a vehicle for harassing patentees, AIPLA believes that strict time limits should apply and be adhered to by the administrative patent judges.”). The concern about the additional costs of harassment to patent owners was a primary reason that the initial U.S. *ex parte* reexamination procedure was so circumscribed. See H.R. Rep. No. 96-1307, pt. 1, at 3-4, reprinted in 1980 U.S.C.C.A.N. 6460, 6463 (1980).

²⁰⁹ See Graham, *supra* note 200, at 86 (extensive use of pretrial discovery means that the average cost of a patent litigation in the U.S. is between one and three million dollars).

patents.²¹⁰ Patent litigations can drag on for years and may settle without a public resolution to the validity issues.²¹¹ Also, patentees are awarded a presumption of ownership that may preclude an even-handed review of whether the patent should have issued.²¹²

The extent to which the patent ownership factor influences innovation may depend on the industry. When patent rights are aggressively sought by a large and varied number of competitors, an examination standard that is low may be more likely to give rise a “thicket” of rights that must be negotiated to bring any invention to market.²¹³ Alternatively, in a market wherein companies depend on a relatively few patents covering independent products, the danger of invalid third-party patents may be minimal.

b) *Efficient Enforceability with Full Compensation*

Perhaps the most important but often overlooked aspect of any property right is the owner’s ability to enforce the right against infringers. Surprisingly, the world’s intellectual

²¹⁰ See *Merges*, *supra* note 100, at 610 (noting that, in view of the high costs of district court litigation, a substantial reexamination procedure has obvious appeal). (six impossible)

²¹¹ See *Shapiro*, *supra* note 189, at 142-44 (“As a matter of economic theory, there is no reason to expect the two parties’ collective interests in settlement . . . to coincide with the public interest . . .”). Typically, a patent case will settle with the accused infringer acknowledging infringement and a valid patent in exchange for a smaller damage award than originally sought. Such arrangement can fall under antitrust scrutiny when the converse occurs, and it appears that a patent holder is compensating an accused infringer for dropping the litigation and staying off of the market. See *In re: Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2004), *cert. denied*, *Andrx Pharmaceuticals, Inc. v. Kroger Co.*, ___ U.S. ___, 125 S.Ct. 307 (2004).

²¹² See *NAS REPORT*, *supra* note 12, at 98 (chart stating that both the EPO opposition proceeding and U.S. litigation accord patent owners a presumption of validity that must be overcome by a challenger).

²¹³ See *Shapiro*, *supra* note 189, at 120-122.

property regimes are quite different in their enforcement mechanisms. Harmonization is now being addressed, but it is a complex endeavor.²¹⁴ Enforcement mechanisms involve everything from the powers of the courts in the context of private infringement actions to the system of compensation for government infringement/takings of patent rights. As there are strong elements of institutional traditions in each country's procedures, some aspects are more malleable than others. But there is no doubt as to the critical nature of enforcement; it is the *sine qua non* of property, and a hobbled enforcement regime can greatly reduce its incentive value.

One traditionally views enforcement as a collection of two powers: the ability to prevent trespass/infringement (injunction)²¹⁵ and the potential to collect compensation from infringers for any harm to the property (damages).²¹⁶ Many regimes include mechanisms to increase damages awards to punish willful behavior,²¹⁷ but punitive damages are generally not available.²¹⁸ If the analysis is refocused on the perspective of the potential innovator and what protections are

²¹⁴ See, e.g., Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, 2004 O.J. (L 157) 17 [hereinafter "Enforcement Directive"] (setting forth several provision to unify intellectual property enforcement rules across the European Union).

²¹⁵ See, e.g., 35 U.S.C. § 283 (2000) (providing for injunctive relief to compensate for patent infringement harm, the terms of which are at the discretion of the court).

²¹⁶ See, e.g., 35 U.S.C. § 284 (2000) (providing for damages "adequate to compensate for the infringement").

²¹⁷ In the United States, a damage award up to three times actual harm is permitted at the discretion of the court. See 35 U.S.C. § 284 (2000). In the EU, countries can employ various mechanisms to supplement actual damages, but the most common, as mentioned in the recent Enforcement Directive, is an infringer's profits. See Enforcement Directive, *supra* note 214, at 23. In Japan, there is no supplement, but damages may be measured by an infringer's profits as an alternative to patentee damages. See Japan Patent Law Section 101(2).

²¹⁸ See ADELMAN, *supra* note 25, at 1160 ("Foreign legal systems almost universally reject the notion of an award of punitive damages for patent infringement.").

necessary to retain the full weight of the patent incentive, one can conclude that almost everything comes down to basic damages. This is because the value of the patent right relates almost solely to the ability to profit, and a patentee should be indifferent if he or she can obtain the same profits through enforcement as would be obtained in the normal course of business.²¹⁹ Of course, the costs of enforcement would seem to require some premium be available above the straightforward assessment of the actual harm. Thus, heightened damages, to the extent that they ensure patentee indifference, can increase innovation beyond actual damages.

There is a limit to the amount of infringement damages that will induce innovation. At some point, the amount of damages could be so high that a patent holder may be able to obtain a larger share of the market than appropriate due to competitor's fears that their marketing activities may arguably fall within the scope of the patent. Because enforcement mechanisms are unlikely to be correct one hundred percent of the time, there is always to the possibility that a non-infringer will be found liable.²²⁰ If excessively high damages make even the slight chance of losing unbearable for most challengers, it could outweigh the advantages of challenging an improperly asserted patent. Taking this limitation into account, it is reasonable to presume that increasing damages will encourage innovation in a linear fashion until the challenge disincentive offsets the gains:

²¹⁹ Even the injunctive right can be included in the damages analysis. We know the ability to exclude others from the market is ultimately worth an assessable price, because courts award past damages even in the absence of actual patentee loss. In the U.S, this minimum amount is a reasonable royalty. *See* 35 U.S.C. § 284 (2000).

²²⁰ *See* JAFFE & LERNER, *supra* note 13, at 114-15 (arguing that the Federal Circuit has increased patent owners' remedies significantly, leading to a potentially dangerous situation: "Even if an alleged infringer is convinced that it is in the right, given the uncertainty of the litigation process and the possibility of a very costly punishment, it may choose to settle.").

Insert Figure 6 Here

Concern that an excessively high penalty for infringement could be a force that discourages innovation is an undercurrent in the debate regarding when and to what extent patent damages should serve as a deterrent rather than a compensation mechanism.²²¹ In the United States, an infringer whose conduct is found to be willful may be liable for up to three times the amount of actual damages.²²² The circumstances under which this provision can be imposed has been recently restricted,²²³ but it remains a controversial remedy. Some countries go further and actually apply criminal penalties to patent infringement.²²⁴ This is perhaps more troublesome, as a prospective innovator is indifferent to an accompanying fine that is forfeited to the state, and would be unlikely adjust his or her efforts in response. To the extent such powerful remedies exceed the true market value of the invention, the contribution to pioneering innovation incentives may be less than the reduction in follow-on innovation.

²²¹ See, e.g., Mark A. Lemley, *Ending Patent Law's Willfulness Game*, 18 BERKELEY TECH. L.J. 1085, 1122-23 (2003) (noting that over-deterrence increases litigation cost barriers).

²²² See 35 U.S.C. § 284 (2000).

²²³ See *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344-46 (Fed. Cir. 2004) (eliminating the presumption of willfulness when a defendant has either not obtained legal advice, or refuses to waive privilege on legal advice obtained).

²²⁴ See Larry Coury, *Note: C'est What? Saisie! A Comparison of Patent Infringement Remedies among the G7 Economic Nations*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1101, 1138-39, 1145-46 (2003) (reviewing the infringement remedies of several countries and noting that Germany and Japan provide criminal penalties for patent infringement).

Conversely, while it seems clear that exceptions in damages assessment rules that lead to sub-market compensation would adversely affect innovation, such schemes are nonetheless quite popular when public health issues are at hand. The most common context is the compulsory license, a mechanism explicitly acknowledged by international agreement,²²⁵ but not universally employed.²²⁶ The compulsory license can be justified as a relief valve to the patentee's otherwise total control over the use of the invention; a holdup without any connection to market forces is morally untenable when it comes to essential medications, and economically indefensible.²²⁷ However, compulsory licenses have more recently become a favored instrument to bring down the cost of protected products.²²⁸ This is accomplished due to unclear nature of the required compensation for such a mechanism. The TRIPs agreement provides that "adequate remuneration" must be accorded the patentee in such a case, but fails to define the term, leaving it up to the host country exercising the licensing option.²²⁹ The potential for open abuse aside,

²²⁵ See TRIPS, *supra* note 36, at Art. 31.

²²⁶ For example, the United States has no general compulsory licensing scheme, though it does impose a mandatory licensing scheme for the benefit of the U.S. government in select technology areas. See Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government Takings of Private Patent Rights*, 40 AM. BUS. L.J. 125, 146-47 & n.91 (2002).

²²⁷ There can be economically rational reasons for not using or licensing a patent, such as when a company invents a technology useful only to a competitor, but refuses to allow the competitor access due to the high transaction costs of coming to an agreement on an appropriate licensing fee. See LANDES & POSNER, *supra* note 19, at 320-21.

²²⁸ See, e.g., F. M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT'L ECON. L. 913, 913-915 (2002) (describing the obligation of developing countries to initiate patent protection for pharmaceuticals and the potential of compulsory licensing to work as a means of holding down the expected price increases).

²²⁹ See TRIPS, *supra* note 36, at Art. 31(h).

one can seriously argue whether a compulsory license should give rise to some discounted fee or must correspond to market costs.²³⁰ Assuming the former, the use of this mechanism necessarily reduces the patentee's potential for profit and should correspondingly reduce the incentive to innovate. Whether the reduction is justified in comparison to the immediate health care gains is a question of public policy, but one that should not be ignored.

Although the United States has no compulsory licensing provision in its intellectual property law, a comparable effect occurs when the U.S. government infringes a patent. By statute, the federal government is committed to pay "reasonable and entire compensation" to any patentee whose patent is infringed by or under the authority of the government.²³¹ Although the courts have been fairly clear in stating that this measure of compensation is based in the U.S. Constitution's Fifth Amendment requirement of "just compensation," it is not entirely certain that market value of the right infringed is always required.²³² As with the compulsory license, if a minor royalty fee instead of full patent damages measures compensation, some impact on innovation would be expected.²³³

2. A Cultural Embrace of Private Property Enhances Incentives

Institutional structure and legal regimes exist against a larger backdrop or culture that reflects a society's values and desires. There are of course many variations in societal makeup,

²³⁰ See Scherer & Watal, *supra* note 228, at 920-22.

²³¹ See 28 U.S.C. § 1498 (2000).

²³² See Cahoy, *supra* note 199, at 155-161 (reviewing arguably inconsistent case law that alternatively suggests that a reasonable royalty is all that is ever required for § 1498 compensation or lost profits may be obtainable).

²³³ See *id.* at 169-71.

each having developed as a result of a slightly different history. How much of what is perceived to be characteristic of a culture is a consequence of geography and economics is certainly debatable.²³⁴ Even today, there is heated discussion over questions such as whether certain societies can support democratic political rule, or for that matter if such a system is actually an improvement over a long-standing monarchical or authoritarian system.²³⁵ To be sure, one must take care in attributing a certain societal behavior to one ethnic group or another based on limited or biased perspective. But it does seem fair to make the more limited judgment that there are values in business and economic relationships that seem to be embraced by some societies more than others.²³⁶

²³⁴ See, e.g., David Landes, *Culture Makes Almost All the Difference*, in *CULTURE MATTERS: HOW VALUES SHAPE HUMAN PROGRESS* 2-3 (Lawrence E. Harrison & Samuel P. Huntington, eds., 2000) (discussing the connection between culture and economic development in countries like South Korea, Turkey and Nigeria while noting that people can disagree).

²³⁵ See, e.g., Robert J. Barro, *A Democratic Iraq Isn't an Impossible Dream*, *BUS. WK.*, Mar. 31, 2003, at 28 (discussing the challenges facing Iraq in shifting from a totalitarian to a democratic government, and concluding that the problems are not insurmountable).

²³⁶ The recent economic turmoil in Russia provides an excellent example of the havoc a lack of private property incentives can wreak. See Erin E. Arvedlund, *Investors of the World, Here's the Word on Putin Inc.*, *N.Y. Times*, Mar. 2, 2005, at A.4 ("Instead of embracing free-market capitalism, Russia has veered away: renationalizing oil assets, weakening property rights and signaling to foreign investors that their millions — and their presence — are not entirely welcome.").

One cultural value in which many scholars have recently taken an interest is private property ownership.²³⁷ Great differences exist across countries in the degree to which individuals own and invest in private property.²³⁸ It has been argued that at least some of this difference is attributable to a variation in cultural respect for private property rights — a respect that is also reflected in the institutions and legal rules developed by the society.²³⁹ A lower cultural value for private property ownership could play a role in reducing the incentive to invest in property in two ways: (1) it may promote alternatives to property ownership that attempt to achieve the same goals, perhaps to the detriment of property owners; and (2) the sanctity and dependability of private property interests may be subordinate to other social goals when convenient. The question of property valuation is absolutely critical to the success of patent systems, which are built on nothing more than the perceived value of private property rights.²⁴⁰

In the context of the present analysis, it is important to concentrate on the more specific issue of respect for intellectual property rights; while it has been suggested that cultural beliefs

²³⁷ See, e.g., HERNANDO DE SOTO, *THE MYSTERY OF CAPITAL: WHY CAPITALISM TRIUMPHS IN THE WEST AND FAILS EVERYWHERE ELSE* 153-54 (2000) (discussing the confounding problem developing countries seem to have with opening up their property systems).

²³⁸ See, e.g., Lynn Fisher & Austin Jaffe, *Determinants of International Home Ownership Rates*, 18 HOUSING FIN. INT'L 34 (2003) (observing international variation in home ownership rates and suggesting that contributing factors may be “Legal, economic, political, and cultural institutions.”).

²³⁹ See, e.g., DE SOTO, *supra* note 237, at 171-74 (arguing that extralegal social contracts are an implicit part of every nation’s property law, and “property arrangements work best when people have formed a consensus about the ownership of assets and the rules that govern their use and exchange).

²⁴⁰ See NORDHAUS, *supra* note 23.

impact intellectual property rights, specifically,²⁴¹ it is not entirely clear that they will mirror the general attitude about property ownership. A difference in perceptions about intellectual property may arise due to a lack of experience with information ownership or fear regarding the ability to control such intangible expressions.²⁴² Even within a single country's more homogenous population, it is possible for different industry sectors to have diverse cultures regarding information ownership. For example, one might argue that the computer software industry in the United States experienced a delay in the integration of patent rights for longer than expected after they became available due to a more communal culture.²⁴³ In contrast, in the biotechnology industry, company management, as well as institutional investors, demand dependable, predictable development and ownership of patented innovations.²⁴⁴

²⁴¹ See Park & Ginarte, *supra* note 69, at 60 (reflecting on results indicating that, in some economies, stronger patent laws do not necessarily indicate more R&D investment, and concluding "either their R&D responds to different incentive (like cultural rewards) or a significant part of their R&D activity is imitation"). See also Schankerman, *supra* note 101, at 104 ("The finding that patent rights are surprisingly less valuable in pharmaceutical where there is stringent price regulation in France, highlights the important point the R&D incentives are shaped not only by patent law but also by other institutional constraints that affect the appropriability environment.")

²⁴² For example, some nations with relatively strong tangible property histories like India may incorporate weak intellectual property laws to serve a national interest in an area such as pharmaceuticals. See Gupta, *supra* note 90, at 602-05.

²⁴³ See, e.g., FTC REPORT, *supra* note 11, Ch. 3(V)(D)(2) (describing the option of open source software as an alternative to legal property controls).

²⁴⁴ See, e.g., *id.* at Ch. 3(III)(D)(1) (noting the almost universal acclaim for the importance of patents in the biotechnology industry, including "Participants stated that the biotechnology industry would not have emerged 'but for the existence of predictable patents' . . .").

One would expect that increasing respect for private property supports the innovation encouraged by patents fairly directly and proportionally. Greater security and predictability of the property investment mechanism would reasonably enhance its incentive power.

Insert Figure 7 Here

Of course, a private property incentive system is not the only option to produce innovation. The most important alternate system is government investment, development and (sometimes) ownership of innovation.²⁴⁵ The extent to which either is employed says a great deal about a society's beliefs regarding private ownership of information. Those that favor market control in the production of goods will obviously tend to embrace private property rights. However, even strong market economies have some government involvement in innovation, and it need not act as a barrier to privately financed innovation; public and private systems are not necessarily diametrically opposed, and there can be synergy. To understand the effect, it is necessary to consider the influence of alternate systems with respect to either their contribution to or detraction from private innovation.

While government control is generally considered to be an imperfect substitute for private property ownership — experience suggests that private property ownership is a better model for ensuring certain resources are efficiently allocated²⁴⁶ and innovations are created that

²⁴⁵ See NATIONAL SCIENCE BOARD, SCIENCE AND ENGINEERING INDICATORS 2002, p. 4-9 (2002), available at <http://www.nsf.gov/sbe/srs/seind02/pdf/c04.pdf> [hereinafter "NSB REPORT"] (the federal government provided 26.6 % of the United States' R&D funding in 2002).

²⁴⁶ See POSNER, *supra* note 83, at 36-39.

meet the needs of society²⁴⁷ — it is often employed as a gap filler in those areas that do not have strong market incentives.²⁴⁸ This is particularly common in the context of basic scientific research; government organizations like the U.S. National Institutes of Health and national research universities may spend heavily to investigate molecular mechanisms, newly-created compounds, etc. without any assurance that a profitable application will develop.²⁴⁹ Unfortunately, if government-sponsored basic research uncovers an important and highly profitable indication, the government is rarely in a position to conduct the follow-on research and development necessary. But if the innovation could be transferred to private ownership, private investment in the necessary R&D can occur. This was the impetus behind the so-called Bayh-Dole Act in the United States, a provision that permits private companies to take ownership rights in intellectual property developed with federal government funding.²⁵⁰ Such government funding of innovation can therefore positively influence the amount of private innovation, so long as the property rights conferred are reliable and predictable.

Arguably, there is also a detracting role in government-sponsored basic research that bleeds into areas with clear market value. It may reduce the incentive for private companies to invest in parallel, since they will be in competition with a government entity that does not have

²⁴⁷ See LANDES & POSNER, *supra* note 19, at 12-16.

²⁴⁸ See, e.g., NSB REPORT, *supra* note 245, at 411-412 (noting the large amount of federal R&D spending in health-related basic research).

²⁴⁹ See Eisenberg, *supra* note 45, at 1046-48 (describing the communal ownership ideal in scientific societies that rewards “recognition and esteem”).

²⁵⁰ Pub. L. No. 96-517, 94 Stat. 3018 (codified as amended at 35 U.S.C. §§ 200-212 (2000)).

the same sensitivity to market forces.²⁵¹ A tax revenue-supported competitor is undesirable in that it does not have to manage a research program with the same eye toward profit and secrecy. The effect is enhanced if the entity is also immune from existing private intellectual property rights.²⁵² From a societal perspective, competing government research may be acceptable if it can completely supplant the private research it precludes, though it is questionable whether this is the most economically efficient outcome.

On the other hand, government control *following* private investment encouraged by private property rights seems more likely to have a negative effect on private sector innovation. Price controls are a common such restriction. Though rare in the United States, many countries control the price of goods that satisfy essential public policy goals such as health care. Branded pharmaceuticals provide the best example. Maximum prices for pharmaceuticals are often set by a government entity or restricted through a maximum level of reimbursement offered by a government health care system.²⁵³ It is widely argued (by patent owners, generally) that price controls over patented goods reduce the incentive to innovate. This is not unreasonable. While

²⁵¹ The equity of public support for innovation that becomes private property, potentially to the detriment of members of the public who do not have access to it, has been debated for some time. See Adam Jaffe & Josh Lerner, *Reinventing Public R&D: Patent Law and Technology Transfer from Federal Laboratories*, 32 RAND J. Econ. 167 (2001).

²⁵² Under U.S. law, state governments are currently immune from suit in federal court for patent infringement. See, e.g. Christina Bohannon, *Beyond Abrogation of Sovereign Immunity: State Waivers, Private Contracts and Federal Incentives*, 77 N.Y.U. L. REV. 273, 282-88 (2002).

²⁵³ See AUSTRALIAN PRODUCTIVITY COMM'N, INTERNATIONAL PHARMACEUTICAL PRICE DIFFERENCES 21-25 (Jul. 2001) available at <http://www.pc.gov.au/study/pbsprices/finalreport/> (“[M]ost OECD countries have moved away from [direct price] controls in favor of reimbursement pricing systems..”)

the ability to sell a patented good or service at the maximum price the market will support is not an explicit part of the patent property right,²⁵⁴ it can be viewed as an implicit restraint on alienation in the sense that a sale of a patented good includes a limited license for use of that object and future resale.²⁵⁵ And from the perspective of the patentee, the ability to exact short-term, high prices are intimately related to the worth of the patent incentive.²⁵⁶ If a cap is placed on the profit potential, it may not constitute harm to the right, *per se*, but it indirectly impacts it by reducing the effect of the reward, creating a kind of patent tax that reduces innovation.

Other types of government incursions include outright appropriation of the patent right (or rights) covering a particular good. In cases where compensation is required, this is essentially a damages issue as mentioned above.²⁵⁷ Recent events in countries new to the world of intellectual property suggest back-door appropriation using administrative procedure may be an attractive substitute when property is less revered.²⁵⁸ Additionally, programs have been

²⁵⁴ Patents, of course, do not give one the right to do anything, but only the right to exclude. *See supra* note 143 and accompanying text.

²⁵⁵ *See Cahoy, supra* note 47, at 140-143 (reviewing the rights transferred as part of the implied license accompanying the sale of a patented good). *See also* Mark D. Janis, *A Tale of the Apocryphal Axe: Repair, Reconstruction and the Implied License in Intellectual Property Law*, 58 MD. L. REV. 423, 492-96 (1999).

²⁵⁶ *See* NORDHAUS, *supra* note 23, at 76.

²⁵⁷ *See supra* notes 215-219 and accompanying text.

²⁵⁸ *See, e.g.*, Phelim Kyne, *Pfizer to File Official Appeal for Viagra Patent in China*, WALL ST. J., Sep. 27, 2004 (WSJ online) (“For many legal experts and foreign investors, Pfizer's patent woes have become a litmus test of China's commitment to international standards of intellectual property rights, or IPR, protection.”).

proposed in which governments buy back intellectual property rights to essential medications as a possible means of asserting public control over essential medications.²⁵⁹

The tendency of a government to take such action may reflect the overall position of intellectual property rights with respect to immediate social goals in a given culture. An interesting case is provided by the United States' response to the anthrax letter attacks in the fall of 2001.²⁶⁰ When it was determined that the German pharmaceutical company, Bayer AG, held title to the essential patents on the only medicine approved to treat inhalational anthrax, several figures in the U.S. government suggested appropriating the patent rights to as a means of avoiding Bayer's market price.²⁶¹ However, the Department of Health and Human Services eventually negotiated a special price for bulk purchases (which was actually higher than the price the government paid under its strictly controlled Veteran's Administration and Medicaid programs).²⁶² The fact that, even in a time of crisis, the United States chose to negotiate with the property owner rather than usurp the property right may convey a strong message about the culture of private intellectual property in this context.

A consternating problem with including culture in list of patent strength factors is that it suggests the existence of an obstacle that cannot easily be overcome. Several economists have recently suggested that endemic cultural characteristics explain why countries that begin to industrialize at roughly the same time seem to progress and succeed at significantly different

²⁵⁹ See, e.g., Michael Kremer, *Patent Buy-Outs: A Mechanism for Encouraging Innovation*, 113 Q. J. ECON. 1137 (1998) (suggesting a mechanism in which the government values a patent and then offers to purchase it for the public domain at a fixed mark-up).

²⁶⁰ See Cahoy, *supra* note 224, at 125-27.

²⁶¹ *Id.*

²⁶² *Id.*

rates.²⁶³ Property rights, however, may not be set in stone. Evidence suggests that appreciation and respect for property commonly associated with certain Western societies can be both learned and unlearned.²⁶⁴ However, it is reasonable to presume that, even if cultural attributes can be evolve to become more favorable to private property rights, it is not as simple as revising a legal rule.²⁶⁵ A lengthy political process is likely required. In the short term, the disincentives must be minimized as best can be. Perhaps the more important benefit to recognizing cultural respect as a patent strength variable is a better understanding as to why optimizing the other factors may still leave a patent system lacking.

C. A Multi-Angled Snapshot of Patent Incentive Strength

Taking all of the above factors into account, one can see that the strength or power of a particular system of patent rights is really a collection of independent variables affecting a dependent variable, private innovation, in subtly different ways. Each has the power to hobble the patent incentive if sufficiently out of the optimum range. None is powerful enough on its own to support the incentive structure without the others. An optimum patent system requires all factors to be at the appropriate level to support the greatest amount of innovation. Keeping in

²⁶³ See generally CULTURE MATTERS: HOW VALUES SHAPE HUMAN PROGRESS (Lawrence E. Harrison & Samuel P. Huntington, eds., 2000)

²⁶⁴ Michael Fairbanks has boiled down the necessary elements of a cultural change process to ten steps. See Michael Fairbanks, *Changing the Mind of a Nation: Elements in a Process for Creating Prosperity*, in CULTURE MATTERS: HOW VALUES SHAPE HUMAN PROGRESS (Lawrence E. Harrison & Samuel P. Huntington, eds., 2000). While these are broad, general principles, they could be applicable to property rights.

²⁶⁵ See DE SOTO, *supra* note 237, at 164-71 (explaining why cultural revision is not as simple as imposing “mandatory law” that achieves the desired property rights on paper).

mind that seeking patent rights is generally viewed as the alternative to keeping an innovation a trade secret²⁶⁶ (or not inventing at all if trade secret protection will not provide an opportunity to profit on a particular type of invention), one can imagine the dynamic underlying a private innovation incentive's power to push innovators into the patent system:

Insert Figure 8 Here

As the innovation strength of a patent system increases, innovators are more likely to invest in innovation and seek patents.

Naturally, the most useful application of the above factors would be to quantify the strength level of each to form an overall “index” for the system of interest. For example, one could take a particular patent system, rate each factor on a numerical scale based on the described relationships, and compare to another to determine which one provides greater incentives for private innovation. Unfortunately, the simplifications involved in reducing each variable to a single number may lead to inaccuracies that render the analysis less meaningful.²⁶⁷

²⁶⁶ See LANDES & POSNER, *supra* note 19, at 326-29.

²⁶⁷ One of the most successful recent attempts to create such a comprehensive patent strength index — Park and Ginarte's 1997 cross-national study of patent rights — demonstrates the compromises that must be made. See Park & Ginarte, *supra* note 69. The authors created an index of patent rights for sixty countries over a thirty-year period that considered such variables as the “coverage” of a nation's patent laws and the membership in international agreements. *Id.* at 52-53. However, the assigned numbers are arbitrary, the study fails to take into account the probability that more protection isn't necessarily better for all patent characteristics, and it links patent strength with the very broad measure of R&D spending. Overall, it is a valiant attempt to take a comprehensive view of the nature of patent property protection, but the results are arguable on many levels.

Another problem with attempting to quantify the results is that one must make judgments as to which factors have the most influence, or arbitrarily set them all as equal. It is reasonable to add the factors and compare results from country to country (or industry to industry). But while patent system strength is certainly the sum of these parts, the weight that should be attributed to each is not entirely clear. In other words, should a factor with as broad an impact as respect for property rights have a weight equal to one narrower, like the scrutiny of patent validity? In fact, it seems rather unlikely that such equivalency is accurate. Therefore, a complete assessment of a patent system using the above variables should include an appropriate multiplier. Doing so would pose an extremely difficult endeavor.

At this stage, the identification of factors and a visualization as to how each affects innovation are best used as intuitive guidelines as to why certain systems function as they do, and how future changes are likely to affect the system. It may be a more appropriate starting point for future analysis that can eventually answer the broad, overall questions regarding the success of the patent system. In the interim, a conceptual multi-factored approach is an important component to the debate about reform in patent property rules for health care innovation.

IV. Using the System to Analyze Health Care IP

As intimated above, the state of patent protection can be quite different from country to country. This is particularly true in the context of health care, which is even more subject to protection and remedy exemptions as well as less favorable cultures for proprietary control than other fields of invention. Some of these differences could be important enough to make innovation significantly more favorable in some areas than others. Determining what factors to

include in the analysis is key. The more comprehensive approach on incentive factors is useful in this regard, and should provide the best view of overall system vitality.

Turning to the questions posed at the outset of this article, are there problems inherent in certain health care innovation that will inevitably lead to creation and access problems?

Generally, studies describe patent protection in countries like the U.S. as robust.²⁶⁸ However, an overall picture of health care in those countries may be difficult to paint because so many differences exist in the way industry sectors are treated.²⁶⁹ It is informative to consider recent issues individually to determine if and how incentive failures could be a root cause.

A. Weak Pipelines in Pharmaceutical Innovation

Surveys and anecdotal evidence indicate that the pharmaceutical industry is one of the few market segments in which patents are considered to be absolutely critical to the future of the industry.²⁷⁰ In part, this may be due to the more silo-like nature of an industry that tends to be

²⁶⁸ See, e.g., Park & Ginarte, *supra* note 69, at 53 (intellectual property rights strength index showing the U.S. to have a composite score that is third out of sixty countries); JAFFE & LERNER, *supra* note 13, at 125 (arguing that the U.S. system has become decidedly pro-patent and citing several studies in agreement); OECD, *supra* note 107, at 17-18 (most patent regimes have strengthened rights in the past two decades).

²⁶⁹ See Burk & Lemley, *supra* note 127, at 1675 (reviewing the utility in industry-specific patent tailoring, and stating that it has already occurred in the biotechnology and chemical/pharmaceutical industries, among others: “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.”); NAS REPORT, *supra* note 12, at 85 (describing non-statutory mechanisms for applying slightly different legal patent standards to various industries).

²⁷⁰ See, e.g., FTC REPORT, *supra* note 11, at Ch.3(II)(A) (“Representatives from the pharmaceutical industry stated that patent protection is indispensable in promoting pharmaceutical innovation for drug products containing new chemical entities.”); NAS REPORT, *supra* note 12, at 41; Arora, et al, *supra* note 70, at 35.

based on one company reaping the benefits of a new chemical product until the basic patents run out.²⁷¹ The pharmaceutical model suggests that strong innovation incentives should be propelling research forward without fear that follow-on innovation is short-circuited by competitors. Indeed, the search for the “blockbuster” drug is the widely believed research paradigm for the industry.²⁷² However, recent reports indicate that pharmaceutical company pipelines are barer than one would expect, and fewer new medicines wait in the wings.²⁷³ Product extension may be the more common goal of the modern branded industry.²⁷⁴

There could certainly be underlying scientific factors for the lack of groundbreaking research. Some believe that much of the low-hanging fruit of small molecule drug design has been harvested,²⁷⁵ leading to fewer successes for each research dollar spent.²⁷⁶ But it is also

²⁷¹ See FTC REPORT, *supra* note 11, at Ch.3(II)(F) (“Fewer patent thicket issue arise in the pharmaceutical context than in industries where innovation is less discrete and individual products are covered by many patents.”). In contrast, other industries tend to dictate the product first, and patented innovation follows.

²⁷² See Robert Franco, *Beyond the Blockbuster*, PHARM. EXECUTIVE, Nov. 2002, at 74 (noting the blockbuster model tends to dictate the strategy of “Big Pharma,” but suggesting that a more moderate approach that aims toward slightly less successful drugs could be more profitable across the board).

²⁷³ See, e.g., Jesse Eisinger, *What Ails the Drug Industry? Go Ask Wall Street And Its Short-Term Vision*, WALL ST. J., Oct. 13, 2004, at C.1 (arguing that the pharmaceutical industry has recently chosen a short sighted path of fast growth and immediate profits over significant and risky R&D spending, and stating that Wall Street investors are partially to blame).

²⁷⁴ See, e.g., ANGELL, *supra* note 7, at 74-80 (due to reasons such as patent extension, “Every now and then, drug companies bring an innovative drug to market, but mainly they turn out a seemingly inexhaustible supply of leftovers — “me too” drugs that are versions of drugs in the distant past”).

²⁷⁵ See, e.g., Jesse Eisinger, *The Cure for What Ails Pharmaceutical Companies*, WALL ST. J., Oct. 18, 2004 (online ed.) (letter from Stewart Adkins, Senior Pharmaceutical Analyst, Lehman Brothers) (“The focus on small

possible that pharmaceutical companies are making research choices toward more conservative drug discovery.²⁷⁷ An in-depth look at the patent factors demonstrates that there could be also be disincentives lurking in the pharmaceutical innovation scheme that may slow progress in risky compound research.

First, it almost goes without saying that the lack of patent protection for pharmaceuticals in some countries has the potential to constrain worldwide revenues for certain products.²⁷⁸ Although these exceptions are expected to disappear with the next few years, the revised protections apply prospectively and will have little effect on new pharmaceutical products for some time.²⁷⁹ Still, given that protection is available in the most profitable markets — including

molecules as being the only long term credible solution to disease treatment (thus avoiding the need for injection, since large biological molecules are digested in the gut) had blind-sided most large pharma companies to the commercial potential that biotech offered and still does.”)

²⁷⁶ See, e.g., DiMasi, *supra* note 79, at 154; Scott Myers & Ann Baker, *Drug Discovery — An Operating Model for a New Era*, 19 NATURE BIOTECH. 727, 727 (2001) (noting reductions in pharmaceutical company research efficiency).

²⁷⁷ See, e.g., NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT (“NIHCM”), CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION 3-4 (2002), available at <http://www.nihcm.org/innovations.pdf> (reviewing pharmaceutical industry innovation indicators like NMEs and priority NDAs and determining that “Highly innovative drugs — medicines that contain new active ingredients and also provide significant clinical improvement — are rare” and are becoming increasingly so.).

²⁷⁸ See *supra* notes 105-110 and accompanying text.

²⁷⁹ See, e.g., Gupta, *supra* note 90, at 602-5.

the United States in which almost fifty percent of worldwide pharmaceutical profits are derived — there should be an adequate basis for incentives.²⁸⁰

More interesting are the intellectual property restrictions that exist in the profit centers. In the United States, Hatch-Waxman Act reforms in the mid-1980s deprived pharmaceutical patent owners of some powers, but attempted to balance the reduction by permitting patent term extensions in certain situations.²⁸¹ Significantly, the rules permit a maximum usable patent term of fourteen years,²⁸² significantly less than the average time most patentees have to exploit their patent grant.²⁸³ Hatch-Waxman rules also permit generic manufacturers to challenge the validity of pharmaceutical patents without the risk of infringement damages,²⁸⁴ an advantage over

²⁸⁰ See EFPIA REPORT, *supra* note 183, at 6 (showing that 49.2% of world pharmaceutical sales took place in North America in 2003).

²⁸¹ See, e.g., H.R. Rep. No. 98-857, pt.2, at 27-30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2711-14 (considering whether the Hatch-Waxman Act would result in an unconstitutional taking of intellectual property and determining that it does not).

²⁸² See 35 U.S.C. § 156(c)(3) (2000). See also Gerald Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 190 (1999) (“The length of the exclusivity periods are strictly arbitrary legislative numbers pulled out of the air.”).

²⁸³ See PHARMACEUTICAL RESEARCHERS AND MANUFACTURERS (“PhRMA”), PHARMACEUTICAL INDUSTRY PROFILE 2004, p. 31, fig.4.2 (2004), available at <http://www.phrma.org/publications/publications//2004-03-31.937.pdf> (figure suggesting that the average pharmaceutical patent life is 11-12 years, whereas other industries enjoy an average patent life of 18.5 years).

²⁸⁴ See 21 U.S.C. § 355(j)(2)(A)(vii) (2000). This is due to the fact that the filing of an abbreviated new drug application (for a generic drug) constitutes a technical act of infringement, obviating the case and controversy requirement of committing actual infringement before challenging a patent in court. See BEERS, *supra* note 150, at § 3.03[B][3]; Mossinghoff, *supra* note 282, at 190.

competitors in other industries. The revisions have been extremely successful in fostering competition in the United States, but may have taken a toll on branded pharmaceutical company incentives.²⁸⁵

Additionally, there is a growing backlash against the use of property rights to obtain the full profit the market will bear. In most industrialized countries, there are direct or indirect price controls that keep profits low. In those without price controls, like the United States, pharmaceutical companies are encouraged to make their products available at subjectively “reasonable” prices (some have even suggested a ceiling based on a theoretical maximum rent to compensate for research costs²⁸⁶) to all who can use them. Generic equivalents are often promoted as more desirable alternative, even before core patents on the branded products have elapsed.²⁸⁷ While such sentiments certainly have a pleasant moral underpinning, one must keep

²⁸⁵ See PHRMA, INSIGHTS 2003: HIGHLIGHTS FROM THE PHARMACEUTICAL INDUSTRY PROFILE 11, fig.9 (2003), available at <http://www.phrma.org/publications/publications//2003-10-07.892.pdf> (figure showing that the generic share of the pharmaceutical market in units sold has increased from 19% in 1984 to approximately 50% in 2002); CONGRESSIONAL BUDGET OFFICE (“CBO”), HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xiii (1998), available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (stating that from 1984 to 1998, “expected returns from marketing a new drug have declined by about 12 percent” due to generic competition).

²⁸⁶ See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 101 (2004) (arguing that pharmaceutical prices should be set with a monopoly rent sufficient to compensate for actual research costs); LANDES & POSNER, *supra* note 19, at 315-16.

²⁸⁷ For example, there has been somewhat of an outcry among health care advocates that a combination drug treatment for AIDS, available in India due to pharmaceutical compound exclusions, is not available in most of the world due to patent restrictions from the various branded drug companies who separately control each drug. See

in mind that they suggest artificially low (submarket) price caps for future pharmaceutical products. In essence, this can be viewed as an erosion of the private property culture in pharmaceuticals.

In sum, despite the fact that the public often perceives the pharmaceutical patent regime to be an oppressive wall of profiteering-enabling restrictions, patent incentives may actually be too weak. It is possible that the current pressures on existing patents and the uncertainties future of pharmaceutical patent protection is applying an unintended downward pressure on the incentives to undertake the most risky research. Companies may be opting to preserve current product dynasties at the expense of future cures. Such strategies are likely to take a toll on the future of pharmaceutical company health as well as the public welfare.

If the problem is weak incentives, the solution is not necessarily to increase patent property rights across the board, particularly for pharmaceuticals already in existence. A more intelligent approach is to consider the patent factors that may be weakened (term, validity, culture), and determine how incentives may be restored for future innovation. Primarily, it requires an understanding that patent incentives must promise more than reasonable compensation for R&D effort, but rather the prospect of great rewards for great advancements that will not be retroactively appropriated simply because they are important.

B. A Dwindling and Antiquated Vaccine Industry

The anemic vaccine industry has been a source of concern for some years. There are enough core manufacturers to provide an adequate supply for the world's basic immunization

Donald G. McNeil, *Study Finds Generic AIDS Drug Effective*, N.Y. TIMES, Jul. 2, 2004, at A.5 (describing the patent issue and the Indian generic formulation).

needs, but barely.²⁸⁸ Manufacturers of vaccines with recurrent, adult indications like yearly flu varieties have been on shaky ground, with many governments enacting some level of control over the industry players to ensure supply.²⁸⁹ Recent events in the United States demonstrate the danger of depending on the shrinking number of companies in this segment.²⁹⁰ Perhaps the most striking fact about the vaccine industry is its reliance on technology that has remained essentially unchanged since the 1940s.²⁹¹ Chicken eggs are still inoculated with virus and harvested after six months of incubation, and contamination or other batch failures requires an additional six months.²⁹² Given the need for a dependable supply and the ever-growing power of molecular biology research techniques, the apparent lack of R&D spending to derive new methods of production and new vaccines could indicate a problem of incentives.

A review of the significant patent factors suggests, however, that vaccine manufacturers probably experience patent incentives that are actually closer to optimum than those for pharmaceuticals. The legal rights available for vaccines are reasonably strong. Vaccines are

²⁸⁸ See Carol Bellamy, *Vaccine Supply Barely Meets Demand*, in WHO/UNICEF, *Vaccines and Immunizations*, Technical Update, May 2003, at 2-3 (noting that the number of vaccine manufacturer for WHO programs has dropped by half in just the last five years).

²⁸⁹ See, e.g., Gardiner Harris, *In American Health Care, Drug Shortages are Chronic*, N.Y. TIMES, Oct. 31, 2004, at 4.12 (“In Europe, where governments play a much larger role in managing health care, shortages are much less common.”)

²⁹⁰ See, e.g., Connolly, *supra* note 8, at A.6

²⁹¹ See Japsen, *supra* note 9, at 1.

²⁹² *Id.*

patentable, even in countries that have in the past excluded pharmaceuticals,²⁹³ and new methods of making existing vaccines could also qualify for protection. Because vaccines are considered biologic products (as opposed to “drugs”), they do not fall under U.S. rules that promote generic competition, including the abbreviated application process that permits clinical use during a patentee’s term.²⁹⁴ The difficulty in manufacturing vaccines, and the fact that many older versions are no longer under patent, means that they have not generally be subjected to compulsory licenses or rampant private infringement. Very little public outcry has ensued over proprietary rights for vaccines. One patent-related disincentive might include the fact that there is no term extension for biologics,²⁹⁵ and the long time period for biologic approval could eat into the patent enforcement period.²⁹⁶ On balance, vaccines have no obvious lack of patent incentives that explain the dearth of innovation.

Other factors, must explain the lack of vaccine innovation. The unusual market dynamics that make the business of vaccines a somewhat special case are the most likely suspect. In general, vaccines are administered infrequently, sometimes only once during childhood, so a

²⁹³ For example, Wyeth’s FluMist aerosol flu vaccine is patented. *See, e.g.* Immunization Advisory Centre , *Release of Long-Awaited Intranasal Flu Vaccine*, IMNUZ, Aug. 2003 at 5, *available at*, http://www.imac.auckland.ac.nz/resources/immuz/immuz3_2.pdf The prohibitions are generally restricted to drugs as opposed to biologics. *See Gupta, supra* note 90, at 602-05.

²⁹⁴ *See* 21 U.S.C. § 321(p) (2000) (defining new drug under the Food, Drug and Cosmetic Act).

²⁹⁵ The Hatch-Waxman provisions apply only to drugs, not biologics. *See BEERS, supra* note 150, at § 4.04[A]. Vaccines are considered biologics.

²⁹⁶ *See* Lars Noah, *Triage in the Nation’s Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 748-49 (2003) (describing the stringent FDA approval procedure for new vaccines).

market of chronic users will never develop.²⁹⁷ A large portion of the vaccine market consists of government third-party payers (purchasing it for children, the elderly and financially disadvantaged) who are able to negotiate bulk prices that keep industry profits small.²⁹⁸ Arguably, even if there were a latent private market for innovative vaccines, existing vaccines are effective for many infectious diseases, and it is unclear that better alternatives would support prices high enough to create incentives for massive research and development spending. Also, many vaccines are effective for a particular season of infections, and must be discarded following that, leading to massive losses for unsold products.²⁹⁹ Vaccine production has been reduced to a niche industry; there is insufficient demand to change this.³⁰⁰

Oddly, this response to the market is precisely what is desired from a privately funded innovation system. The fact that vaccines are not a very profitable business should dissuade companies from funneling research dollars in this direction. The solution to the vaccine crisis, as a public health issue, is finding ways to create a more profitable market rather than modifying intellectual property rules.

²⁹⁷ See *Vaccine production economics to ensure a sustainable, high quality, and affordable supply of vaccines in WHO/UNICEF, Vaccines and Immunizations*, Technical Update, May 2003, at 5-6.

²⁹⁸ See Noah, *supra* note 296, at 751-53 (arguing that government efforts as cost containment have backfired in pushing the prices too low to create an incentive for market retention).

²⁹⁹ See Japsen, *supra* note 9, at 1.

³⁰⁰ See Jason C. Hsu & Eduardo S. Schwartz, *A Model of R&D Valuation and the Design of Research Incentives*, NBER Working Paper No. w10041 (Oct. 2003) (analyzing firm underinvestment in vaccine R&D and determining that purchase commitment plans would serve to alleviate the crisis).

V. Conclusion

A thorough understanding of the ability of a patent system to create incentives for innovation is of fundamental importance for setting innovation policy. Uncertainty prevents an optimal utilization of the system and the ability to make intelligent modifications to it. Because a multitude of studies and years of experience have left most of the key questions unanswered, it may be time to consider a new perspective.

This article explains that an effective effort to optimize patents must begin with an understanding that the patent right is a collection of independent variables that have an impact on the incentive to invest in innovation. These variables can be broadly categorized as (1) “legal factors” such as the scope of subject matter and the extent of the right in terms of breadth and length; and (2) “cultural/institutional factors” such as the enforceability of the right and restraints on alienation like price controls. In order to evaluate current innovation problems and determine how legal and market revisions to the relevant rules will affect innovation in the future, it is important to consider a comprehensive index of incentive alignment factors as proposed in this article. In the context of health care, it is critical to understand if and how patent rights truly encourage innovation to ensure that the benefits of property rights and access to essential medicines effectively coexist.

ARTICLE FIGURES

Figure 1

Patentable Subject Matter

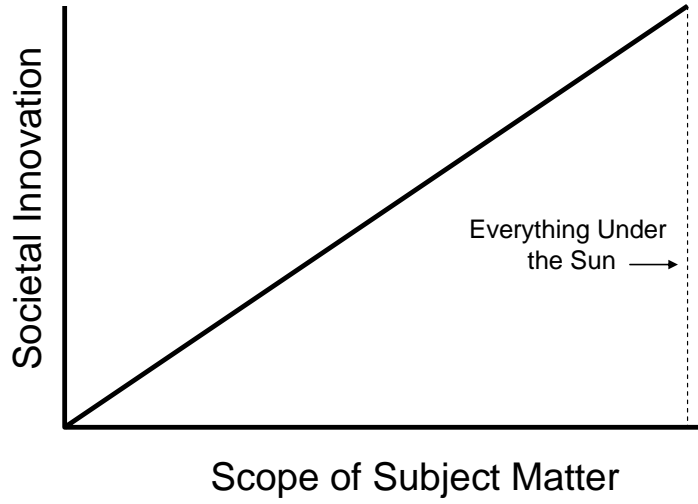
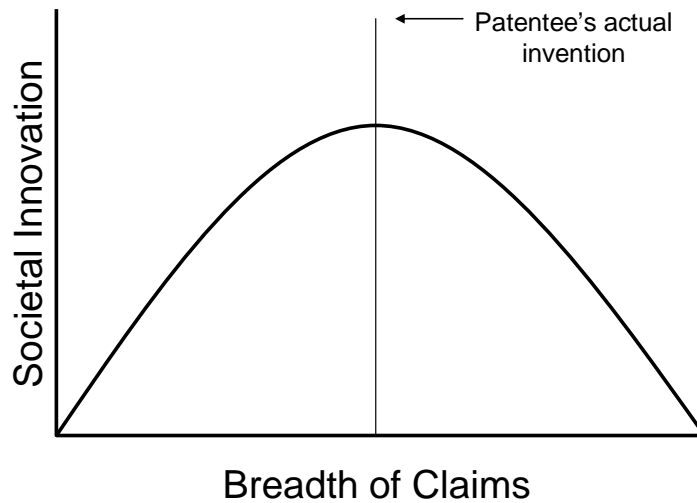


Figure 2

Claim Scope



ARTICLE FIGURES

Figure 3

Rights of Exclusion

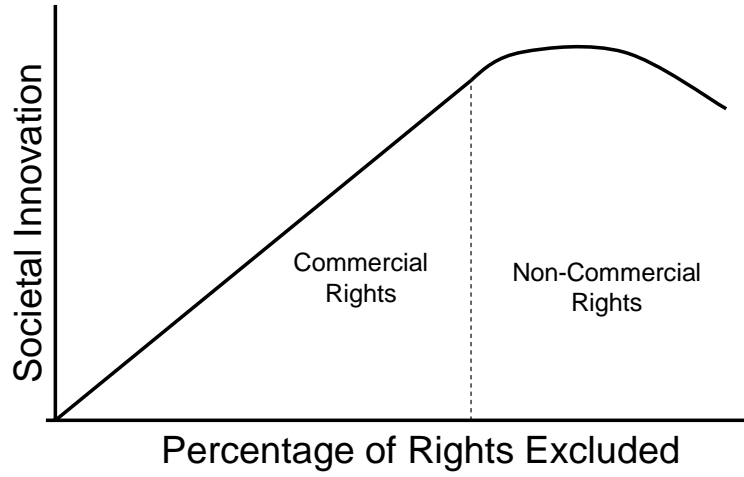


Figure 4

Patent Term

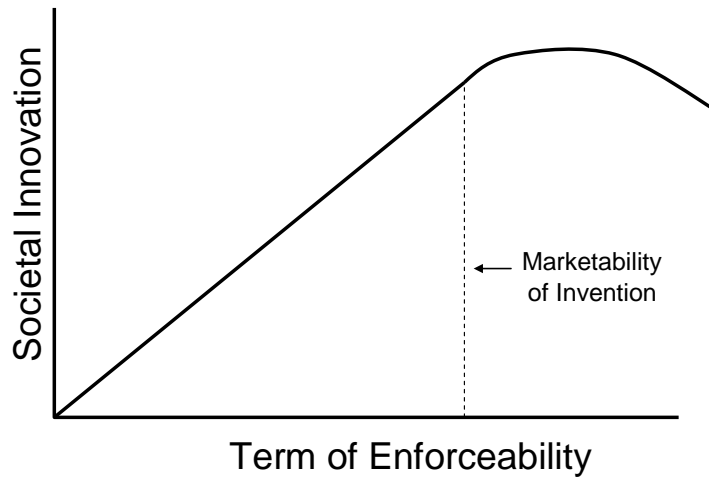


Figure 5

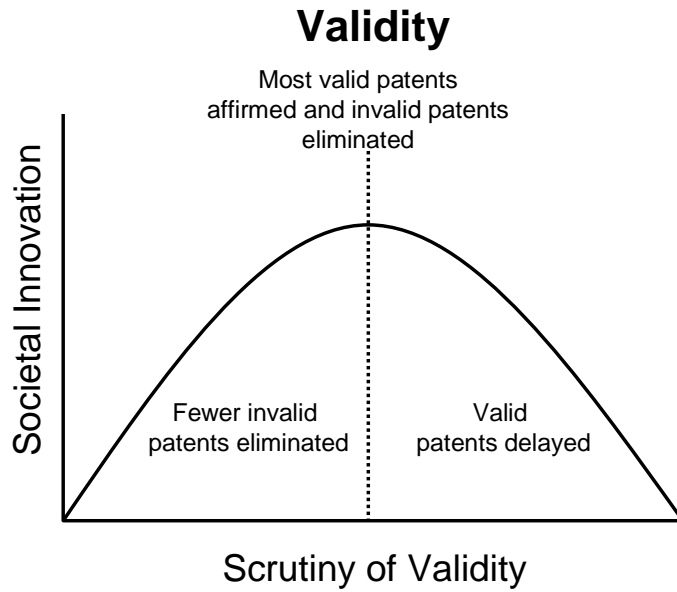
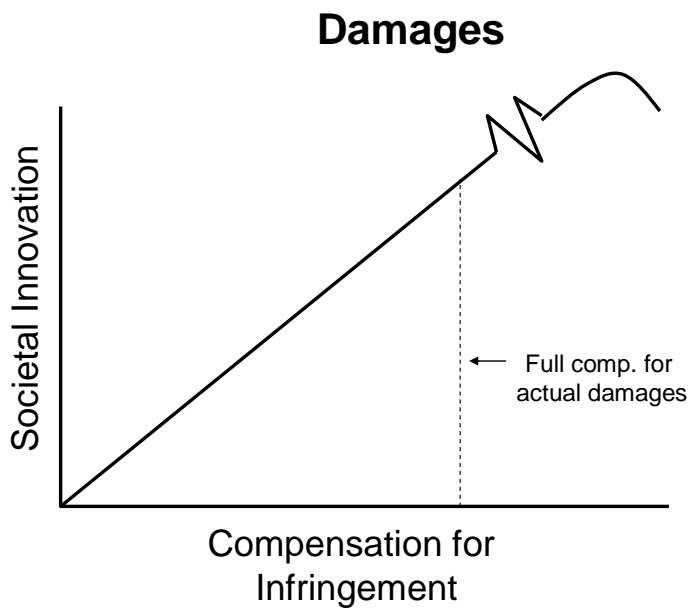


Figure 6



ARTICLE FIGURES

Figure 7

Private Property Culture

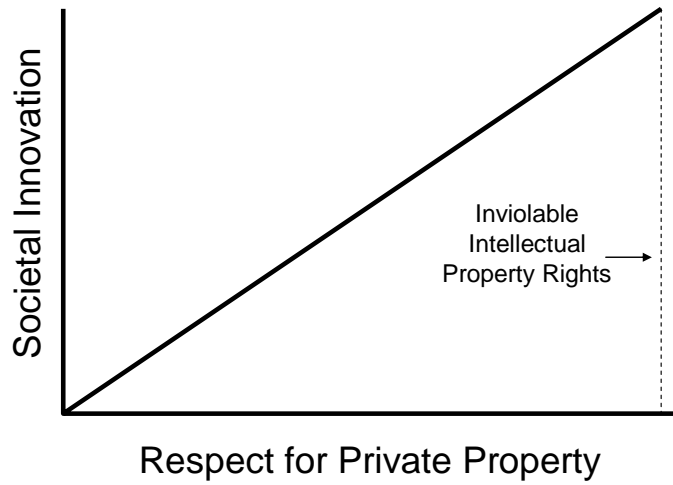


Figure 8

Innovation Model

