ARTICLE

THE ROLE OF PATENT SCOPE IN BIOPHARMACEUTICAL PATENTS

NATASHA N. ALJALIAN*

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INTRODUCTION

Patents play an important role in encouraging and stimulating research, development and invention. This is particularly true in the biopharmaceutical industry, in which risk-laden research requires intensive investments of time and capital. As a result, patent protection is imperative in the biopharmaceutical industry. Patent scope and the determination of this scope play an important role in determining the strength of these rights. Section I of this article will provide an overview of the United States patent system. Sections II and III will address patent instruments used to determine patent rights and related philosophical and economic policies and concerns. Section IV will address the instrument of patent scope in particular, and Section V will present an overview of the biopharmaceutical industry today.

Doctrines of patent law, including written description, patent infringement, claim construction, and the doctrine of equivalents, are the focus of Section VI. Section VII discusses patent scope in the biopharmaceutical industry. The effects of the Bayh-Dole Act, competition, the doctrine of equivalents, and diffusion of technology through licensing are considered in this context. The influence of broad patent scope on research and development are also examined in this section. Section VIII proposes solutions to limit patent scope while maintaining the strong patent rights needed to encourage and promote biopharmaceutical research and development.

I. GOALS OF THE U.S. PATENT SYSTEM

"The federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful and nonobvious advances in technology . . . in return for the exclusive right to practice the invention for a period of years."[1] The patent system has been described in

* Boston University School of Law (LL.M. 2004); St. John's University School of Law (J.D. 1999, *cum laude,* Editor in Chief, *St. John's Law Review*). The author has served as a Corporate Associate at Goodwin Procter in Boston, Massachusetts, and Willkie Farr & Gallagher in New York, New York. She is currently serving a federal judicial clerkship with the Honorable William G. Young, Chief Judge of the United States District Court, District of Massachusetts. The author extends sincere gratitude to Professor Michael Meurer of the Boston University School of Law for his guidance and direction.

[1] The Supreme Court articulated this view in Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51 (1989). The United States Patent System finds its grounding in the United States Constitution, which gave Congress the right to design a system to promote "science and useful arts." U.S. CONST. art. I, § 8 ("Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries"). "Science and useful arts" at that time were typically "mechanical inventions useful in agrarian economy," as the United States patent law system was designed over a century ago to address a "simpler industrial era." Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology Specific?* 17 BERKELEY

varying ways. Abraham Lincoln described it as "add[ing] the fuel of interest to the fire of genius."[2] Some see it as a "tradeoff between increased inventive effort resulting from longer anticipated patent life and greater deadweight costs associated with longer monopoly."[3] Justice Story stated the Supreme Court's view almost two centuries ago that "[w]hile one great object [of our patent laws is], by holding out a reasonable reward to inventors and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius, the main object was 'to promote the progress of Science and useful Arts.'"[4]

The judiciary has emphasized and adopted the utilitarian, or economic, view of the U.S. patent system.[5] As the Supreme Court has stated, "[a] patent

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TECH. L.J. 1155, 1159 (2002); *see also* Dan L. Burk, *Tailoring Patent Policy to Specific Industries*, 7 MARQ. INTELL. PROP. L. REV. 1 (2003) (remarks from speech at the Sixth Annual Honorable Helen Wilson Nies Memorial Lecture in Intellectual Property Law). The authors of the Constitution believed that "ingenuity should receive a liberal encouragement." V Writings of Thomas Jefferson, at 75-76.

[2] JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 22 (1st ed. 2003) (quoting speech given by Abraham Lincoln inscribed over door of the United States Department of Commerce in Washington D.C. where the United States Patent and Trademark Office used to be housed).

[3] Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 868 (1990).

[4] Pennock v. Dialogue, 27 U.S. 1, 19 (1829).

[5] This view seeks to foster the "introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1973). The United States has officially adopted the Utilitarian, or Economic Incentive, approach to intellectual property law. Mazer v. Stein, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that . . . [it] is the best way to advance public welfare through the talents of . . . inventors in Science and the useful Arts.") (quotations omitted); *see also* Feist Publications, Inc. v. Rural Telephone Serv. Co., Inc., 499 U.S. 340 (1991). Intellectual property rights do not focus on equity, fairness or justice. "Intellectual property in the United States is fundamentally about incentives to invent and create." ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 10 (3d ed. 2003). The framers of the Constitution were motivated by economic concerns. They were also motivated by the misuse of patents in England and the practice of granting patents to those inventions already in public use. *See generally Bonito Boats*, 489 U.S. at 147-49 (quoting 13 WRITINGS OF THOMAS JEFFERSON 335 (Mem. ed. 1904)). For Jefferson, for example, a central tenet of the patent system in a free market economy was that "a machine of which we were possessed, might be applied by every man to any use of which it is susceptible." *Id*. at 147. To avoid the grant of patents on items in the public domain, which Jefferson equated to an ex post facto law, an integral part of the patent system is that an invention must be "new" and "not be known." *Id*. This important notion is the foundation of section 101 of the current patent law, which requires an invention be "new and useful" and section 102, which establishes the

system must be related to the world of commerce."[6] It is true that the patent system, while offering protections, may appear at times unfair to inventors.[7] This perspective is reflected in the patent laws of other countries and corresponds to John Locke's Natural Rights Perspective.[8] Although courts have in the past wavered between the two approaches, the Supreme Court has rejected the natural rights view of patent law.

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novelty and no prior use standards of patentability. *Pennock*, 227 U.S. at 2 (noting that items in public commerce could not receive patent protection and that "if [an inventor] suffers the thing he invented to go into public use, or to be publicly sold for use" that "[h]is voluntary act or acquiescence in the public sale and use is an abandonment of his right"). This has also been articulated by the Court in *Graham v. John Deere*, which stated that Congress may not "authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." 383 U.S. 1, 6 (1966). The importance of the utilitarian goal of patent law is reflected in the great effect patent law has on domestic and global economies. *See* MUELLER, *supra* note 2, at 16.

[6] Brenner v. Manson, 383 U.S. 519, 536 (1966). The framers of the Constitution decided to forego the "prize" system and to "harness the energies of private enterprise to advance the useful Arts." John R. Thomas, *Liberty and Property in the Patent Law*, 39 HOUS. L. REV. 569, 571-72 (2002) (quotations omitted).

[7] For example, unlike in copyright law, independent invention is not a defense available to inventors seeking a patent.

[8] This perspective is also known as the "fruit of one's labor" or "sweat of one's brow" theory. In the patent context, the *Parke-Davis* and *Chakrabarty* decisions together establish that one can patent "anything under the sun" so long as "sufficient human intervention" is present and the "*discovery is not nature's handiwork, but his own*." Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 115 (S.D.N.Y. 1911); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1979). The Lockean theory follows this notion in an elementary fashion: a person owns his own labor, and physical objects in nature are available to all. When one observes nature and combines nature with one's own labor, one has the right to claim ownership of the fruit of one's labors so long as one does not deplete the natural source. In Locke's own words:

> Though the earth and all inferior creatures be common to all men, yet every man has a "property" in his own "person." This nobody has any right to but himself. The "labour" of his body and the "work" of his hands, we may say, are properly his. Whatsoever, then, he removes out of the state that Nature hath provided and left it in, he hath mixed his labor with it, and joined to it something that is his own, and thereby makes it his property. It being by him removed from the common state Nature placed it in, it hath by this labour something annexed to it that excludes the common right of other men. For this "labour" being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough, and as good left in common for others.

JOHN LOCKE, TWO TREATISES ON GOVERNMENT (3d ed. 1698). Accidental or lucky discoveries are unsupported by this Lockean theory, as in those instances one does not consciously labor to come upon such discoveries.

II. PATENT INSTRUMENTS

Several "policy levers" or "patent instruments" must be taken into consideration when discussing patent rights.[9] These tools help define the parameter and strength of rights given a patentee, and include patent duration, patentable subject matter, recognition of definitive "property" rights, standards of patentability, and patent scope. These patent instruments may be best understood when considered in the context of the reward theory of patent law.[10]

Patent term has drawn particular attention from academic commentators. The current patent system allows for twenty years of coverage from the earliest effective United States filing date.[11] Whether or not correct, Congress has

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[9] For a general discussion of policy levers and their use and effects on different industries, see Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003).

[10] *See infra* text accompanying notes 12, 13, 16 and 26.

[11] 35 U.S.C. § 154(a)(2) (2000); 1 PAT. APP. HANDBOOK § 5:6 (July 2003). Drugs requiring FDA approval have been given an extension of patent term. The Drug Price Competition and Patent Term Restoration Act provides, in pertinent part, that with certain limitations, "[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing the product shall be extended . . . by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued." 35 U.S.C. § 156 (a), (c) (2000). Such extension is limited by patentee's other patents and diligence. *Id*. at § 156 (c). For example, "[t]he restoration period for [a] patent does not extend to all products protected by the patent but only to the product on which the extension was based." *Id*.; Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1547 (Fed. Cir. 1996); 35 U.S.C. § 156(c); DONALD S. CHISUM, CHISUM ON PATENTS, § 16.04[5] (2002).

Some propose that patent rights, parallel to copyright protection and the real property concept of fee simple ownership, should extend perpetually. Howard F. Chang, *Patent Scope, Antitrust Policy, and Cumulative Innovation*, 26 RAND J. OF ECON. 34, 52 (1995) (noting that some view narrow patents of infinite duration as optimal, while others favor longer patents to reduce underinvestment in cumulative innovation context). It may be argued that a perpetual patent term has several benefits. Edmund Kitch's prospect theory provides that a patent owner would (and should) have the right to control future research on a patented discovery and could use royalties and rents generated from the initial patent to fund such additional research. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977). Kitch would likely argue that this right, to be effective, should be perpetual. Joseph Schumpeter would agree that the economic gain of this type of system would motivate a "monopolist" to remain a monopolist. *See* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 819 (2001).

Other benefits of a perpetual patent term include the avoidance of duplicative research and the standardization of discoveries within a market. Some believe that a perpetual patent term is harmful. Merges and Nelson, whose theories are discussed below, would likely oppose

deemed a twenty year patent term to be an adequate duration of exclusive use to reward inventors.

Patentable subject matter is a fairly expansive instrument as applied in the United States patent system.[12] Though there are limitations on patentable

perpetual patent terms as such terms would likely limit and thwart innovation or desirable "inventing around" by others. Merges & Nelson, *supra* note 3. Further, as "monopolists" are given perpetual rights, the lack of rivalrous competition may cause a monopolist to sit on rights and, once again, stunt improvements and research. Additionally, intellectual property rights create market power, and the potential for deadweight loss and high prices increases with a perpetual patent term. Current law reflects this view, as the Supreme Court stated in *Bonito Boats* that "Congress may not create patent monopolies of unlimited duration" and that the "Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance [of] Science and useful Arts." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989). This is echoed in the Court's decision in *Kewanee Oil*. *See generally* Kewanee Oil v. Bicron Corp, 416 U.S. 470 (1974).

Still others propose a patent term shorter than 20 years. This view would have patent term vary based on the value of an invention, the amount of research and investment made in an invention, or the field in which the invention is made. For example, a drug patent which typically involves great time and investment should be granted, some would posit, longer patent terms in return for such intense investment. *See infra* note 87 and accompanying text. Software patents, on the other hand, could be granted a shorter patent term given the relatively small investment of time or capital needed in connection with discoveries in this field. MUELLER, *supra* note 2, at 25 (noting that "it is not so clear that 20-year patents are needed to bring forth the optimal level of innovation in computer software or business methods").

The discussion of patent duration ties into trade secret principles. An inventor is guaranteed an exclusive period of use through patent protection in exchange for disclosure of an invention. An inventor may opt for trade secret protection; however, should another party discover the same invention, the original inventor does not have the right to exclude the other party from practicing the invention. This is the hypothetical bargain made.

Though the effects of varying patent term can be great indeed, this paper will assume the current state of patent law on this matter to be invariable and fixed. For a general discussion of the effect of patent life on patents, see Bonwoo Koo & Brian D. Wright, *Economics of Patenting a Research Tool*, ENV'T AND PROD. TECH. DIV. DISCUSSION PAPER, *at* http://www.ifpri.org/divs/eptd/dp/papers/eptdp88.pdf (last visited Feb. 26, 2005) (citing Nordhaus's 1969 model and the lines of research which have developed from it).

[12] There are different standards among the United States, European and Japanese patent systems as to what constitutes patentable subject matter. For a general discussion of the expansion and breadth of patentable subject matter in the United States, see Michael North, Note, *The U.S. Expansion of Patentable Subject Matter: Creating a Competitive Advantage for Foreign Multinational Companies?* 18 B.U. INT'L L.J. 111, 112 (2000).

A patent system that originally covered industrial and agrarian inventions now covers business methods, software, biotechnology, pharmaceuticals, genes, DNA – the list continues. Burk & Lemley, *supra* note 1, at 1160; F. Scott Kieff, *Property Rights and*

subject matter, it is deemed appropriate to reward inventors for new discoveries. [13] Patentees are rewarded in relation to the "property right" defined in the written description of patents, which demarcate the "metes and bounds" of the claimed invention.[14] The novelty[15] and obviousness

Property Rules for Commercializing Inventions, 85 MINN. L. REV. 697, 701 (2001). *See also* Diamond v. Chakrabarty, 447 U.S. 303 (1979); State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998); *In re* Alappat, 33 F.3d. 1526 (Fed. Cir. 1994). *But see* Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 3 (2001) (noting that patent law as it currently exists does not adequately address and promote the software industry given the particular nuances of software, such as "rapid sequential innovation, reuse and re-combination of components, and strong network effects that privilege interoperable components and products").

The United States Supreme Court, in *Diamond v. Chakrabarty*, granted patent protection to almost any invention. The expansive practice of the United States patent system has been challenged by individuals through test patent applications like Jeremy Rifkin's now famous application for a patent on the human-animal chimera. The Supreme Court acknowledged and responded to the amicus curiae brief submitted by Rifkin in *Chakrabarty* by indicating that Congress should address this potential "parade of horribles." Diamond v. Chakrabarty, 447 U.S. 303, 317 (1979).

[13] This is to be distinguished from simple ideas an inventor may have or products which are already in the public domain. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997) (noting that patents are not intended to protect "ideas" and requiring adequate enablement of patent claims).

[14] Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1044 (2003).

Patent law's written description requirement not only requires that a patentee definitively claim the "metes and bounds" of the invention but also requires that a patentee disclose and enable an invention without the need for undue experimentation. 35 U.S.C. § 112 (2002); *id*. at § 112 ¶2 (requiring that a patent applicant "particularly point out and distinctly claim the subject matter which the applicant regards as his invention"). For example, the Federal Circuit in *Eli Lilly* required that a patentee have knowledge of the specific chemical structure to establish and sufficiently disclose an invention. Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997) (explaining that "a definition by function . . . does not suffice to define the genus because it is only an indication of what the gene does rather than what it is"). To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail such that a person having ordinary skill in the art ("PHOSITA") can clearly conclude that "the inventor invented the claimed invention." *Id*.; *see also* Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir. 1993). In predictable fields, however, actual reduction to practice is not necessary. Further, a patentee must provide enabling disclosure which teaches others how to make and use the invention without undue experimentation. 35 U.S.C. § 112; *In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988). Thus, in the context of a chemical, as in *Lilly*, not only must an inventor know the structure, but the inventor must also disclose how to make the chemical. *See generally* Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed. Cir. 1994); Hitzeman v.

requirements, on the other hand, prevent the patentee from receiving a disproportionate reward or a proverbial hunting license.[16]

The patent scope instrument is the primary focus of this paper. As the scope of a patent is the most easily manipulated of the patent instruments, both by courts and patentees, it is worthy of academic consideration and commentary. The judiciary has acknowledged the difficulty in determining the scope of a patent,[17] but the optimal level of protection needed to call forth the right level

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Rutter, 243 F.3d 1345, 1356 (Fed. Cir. 2001) (establishing that a protein is reduced to practice and capable of disclosure only after the inventor has an explicit description of the structure itself). A clear utility is obviously a prerequisite, as, according to the Court, "specific benefit exists in currently available form" when "the metes and bounds" of the claimed invention are "capable of precise delineation." Brenner v. Manson, 383 U.S. 519, 534-35 (1966).

[15] 35 U.S.C. § 102. Generally, products or processes which are "known," "used," "published," or "on sale" may not be patented by an inventor claiming original invention of such previously available products or processes. This concept has been an integral part of U.S. patent law for almost two centuries. *See* Pennock v. Dialogue, 27 U.S. 1 (1829) (establishing that an article which is in the public domain or in public commerce may not be patented). The framers explicitly intended to provide this protection for inventors as well as to prevent governmental abuses. Novelty alone, however, is not enough. Hotchkiss v. Greenwood, 52 U.S. 248, 266 (1850) (establishing years ago that "to receive a patent an invention must possess something more" than novelty); MUELLER, *supra* note 2, at 131 (explaining that there should be a "qualitative advance" or improvement over existing technology).

[16] Patent law also provides that an invention cannot be obvious in light of prior existing art in an analogous field. This avoids the problem of double patenting, which is illustrated by the many challenging the ever-famous Columbia University Axel patents on eukaryotic cells. *Navigating the Patent Maze: The Public Patent Foundation Requests a Re-exam of the Latest Axel Patent* (Mar. 3, 2004), *at* http://lorac.typepad.com/patent_blog/healthrelated_patents/ (indicating that the most recent Axel patent was granted in September of 2002, after the original patents had expired in 2000).

A section 103 analysis is quite similar to that under section 102. Section 103, however, unlike section 102, does not have strict identity or enablement requirements. As such, it is often likely that while something may be novel, it does not have the something "more" required by the Court in *Hotchkiss* and does not meet the nonobviousness requirement. 35 U.S.C. §§ 102, 103; *Hotchkiss*, 52 U.S. at 266-67. The obviousness requirement is limited, however, as only previously existing products or processes in an analogous art can render the patentee's invention obvious.

[17] *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd, 234 F.3d 558, 578 (2000), *vacated by* 535 U.S. 722 (2002) (acknowledging the "conflict and tension between the patent protection offered by the doctrine of equivalents and the public's ability to ascertain the scope of a patent"). *But see* Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502 (1917) (noting that the scope of the grant which may be made to an inventor in a patent . . . must be limited to the invention described in the claims of the patent"). The determination of patent scope happens at the time of an infringement suit or a

of innovation is unsettled and "has attracted surprisingly little attention."[18] Scope is an important patent instrument, particularly in the biopharmaceutical industry,[19] and gives rise to concerns and promotes desirable patent policies.[20]

III. PHILOSOPHICAL AND ECONOMIC POLICIES AND CONCERNS IN PATENT LAW

It is well established that the patent system simultaneously confers benefits upon society and imposes certain costs. Proponents of the utilitarian theory accept that short term costs are required for long term benefits.[21] There are several policies and concerns which should be considered in the biopharmaceutical area.

A. Promoting Research

It is argued that broad patents are crucial to motivate research and development, particularly in pioneer and unpredictable areas.[22] Providing the

declaratory judgment action. *See* Rai, *supra* note 14, at 1045. Without such actions, scope may be unclear or elusive. Patent scope is defined from the perspective of a PHOSITA, not that of an ordinary person. *See id*. at 1046-47.

[18] Merges & Nelson, *supra* note 3, at 842. "Property rights that are too narrow will not provide enough incentive to develop the asset, while overly broad rights will preempt too many competitive development efforts." *Id*. at 875. *See* MUELLER, *supra* note 2. There are different approaches to obtaining broad patent scope. The most obvious are (1) broad patent claim language that encompasses more than that actually invented and (2) the application of the doctrine of equivalents. Claim interpretation is another method of broadening claim scope. A broad claim interpretation increases the set of embodiments and processes that would be considered infringing under a patent. This is especially true in chemical patents, where equivalents are so readily available. Fixing the number of embodiments in a patent scope determination is another approach; patent owners are given greater power and leeway to contract and to disperse the patented discovery (particularly given the threat of infringement suits or declaratory judgment actions). *See infra* notes 233-36 and accompanying text.

[19] *See* Clarisa Long, *Side Bar: The Brouhaha Over Expressed Sequence Tags*, in CHISUM ET AL., PRINCIPLES OF PATENT LAW 725 (2d ed. 2001) (identifying claim scope as one of the most important aspects of biotech patents). *But see* Ronald Gilson, *Patent Breadth, Trade Secret Breadth, and High Technology Industrial Districts*, *available at* http://www.hertig.ethz.ch/LE_2003_files/Papers_and_Presentations/Gilson_High_Tech_Districts.pdf (last visited Feb. 26, 2005). Ronald Gilson contends that though much attention has been given to patent law and its definition of patent breadth through the patent scope instrument, trade secret law also indicates the same issues of breadth in trade secret protection of proprietary know how. *See id*.

[20] Though the other patent instruments play an important role in patent law, patent scope in the biopharmaceutical area is the focus of this article.

[21] *See* MUELLER, *supra* note 2, at 21.

[22] *See* Chairman of Federal Trade Commission Timothy J. Muris, Prepared Remarks

patentee an opportunity to recover costs of research and development encourages and stimulates research.[23] Though some view broad patent rights as having a detrimental effect on research and development, modern day research, particularly biopharmaceutical research, involves significant financial investments and commitment.[24] Accordingly, broad U.S. patent protection[25]

Before the American Bar Association Antitrust Section Fall Forum, *Competition and Intellectual Property Policy: The Way Ahead*, (Nov. 15, 2001) (transcript available at http://www.ftc.gov/speeches/muris/intellectual.htm); Carmen Matuttes, et al., *Optimal Patent Design and the Diffusion of Innovations*, 27 RAND J. ECON. 60 (1995); Chang, *supra* note 11, at 35. Some believe that great patent rights should be allowed "where the invention discloses a general principle or a new class of valuable chemical compounds." Karl-Hermann Meyer-Dulheuer, *Broad Patent Claims in Chemistry and Biotechnology*, *at* http://www.bio-patent.de/wmrc.pdf (last visited Feb. 2, 2004). Others argue that where gene patents are concerned, for example, broad patent rights will preclude additional research and the public will lose any potential benefit from developed and marketed products. Accordingly, narrow patent rights that will encourage and support research in the gene patent field are urged. "Current law . . . assume[s] that the normal scientific . . . development process should be rewarded by a patent; it is thus often possible to obtain a patent on almost any new product, although it may be a relatively narrow patent drafted around previous patents." John H. Barton, *Reforming the Patent System*, 287 SCIENCE 1933 (2000). The Supreme Court has defined a "pioneer invention" as "a patent covering a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art." Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 561-62 (1898). The Supreme Court has offered little direction, however, as to whether the historic pioneer invention doctrine has any place in the modern day patent protection analysis. Ted Baker, *Pioneers in Technology: A Proposed System for Classifying and Rewarding Extraordinary Inventions*, 45 ARIZ. L. REV. 445, 454 (2003). The Federal Circuit in *Texas Instruments* relegated the doctrine to an absence of prior art and not "a manifestation of a different legal standard based on an abstract legal concept." Texas Instruments. Inc. v. U.S. Int'l Trade Comm'n, 846 F.2d 1369, 1370 (Fed. Cir. 1988).

[23] *See* Blaise Zerega, *Keep Your Genes On, Gene Patenting Will Have Dangerous Repercussions for the Biotech Century, Warns the Economist Jeremy Rifkin*, RED HERRING, Apr. 1, 1999.

[24] *See infra* note 87 and accompanying text.

[25] *See* MUELLER, *supra* note 2, at 22 (noting that when a patented product is manufactured and sold domestically by a patent holder or his licensee, the American economy is stimulated and "this activity generates sales, creates jobs, and spurs investment"). *See also* Sahil Gupta, *The Problems Raised by Biotech Inventions for Patent Scope Interpretation*, *at* http://www.inter-lawyer.com/lex-e-scripta/articles/patent-scope.htm (last visited Feb. 26, 2005). Some posit that biotech in the United States has developed quickly as compared to other countries, particularly those countries that have not adopted patent law changes as quickly or readily as the United States. *See* Kieff, *supra* note 12, at 725-26 (citing OFF. OF TECH. ASSESSMENT, U.S. CONG., *Biotechnology in a Global Economy* (1991)); IAIN COCKBURN ET AL., PHARMACEUTICALS AND BIOTECHNOLOGY, IN U.S.

INDUSTRY IN 2000: STUDIES IN COMPETITIVE PERFORMANCE 363, 390 (David C. Mowery ed., 1999), *available at* http://www.nap.edu/openbook/0309061792/html/363.html (reviewing and explaining reasons for the relative performance of the United States biotechnology industry).

Expansive United States patent rights encourage the commercialization of patents in this country and tend to benefit companies holding important and broad patents. *See Geron's Stock Soars on Patent Grant*, AP ONLINE, June 10, 2003, *available at* 2003 WL 57304843 (indicating a sharp increase above the 52-week high upon the patent grant). The "Wall Street notion" is that broad patent protection is valuable. *See* Kathleen Madden Williams, *New Draconian Restrictions on U.S. Patent Scope* (June 2001), *at* http://www.palmerdodge.com/pdf/festo.pdf. The Federal Circuit's ruling in *Merck & Co. v. Teva Pharms. USA Inc.*, 2005 WL 181711 (Fed. Cir. Jan. 28, 2005), caused a ten percent one-day drop in Merck's shares. *See* Nicole Ostrow and Susan Decker, *Merck Shares Drop on Fosamax Ruling*, BLOOMBERG NEWS, Jan. 28, 2005, *available at* LEXIS, News Library, Allbbn File (noting the sharp decline in stock price after the court, reversing the district court decision, found Merck's patent claims to be invalid and, as such, allowing Teva to sell a generic version of the drug in early 2008).

A comparison of the U.S. and Japanese patent systems would find many differences, which incidentally leads to problems for American companies doing business in Japan. *See* Nancy J. Linck & John E. McGarry, *Patent Procurement and Enforcement in Japan – A Trade Barrier*, 27 GEO. WASH. J. INT'L L. & ECON. 411, 411 (1993-1994); Ames Gross, *Japanese Patent Law: An Introduction for Medical Companies* (Jan. 1998), *at* http://www.pacificbridgemedical.com/publications/Japanese_patent_law.pdf (last visited Feb. 26, 2005). The Japan Patent Office grants patents that are narrow in scope, while the American system tends to grant broad patents. *See id*. The doctrine of equivalents exists in Japan, but is rarely applied. *See id*. Further, Japanese courts generally limit patent scope to those embodiments found in the specification. *See id*. (stating that "courts generally assume that the inventor knows everything about the invention and therefore should know and protect against every potential infringement"). Comparatively, United States courts look to the "overall object of the invention . . . to interpret the disputed inventions" *Id*. (quoting TOSHIKO TAKENAKA, INTERPRETING PATENT CLAIMS: THE UNITED STATES, GERMANY AND JAPAN, 199-200 (1995)).

Japanese courts specifically limit patent scope to the "particular nuances of the effects of the invention mentioned in one or more examples in the specification." Marvin Motsenbocker, *Proposed Changes to Japanese and United States Patent Law Enforcement System*, 3 PAC. RIM L. & POL'Y J. 391, 403 (1995). *See* Gross, *supra*. The courts also review "broad, fundamental patent claims" based on required "descriptions in the specification that clearly demonstrate the defendant's invention is within the scope of the patent." *Id*. Due to the Japanese courts narrow view and interpretation of patent scope, the Japanese system is seen as a "weak" system of protection compared to that of the United States. *See id*. In comparison, the European system gives greater leeway in the drafting of claims. The European Patent Office has stated that "the mere fact that a claim is broad is not in itself grounds for considering an application as not complying with the requirement of sufficient disclosure unless convincing arguments are available against the scope of the invention as claimed." Meyer-Dulheuer, *supra* note 22.

or, in other words, a reward for the "services rendered"[26] is imperative.

B. Diffusion of New Technology

An obvious concern that accompanies patenting is the decrease in the amounts of goods available in the market to a consumer, given a patent holder's right to exclude others from making, using, or selling the patented technology.[27] The effect on the market is not only decreased supply, competition and choice, but also increased prices beyond reasonable expectations.[28] A patentee's control over new technology has a direct effect on future research and development of therapies and diagnostics.[29]

C. Predictability and Notice

One important aspect of patent law is that a patent serves notice to others of "clear and fixed" property rights.[30] Though scope at times is difficult to

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[26] MUELLER, *supra* note 2, at 25. Inventors have provided a valuable service to society and in return they are rewarded by society with exclusive rights to the invention. The hypothetical bargain is that a patentee must disclose information regarding a discovery in exchange for exclusive rights. The inventor has provided a service for which he should receive a reward from society. *See id.* Mueller indicates that a concern with the reward theory, which was seen as a concern in the Lockean theory, is that of accidental or "lucky" inventions. *Id*.

[27] *See id*. at 20; Paul E. Schaafsma, *An Economic Overview of Patents*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 241 (1997); Wenger, *supra* note 4 (stating "that right-to-sue [sic], over a longer period of time, is all you really get when you obtain a full-fledged patent").

[28] Since a patent holder can determine and set prices, they may not reflect the actual market price. Patents eliminate competition, which generally regulates market prices, potentially resulting in inflated pricing. *See generally* MUELLER, *supra* note 2, at 25. Deadweight loss is a loss of value due to the fact that those who value a product less than a monopoly price but greater than the cost of production opt not to buy a product, as compared to a competitive environment which would drive the price down to the cost of production, thus eliminating deadweight loss. *See* Aidan Hollis, *The Link Between Publicly Funded Health Care and Compulsory Licensing*, *available at* http://www.cmaj.ca/cgi/reprint/167/7/765.pdf (last visited Feb. 26, 2005); Paul Klemperer, *How Broad Should the Scope of Patent Protection Be?*, 21 RAND J. ECON. 113, 115 (1990), *available at* http://www.cepr.org/pubs/dps/DP392.asp; Schaafsma, *supra* note 27, at 249; MUELLER, *supra* note 2, at 20.

[29] *See infra* notes 199-207 and accompanying text.

[30] Michael F. Heim & Russell A. Chorush, *Patent Validity and Scope* 3, *at* http://www.conleyrose.com/documents/pat_val_and_scope.pdf (last visited Feb. 26, 2005). The United States Supreme Court articulated this more than a century ago in *White v. Dunbar*:

> Some persons seem to suppose that a claim in a patent is like a nose of wax which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words

define, it is important in providing clarity, efficiency, and predictability of patent rights.[31] Broad or unclear patents risk a decrease in competition and development by discouraging others from conducting research in a patented area or field. Once patents are issued, whether or not valid, they are viewed as "scarecrow[s]" that chill new research, development, and improvement in areas where the potential for infringement is uncertain.[32] Of particular concern in

express . . . . The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.

119 U.S. 47, 51-52 (1886).

[31] Predictability, both for patent owners and inventors, is paramount. It is "difficult [to] preserve expectations when frequently revising standards affecting the scope of patent coverage." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1374 (Fed. Cir. 2003) (Rader, J., concurring).

[32] *See* MUELLER, *supra* note 2, at 21; Chang, *supra* note 11, at 34. This also arises when patent holders refuse to practice technology themselves or withhold licenses to others. The refusal to license may be considered a violation of antitrust laws unless a valid justification exists. *See* Christopher R. Carroll, *Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences*, 2002 U. ILL. J.L. TECH. & POL'Y 435, 455 (2002). "[The] general right unilaterally to refuse to deal is a fundamental and well-recognized part of antitrust law." R. Hewitt Pate, *Address at the American Intellectual Property Law Association* 14, *available at* http://www.usdoj.gov/atr/public/speeches /200701.htm (last visited Feb. 26, 2005). Many see the role of the Department of Justice as one of influencing policy rather than limiting patent scope via antirust enforcement. *See* David J. Teece, *IP, Competition Policy, and Enforcement Issues*, Testimony Before the Fed. Trade Comm'n and Dep't of Justice (Feb. 27, 2002), *available at* http://www.ftc.gov /opp/intellect/020227davidjteece.pdf. As a result, society will not benefit from research and advancements which might otherwise have been developed. *See* MUELLER, *supra* note 2, at 21. This can also result in holdups:

> If a second firm can market its invention only with the consent of the patentee, the patentee can increase its profits by bargaining to license the complementary technology at less than full value. This hold up problem reduces R&D in complementary technologies by other inventors reducing the expected return on their investment . . . . For at least one firm, the private reward for its innovation will fall short of the social value of that innovation.

Chang, *supra* note 11, at 35. If claimed broadly, a patent may improperly dissuade future research and development. On the other hand, if patentees know rights will be defined and interpreted narrowly, this may help promote worthwhile research and reduce the possibility of infringement. As such, some view a reduction in the sheer number of patents issued as a necessary reform. Gary L. Reback, *Patently Absurd: Too Many Patents Are Just As Bad for Society as Too Few*, FORBES.COM, *at* http://www.forbes.com/asap/2002/0624/044_print.html (last visited Feb. 26, 2005) ("Economists . . . have started to question the USPTO's practices, finding little correlation, if any, between patent proliferation and patent invention. Economists have identified many situations in which patents invention. Economists have identified many situations in which patents actually retard the introduction of new

the biotechnology field is that research, if thwarted, may result in the waste or underutilization of research.[33] Though competition risks inefficiency, waste, and duplicative research,[34] there are serious dangers and risks to innovation if patentees are given exclusive control over a prospect.[35]

D. Development and Commercialization

Some view patents as a motivation for a patent holder to further innovate and improve a patented discovery.[36] This generally mirrors, and is recognized by antitrust law to parallel, the rights of a property owner to do whatever the

products."). *But see* Richard D. Nelson & Roberto Mazzoleni, *Economic Theories about the Costs and Benefits of Patents*, in INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY: SUMMARY OF A WORKSHOP HELD AT THE NATIONAL ACADEMY OF SCIENCES, FEBRUARY 15-16, 1996 (1997), *available at* http://www.nap.edu/readingroom/books/property/3.html (contending that patents induce disclosure and facilitate "wide knowledge about . . . inventions").

[33] *See* Kristi Coale, *Patents: Help or Hindrance?* (May 15, 1998), *available at* http://www.wired.com/news/technology/0,1282,12327,00.html (quoting Professor Michael Heller of the University of Michigan, who stated "[with a misuse of natural resources,] you can look out your window and see the pollution, but it's hard to see what the costs are when a drug isn't discovered"); Rai, *supra* note 11, at 833. Schumpeter's monopoly theory and Kitch's prospect theory risk this underutilization of resources. Merges and Nelson consider competition and rivalrous research important to prevent this underutilization. *See* Merges & Nelson, *supra* note 3, at 876-78.

[34] *See generally infra* note 177.

[35] *See* Gupta, *supra* note 25; James Bessen & Erik Maskin, *Sequential Innovation, Patents, and Imitation* 2 (Working Paper, Mass. Ins. of Tech., Jan. 2000) (noting the "standard economic rational for patents is to protect innovators from imitation and thereby given them the incentive to incur the cost of innovation). The Supreme Court has noted that patent laws have always tried to balance the need to promote innovation and the recognition "that imitation and refinement through imitation are both necessary to" a competitive economy. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 145 (1989).

Kitch would have research remain solely in the hands of the "prospector" or patentee who initially came upon the discovery. *See* Gupta, *supra* note 25. Nelson and Mazzoleni pose four threshold questions when addressing competition and innovation:

> Whether the presence or prospect of patents stimulates or interferes with technical advance in a field . . . . In what fields of technology are technical advances so strongly connected to one another, either temporally or in a system of use, that effective inventing today require access to prior inventions? What are the fields of inventing in which progress generally requires the effective interaction of a number of different organizations? Do patents in fact contribute to or hinder the access and cooperation needed for technical advance in such contexts

See Nelson & Mazzoleni, *supra* note 32.

[36] Rebecca Eisenberg notes the leverage a patent can grant, particularly to small research firms, in securing private capital and financing. *See id.* (identifying motivation for future invention and commercialization as two of four principal purposes of the patent system).

owner wishes with property – develop, sell, use, lease, refuse or grant access.[37] In his Prospect Theory, Edmund Kitch contends that the patent system should mirror early twentieth century mining rights: the first inventor to patent in a technological area should have the complete right to develop within the claims of his invention.[38] In some ways, Suzanne Scotchmer echoes Kitch's view and believes in strong patent rights given the positive effect that patents have on early innovation.[39] Joseph Schumpeter's view of innovation, however, differs

[37] *See* Carroll, *supra* note 32, at 456. The right to refuse to license, to solely develop, and to exclude others from patented material is "fundamental to the patent grant." *Id*. This was a concern in the area of embryonic stem cell patents held by WARF and licensed to the Geron Corporation. WARF technically has the right to refuse to license and sell the ESC lines, and Geron, depending on the terms of its confidential license agreement with WARF, may suppress the ESC technology or may refuse to sublicense. *See id*. at 456. *But see* Andrew Pollack, *"Politically Correct" Stem Cell Is Licensed to Biotech Concern*, N.Y. TIMES, Dec. 11, 2002, § C, at 8, *available at* LEXIS, News Library, Nytimes File (indicating Geron's invitation to work with collaborators). WARF may wish to grant commercial licenses, or if it chooses, to wait for market changes to increase the possibility of additional investors. *See* Carroll, *supra* note 32, at 456. If WARF or Geron refused to share the technology, some feel the market would likely solve the problem. *See* Q. Todd Dickinson, Statement before the Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies (Jan. 12, 1999). It is posited that "a monopolist frequently has more to gain by licensing with restrictions than refusing to license altogether." Dana W. Hayter, *When a License is Worse than a Refusal: A Comparative Competitive Effects Standard to Judge Restrictions in Intellectual Property Licenses*, 11 BERKELEY TECH. L.J. 281, 283 (1996). The rationale for this position is simple: if a party is refused access to patented technology, such party may be inspired to "invent around or leapfrog" a patent. *Id*. at 284.

[38] Kitch posits that inventors have "a variety of resources . . . to develop a known technological possibility." Kitch, *supra* note 11. Chang echoes Kitch and would seek broad patent rights for the inventor of a discovery with what appears to have a low social value in a field where "stepping stone" improvements will inevitably arise. *See* Chang, *supra* note 11, at 34. Kitch regards patents as the modern day parallel to 19th century mining claims in America, where the first to arrive received exclusive mining rights to a particular territory or property within a claim. *See id*. at 21; Kitch, *supra* note 11. Kieff echoes Kitch's view that patent holders should have the right to develop their property rights:

> An owner by virtue of his power to exclude others can generally count on realizing the rewards associated with husbanding the game and increasing the fertility of his land . . . . Without the property right acting to concentrate benefits and costs on owners, too few individuals will invest in making use of inventions to bring them to commercial fruition.

Kieff, *supra* note 12, at 725. Kieff asserts that the argument that property rights in inventions will slow future inventions or innovation is illusory at best, as evidenced by the numerous markets which exist for patented inventions. *See id.*

[39] *See* Suzanne Scotchmer, *Should Second Generation Products be Patentable?* 27 RAND J. OF ECON. 322-31 (1996).

a bit from that of Kitch. Schumpeter believes that the "major engines of innovation" are those companies with monopoly power.[40] According to Schumpeter, monopoly profits provide security, and such security provides the freedom to innovate.[41]

E. Disclosure

Disclosure is the infamous, hypothetical "bargain," or quid pro quo,[42] that is constantly referred to in patent law. In lieu of trade secrecy, a patentee opts for a period of exclusive use in exchange for disclosing how to make and use the invention.[43] This resulting disclosure is deemed socially beneficial. Learned Hand once described this as "a condition upon the inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly."[44] In the United States, patent protection is guaranteed to the first party to invent.[45] Conversely, with trade secrecy, an inventor "lives in constant peril of discovery and disclosure."[46] A patent system encourages parties to disclose by providing an "economic incentive" to overcome the attractions of trade secrecy.[47]

F. Patents and Contracts

Patent rights generally make contracting easier. One opting for trade secrecy protection has great difficult contracting with others for fear of

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[40] Rai, *supra* note 11, at 818.

[41] *See id*. Schumpeter believes that monopoly power also helps entities more fully reap the benefits of their efforts by controlling the diffusion of patented knowledge to competitors. *See id*. The example of Federal Express's overnight shipping industry, however, defies this notion. *See infra* note 76. Fritz Machlup, in 1958, summarized economists' view of the patent system, which was in part unfavorable because it generally leads to monopolies and because patents were not necessary to encourage innovation. *See* Nelson & Mazzoleni, *supra* note 32.

[42] *See* MUELLER, *supra* note 2, at 26; Nelson & Mazzoleni, *supra* note 32 (identifying disclosure as one of four principal purposes of the patent system).

[43] For a general discussion of trade secrecy and the desire for inventors to opt for patent protection instead, see Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987). Eisenberg also notes, however, that patent protection is not ideal. *See id*. (indicating that patent protection can slow the pace of information dissemination and interfere with access or use of such information).

[44] Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516, 520 (2d Cir. 1946).

[45] This differs from the "first to file" system that exists throughout the world.

[46] MERGES, *supra* note 5, at 11.

[47] *See* MUELLER, *supra* note 2, at 26.

disclosure or eradication of the trade secret.[48] Patenting, on the other hand, allows patentees to freely enter licensing agreements and to contract for royalties and rents. Schumpeter would support this theory, as a patent "monopolist" would be able to procure rents to fund additional research in the area.[49]

IV. PATENT SCOPE GENERALLY

Determining patent scope is decisive in determining patent rights. Different interpretations of scope promote different objectives. Granting broad patent scope encourages research and development of pioneer inventions, or of biopharmaceutical or orphan drug discoveries, which require great incentive and motivation.[50] Further, broad scope promises broad patent rights and encourages patentees to opt for patent protection rather than trade secrecy protection. Patents with narrow scope are not flawless,[51] but ensure greater

[48] "Once the information has been disclosed outside a small group . . . it is extremely difficult to control." MERGES, *supra* note 5, at 11. Kenneth Arrow describes information as a public good which is difficult to control and prevent others from using. *See id*.

[49] *See* Carroll, *supra* note 32, at 456. A patent holder can freely license and determine the terms of such licenses. The risk, of course, as discussed above, is that a patentee will choose not to license and that innovation, substitution, and "inventing around" will be stunted. *See supra* note 33 and accompanying text; *infra* notes 71-73 and 192 and accompanying text (discussing the potential for underutilization of resources). *But see* Nelson & Mazzoleni, *supra* note 32 (noting Fritz Machlup's study of economists whose general view was that patents are not needed to encourage innovation). This risk is further amplified as nothing guarantees a monopolist will invest the generated rents into further research on this field.

[50] *See infra* notes 87-88 and accompanying text. Broad patent rights are usually granted through generous claim interpretation or application of the doctrine of equivalents. Though broad patent rights are often frowned upon, certain benefits may exist. In a research situation, even one that is upstream, a few broad patents in a given area require only one or a few licenses and avoid an anticommons tragedy. *See infra* notes 192-95 and accompanying text. Some believe, however, that the United States Patent and Trademark Office ("PTO") has granted patents that are too far reaching and that favor only those large companies financially able to fight for expansive patent rights. *See* Redherring.com, *Patents, Long the Tech World's Currency, Come Under Attack*, (Apr. 19, 2002) http://www.redherring.com /Article.aspx?a=8160. Additionally, during delays between patent filing and issuance in the biotech field, patentees commonly work to enlarge their scope of protection. While a patent is pending, companies and universities are entering licensing agreements and obtaining financial investments, even though no rights have yet been granted. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698-701 (1998). This adds to the problem of vague patent scope and can serve to discourage others from competing or conducting research. *See supra* note 32 and accompanying text.

[51] A plethora of narrow rights often results in an anticommons tragedy. "[P]rivate

predictability of a patentee's rights, notice to subsequent inventors, and diffusion of technology.

Since the early 1980s, courts and legislatures have been expanding intellectual property rights.[52] As a general proposition, courts generally grant extraordinarily broad patent protection for those inventions that are deemed to require broad rights.[53] The risk is that "[a] patent monopoly . . . may be felt to be abusive if the protection it confers is so broad that it goes beyond the actual invention made."[54] In the past, however, the Patent and Trademark Office ("PTO") has granted broad patent claims which preempt broad areas of research.[55] Granting broad patent scope, according to Rai, increases the patent holder's right to exclude and is harmful as a whole.[56] Broad scope may also limit use of the patented invention[57] and decrease societal benefits by reducing improvements and innovation in the patented area.[58] Accordingly, some argue that the patent system should "prevent hoarding and speculation" and limit the breadth of patents.[59] At the same time, the system must balance this policy objective with the patent holder's rights and with the notion that "a patent must not be so narrow as to deprive a patentee of a just reward for making the invention available to the public with all its details."[60]

Though our patent system is a "one size fits all" system and does not have different express standards for various technologies,[61] patent scope has come to

property emerges less successfully in resources . . . with the most divided ownership." Michael Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 630 (1998); *infra* notes 192-95 and accompanying text.

[52] *See* Muris, *supra* note 22. The National Academies of Science (NAS) has started a review of intellectual property rights in the knowledge-based economy. *See id.*

[53] *See* Chang, *supra* note 11, at 36. Some describe the court as bending rules or "crafting a different kind of patent law" to fit specific industries. *See* Burk, *supra* note 1, at 11. *But see infra* notes 240-41 and accompanying text (discussing the appropriate role of courts and Congress in patent law and patent scope determination).

[54] Meyer-Dulheuer, *supra* note 22.

[55] *See* Barton, *supra* note 22.

[56] *See* Rai, *supra* note 11, at 823; *supra* notes 66-75 and accompanying text. It has been argued that this right to exclude will "clog social ordering and bargaining around inventions." *See* Kieff, *supra* note 12, at 717.

[57] *See* Kieff, *supra* note 12, at 717; *supra* note 33 and accompanying text; *infra* notes 71-73 and 192 and accompanying text (discussing unused or underused resources).

[58] *See* Meyer-Dulheuer, *supra* note 22; *supra* note 33 and accompanying text; *infra* notes 71-73 and 192 and accompanying text (discussing underutilization of resources).

[59] Merges & Nelson, *supra* note 3, at 871-74.

[60] Meyer-Dulheuer, *supra* note 22.

[61] *See* Burk, *supra* note 1, at 2; Burk & Lemley, *supra* note 1, at 1156; Comm'n on Intell. Prop. Rights, *Final Report* (Sept. 12, 2002), *available at* http://www.iprcommission.org /graphic/documents/final_report.htm (last visited Feb. 26, 2005) (indicating "the patent

be largely dependent on the technology at issue.[62] The Federal Circuit actively tailors patent law and policy to the technology under consideration.[63] This new approach is viewed as having "a significant impact" on advances in technology and various industries.[64] Some believe the market, rather than the courts, should decide the scope of the monopoly power conferred by the patent system as "market pressures, are likely to substantially limit the real monopoly power one might otherwise expect to be conferred by IP rights."[65]

Discussions of the patent system and patent scope are particularly important in the context of cumulative innovation. Some argue that cumulative research is incompatible with the current patent system.[66] "[T]he jury is still out" on

system has uniform criteria to judge patent applications, [yet] the pattern of technical progress may vary significantly in different fields"). *But see* Burk & Lemley, *supra* note 9, at 1577 (indicating that "patent law is actually as varied as the industries it seeks to foster"); Burk & Lemley, *supra* note 1, at 1155 (noting that "[f]undamental shifts in technology and in the economic landscape are rapidly making the current system of intellectual property rights unworkable and ineffective").

[62] *See* Merges & Nelson, *supra* note 3, at 894 (noting the difference in protection afforded to the pharmaceutical industry and that afforded to the computer software industry). Others contend that in the biotech and software industries, patents are all too often overbroad and this can inhibit improvements and innovation. Muris, *supra* note 22 (noting the some observers assert that "all too often, important patents-especially in biotechnology and software-are overbroad and that overbroad patents can inhibit follow-on innovation.") *See* Suzanne Scotchmer, *Standing on the Shoulders of Giants*, 5 J. ECON. PERSP. 29 (1991); Burk, *supra* note 1, at 11-13 (noting that biotechnology has been required to strictly fulfill the requirements of section 112, namely enablement and written description, but held to a low obviousness standard). *Compare id*. (noting that the software industry is excused from section 112 enablement and best mode requirements but has strict obviousness standards); Burk & Lemley, *supra* note 1, at 1185 (disagreeing with the notion that any differences are merely case-specific differences rather than distinctions based on industry). Broad patent scope has lead to great patent power in the biopharmaceutical industry.

[63] *See* Burk, *supra* note 1, at 11 (indicating that the treatment of biotechnology and software in patent law is proceeding in different directions); Burk & Lemley, *supra* note 9, at 1681-82 (arguing that the current patent system gives the judiciary discretion to tailor the law to a specific industry through flexible standards, or "policy levers," and indicating that disclosure, obviousness, and the doctrine of equivalents are three such levers in the biotechnology field).

[64] Merges & Nelson, *supra* note 3, at 887.

[65] R. Polk Wagner, *Information Wants to be Free: Intellectual Property and the Mythologies of Control*, 103, COLUM. L. REV. 995, 1013 (2003).

[66] "The patent system fits best a model of progress where the patented product, which can be developed for sale to consumers, is the discrete outcome of a linear research process." *Final Report*, *supra* note 61 (indicating as examples of the linear research process the razor, ballpoint pens, and pharmaceuticals).

what is the most effective scheme for cumulative innovation.[67] Economists that study cumulative invention have different views on what is most effective and desirable. According to Kitch, allowing only the original patentee to engage in cumulative and later innovation of a patented discovery increases the incentive for new improvements as resources will be allocated efficiently.[68] Schumpeter agrees with Kitch to the extent that a monopolist should be allowed to exercise the subject of a monopoly completely and without interference.[69] Likewise, Chang desires broad patent rights for an original inventor at both ends of the spectrum, both for those discoveries with extremely high social value as well as those which have low social value but are in an area where improvements are likely.[70]

Merges and Nelson do not agree that an inventor should have the sole right to utilize and exploit a patented discovery.[71] Since follow-on efforts of other inventors could result in improvements or substitutes that are significantly better than the patented technology, broad patents run the risk of discouraging useful research.[72] Merges and Nelson acknowledge that competition may at

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[67] Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When is it the Best Incentive System?* 2 INNOVATION POL'Y AND THE ECON. 51, 69 (2002).

[68] *See* MUELLER, *supra* note 2, at 21 n.60 (suggesting that Kitch viewed technological innovation as "a variety of resources [that] are brought to bear on an array of ['']prospects['] or ['']particular opportunities to develop a known technological possibility['']"); Kitch, *supra* note 11 (suggesting a theory where a single entity dominates a technological prospect and shares and develops the technology through well considered license agreements).

[69] *See* Gupta, *supra* note 25; Rai, *supra* note 11, at 819.

[70] *See* Chang, *supra* note 11, at 34; Nelson & Mazzoleni, *supra* note 32 (recognizing that patented inventions with potential for future improvement or innovation make the effects of broader patent scope more "complicated").

[71] *See* Merges & Nelson, *supra* note 3, at 876-78.

[72] *See* Carrie Conway, *Too Much of a Good Thing Can Be Bad*, 13 FED. RESERVE BANK OF BOSTON REG. L REV., 2003, at 10, 18 (indicating that improvements in drugs, for example making a drug more effective or reducing its side effects, is welcome and increases competition which can serve as an internal check on drug prices). Merges and Nelson posit that as people see things differently, they likewise approach opportunities differently. Prospects must be available, they argue, to a "variety of minds" to fully develop them. Merges & Nelson, *supra* note 3, at 870; *see* Gupta, *supra* note 25. Kitch maintains that the holder of upstream patent rights will enter licensing agreements with a number of researchers, each of whom might pursue a different research path. *See* Kitch, *supra* note 11; *see also* Merges & Nelson, *supra* note 3, at 842 (contending that though a patentee may fully develop and innovate a "prospect" as Kitch would have it, other aspects protected by a broad patent or avenues for licensing may simply be over looked by the patentee); *Final Report*, *supra* note 61; Nelson & Mazzoleni, *supra* note 32 (noting that "there might be very high social costs to granting a broad initial patent that gives monopoly rights to exploration of the prospect."). *See generally* Scotchmer, *supra* note 62. Merges and Nelson argue that companies fail to aggressively act and develop with respect to patented technology, and

times be inefficient, wasteful, and duplicative.[73] While Kitch's view may appear to reduce duplicative research, such duplication can directly lead to new and important innovations.[74] In response to Schumpeter's monopoly view, Merges and Nelson argue that when firms broadly control a given area of technology, they become relatively comfortable and cease to invent or innovate until an outside threat is posed.[75] As such, Schumpeter's view that monopolies are desirable so that patentees may generate rents for further innovation is less convincing.[76]

Some believe that greater patent protection should be granted to important inventions having high social value.[77] Howard Chang puts forth the converse and interesting theory that patent law should grant broad patent protection not only to important, socially valuable inventions, but also to inventions which in and of themselves may have little to no social value but have great potential for future improvement by others.[78] Chang's position on granting broad patent

citing the broad Edison patent as the "best example" of such delay. *See* Merges & Nelson, *supra* note 3, at 884-87. This could also be said of an expansive application of the doctrine of equivalents. Assuming *arguendo* an inventor fully develops a claimed prospect, Merges and Nelson posit that licensing is not efficient as Kitch suggests but is both impractical and expensive. *See id*. at 872-75.

[73] *See* Merges & Nelson, *supra* note 3, at 876-78.

[74] *See* Gupta, *supra* note 25.

[75] *See id*.; Nelson & Mazzoleni, *supra* note 32 (suggesting that "not much happens" when a few control the inventive effort in a field); Burk, *supra* note 1, at 8 (pointing out that due to development and FDA oversight, and the fact that complexities arise in human use and testing, biopharmaceutical research is often characterized by rapid discovery but slow innovation and commercial process); Rai, *supra* note 11, at 822 (explaining that patentees in the biopharmaceutical sector take years in developing a product); Bessen & Maskin, *supra* note 35, at 2-3 (arguing that in the context of cumulative invention, imitation is a motivation and broad patent protection impedes development). *Cf*. *Final Report*, *supra* note 61 (identifying computer software and gene sequencing involve incremental improvements on existing technology and involve little creativity).

[76] *See infra* notes 164-65 and accompanying text (indicating that large pharmaceutical companies are hardly short of money and that a majority of their budgets are funneled not toward R&D but toward advertising, marketing, and the like).

[77] *See* Chang, *supra* note 11, at 34 (agreeing that broad patent protection should apply to inventions with high social value). Others still believe that patent rights are not even needed to stimulate innovation. Federal Express's overnight shipping industry is a good example of the ability of an industry to develop without patent protection. Federal Express did not seek patent protection on the overnight delivery business method. Competitors jumped to innovate, as is well evident today. As such, this "first-mover advantage" led to more effective innovation in this area than a patent would have. MUELLER, *supra* note 2, at 25.

[78] *See* Chang, *supra* note 11, at 34 (arguing that it is difficult to determine the value of a patented invention and when a patentee attempts to do so, he often overvalues or undervalues an invention). *See generally* O'Reilly v. Morse, 56 U.S. 62 (1853) (serving as

protection to discoveries with little value but great room for improvement is highlighted by his primary concerns with duplicative research[79] and trade secrecy.[80]

V. THE BIOPHARMACEUTICAL INDUSTRY TODAY

The pharmaceutical market is stronger today than ever before. According to Dr. Isaac Schiff, Chief of Obstetrics and Gynecology at Massachusetts General Hospital in Boston, Massachusetts, "most people . . . are taking something every day."[81] Worldwide retail drug sales in 2003 totaled $317 billion,[82] more than half of which was accounted for by the pharmaceutical industry in the United States,[83] primarily by large U.S. pharmaceutical companies.[84] Some view this growth as undesirable and claim that the pharmaceutical industry has

an example of the failure to realize the full potential of an invention). *See* Rai, *supra* note 11, at 832; *supra* note 33 (acknowledging Rebecca Eisenberg's point that there is reason to be concerned even when low-value transactions do not go forward) and accompanying text; *supra* notes 72-74 and *infra* note 192 and accompanying text (discussing risks of thwarted research and underutilized resources); Brenner v. Manson, 383 U.S. 519, 536 (1966) (recognizing the importance of granting protections to inventions that may "now seem without use").

[79] *See* Chang, *supra* note 11, at 52 (arguing that without broad patent protection, original inventors and subsequent improvers will hesitate to patent their innovations, thus leading to "duplicative research").

[80] *See id.* (asserting that narrow or weak patent protection may encourage trade secrecy for fear of others monopolizing on a discovery with insufficient protection).

[81] James Gorman, Essay, *The Altered Human Is Already Here*, N.Y. TIMES, Apr. 6, 2004, at F1. Pharmaceuticals are changing the landscape of society and mankind much as computers did. *See id.* There is also a noticeable change from over-the-counter medications to prescription medicines. In 1954, the two highest selling drugs were Bufferin and Geritol. *Id.* The prescription drug business, by comparison, was "tiny." *Id.*

[82] *See* Gorman, *supra* note 81; Elise Ludwig, *Life on the Fat Pharma*, PHILA. WEEKLY, Dec. 5, 2001, *available at* http://www.philadelphiaweekly.com/view.php?id=1224 (emphasizing that the pharmaceutical industry is the most profitable industry in the United States).

[83] *See* Gorman, *supra* note 81 ("In the United States alone, consumers spent $163 billion on drugs."). In 1954, Johnson & Johnson had annual revenues of $204 million. *See id.* (citing a study by IMS Health). Today, Johnson and Johnson has revenues of approximately $36 billion. Topping the list of pharmaceuticals, by class, are cholesterol-reducing drugs, drugs to prevent gastrointestinal and digestive problems, and antidepressants. *See id.*

[84] *See* Matthew Herper, *The Best-Selling Drugs in America*, FORBES, Feb. 18, 2004, *available at* http://www.forbes.com/2004/02/18/cx_mh_0218ims_print.html (noting that of $216 million in 2003 U.S. drug sales, 60% of that came from the top ten drug manufacturers); F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 106 (1993) (noting that more than half of the profits of the pharmaceutical industry came from the top ten drugs).

taken "behaviors and physiological changes that were once simply aspects of life [and] medicalized [sic]" them, turning them into "syndromes or diseases."[85] Setting aside the obvious commercial behemoth the industry has become, "[b]y and large . . . the pharmaceutical road is paved with pretty good intentions."[86] Some welcome the great innovation and development taking place in the biopharmaceutical industry, an industry in which research is characterized as risky, lengthy and expensive.[87] This research has been

[85] Elyse Tanouye et al., *Genetic Giant: Glaxo and SmithKline Give Stock Markets Shock Treatment*, WALL ST. J. EUR., Feb. 3, 1998 at 1. *See* BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS, Rep. of the Pres. Council on Bioethics, at 305 (Oct. 2003), *available at* http://bioethics.gov/reports/beyondtherapy/beyond_therapy_final_report_pcbe.pdf (stating that "aspects of human life that formerly had little to do with doctors and hospitals: childbirth, infertility, sexual mores and practices, aspects of criminal behavior, alcoholism, abnormal behavior, anxiety, stress, dementia, old age, death, grief and mourning"); *see also* Gorman, *supra* note 81 (noting an increase in the use of drugs "for baldness, incontinence, sexual performance and the effects of menopause").

[86] *See* Gorman, *supra* note 81. *But see infra* note 230.

[87] *See* Rai, *supra* note 11, at 822; Rai, *supra* note 14, at 1129 (indicating that patent protection is necessary in biopharmaceutical research given the expensive research and development process). It is said it takes more than a decade and capital in the several hundred millions of dollars to commercialize one drug. *See* Kieff, *supra* note 12, at 724; STANDARD & POOR'S IND. SURVEYS: BIOTECHNOLOGY, Aug. 28, 1997, at 16-17 ("[M]ost new products cost between $200 million and $350 million to fully develop"); Robert Cook-Deegan, *Government Policy and the Commercial Value of Academic Information*, AAAS SCIENCE AND TECHNOLOGY POLICY YEARBOOK 273, 280 (2000), *available at* http://www.aaas.org/spp/yearbook/2000/ (indicating that it takes pharmaceutical companies ten years to develop and commercialize a drug); Veronica Henry, *Problems with Pharmaceutical Regulation in the United States: Drug Lab and Orphan Drugs*, 14 J. LEGAL MED. 617, 617 (1993) (reporting that it costs "approximately $231 million and takes approximately ten to twelve years to develop a new drug in the United States"); Alan Walton, *The Annual State of the Biotech Industry Address: Walton's Words of Wisdom*, BIOVENTURE VIEW, Jan. 1, 1998, *available at* 1998 WL 9219211 ("On average, it takes a new drug 6.1 years in discovery, 6.9 years in clinical development, and 2.3 years waiting for FDA review before approval."); John Gapper, *The Painful Cure for Big Pharma*, FIN. TIMES, Dec. 9, 2003, at 23 (indicating that by the time a drug goes to market approximately half of its patent life remains); Burk & Lemley, *supra* note 9, at 1590 (noting that biopharmaceutical and biotech patent prosecution takes a much longer time than does the prosecution of patents in other fields). Biopharmaceutical research is a risky proposition. *See* Raymond Van Dyke, *Biotech Growth in 2003: The Catalysts For Success*, WASH. BUS. J., Mar. 3, 2003, *available at* http://www.washington.bizjournals.com/washington/stories/2003/03/31/focus6.html (noting that only a few products are marketable and all of those do not make it through the FDA regulatory process); Conway, *supra* note 71, at 12 (noting that only approximately 10% of drugs make it to the human testing stage and only a small fraction of those make it to market).

stimulated in large part due to strides in human gene research.[88] The need to clarify the scope of patents in this industry is an important one to encourage future research and investment. Research in this field is risky, expensive, and lengthy enough, without the added burden of scarecrow patents and infringement suits.[89]

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[88] *See* Tanouye, *supra* note 85 (noting a large upsurge in scientific development due to advancements in human gene research); Rebecca S. Eisenberg, *Will Pharmacogenomics Alter the Role of Patents in Drug Development?* 3 PHARMACOGENOMICS 571-74 (2002) (indicating the importance gene research will play in determining patient respond to drugs and in obtaining regulatory approval).

Gene patenting is the patenting of a process that involves DNA or a DNA-related substance. *See* American Medical Association, Gene Patenting, *at* http://www.ama-assn.org/ama/pub/category/2314.html. (last visited Feb. 26, 2005). It has been estimated that as of 2003 the PTO had granted 6,000 gene patents, with thousands more pending. *See* Kim Coghill, *Issue of Patenting Genes Still Troubling for Biotech Industry*, BIOWORLD TODAY, June 25, 2003, *available at* 2003 WL 6613422. Reminiscent of Kitch's mining rush, Celera Genomics had filed patents on more than 10,000 human genes, Human Genome Sciences on 7,500 gene sequences, and Incyte Genomics had 7,000 patents on genes pending. *See* Tom Abate, *Call it the Gene Rush – Patent Stakes Run High*, S. F. CHRON., Apr. 26, 2000, at A8. The emerging gene and gene-related patent thickets and anticommons concerns are obvious. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, INNOVATION POLICY AND THE ECONOMY, 3 (Adam Jaffee et al., eds. 2001). These concerns are amplified given the constant race of competitor inventors to the patent office.

Some argue that patents serve as incentives and encourage disclosure. *See* John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689, 690 (1998) (indicating that patents are needed to attract investment and promote disclosure). Query, however, whether this disclosure is simply theoretical, as the sheer number of gene patents essentially precludes the use of any of the disclosed information by researchers unless multiple licenses and permissions are obtained.

In the context of gene fragments, Heller and Eisenberg note the "widespread intuition that issuing patents . . . makes little sense." Heller & Eisenberg, *supra* note 50; *see* Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVIEWS GENETICS 803 (2002) (indicating the issue of gene patents is detrimental to health care and biomedical research). It is argued that patents on genes or receptors will wall off entire fields of research without generating any marketable product development. *See* Gupta, *supra* note 25. Similarly, in *Ex Parte Fisher*, the USPTO Board of Appeals affirmed the PTO's rejection of claims to expressed tag sequences, or ESTs, because they lacked section 101 utility and were not enabled as required by section 112. Appeal No. 2002-2046, *available at* http://lorac.typepad.com/patent_blog/files/fisher_est_sequences.pdf. The Federal Circuit will hear arguments, and rule, on the patentability of ESTs in early 2005.

[89] Encouraging biopharmaceutical research and development is a social benefit and should be encouraged. *See generally* Gorman, *supra* note 81 (noting some areas in which the biopharmaceutical industry will grow: "drugs to improve male sexual performance, anti-Alzheimer's drugs, and drugs for incontinence and osteoporosis" and noting other areas

Patentable drug discoveries can include a new use for or an improvement on an old product, finding a purer version of an existing product, or an accidental discovery.[90] Often, these uses are unforeseeable at the time of invention or patent application.[91] Merges and Nelson contend that these types of research should be encouraged and rewarded, but also acknowledge that the PTO is "struggling with how to do this."[92] The issue of scope in the context of biopharmaceutical and biotech research arises in numerous situations. For example, part of the debate in this area is whether these discoveries should be allowed the dual protection of both product and process patents,[93] which some

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where drugs would become "best-sellers" are "psychostimulants, and anti-obesity drugs" and drugs "that increase intelligence and greatly improve memory").

Traditional patent rights are not the only protections for pharmaceuticals. Orphan drugs are drugs that treat rare diseases. Congress amended the Food Drug and Cosmetics Act to promote research and development of these drugs. The Orphan Drug Act of 1983 ("ODA") created a mini-patent of sorts for orphan drugs. Congress announced its findings that:

> because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss . . . . [Further,] there is reason to believe that some promising orphan drugs will not be developed unless changes are made in applicable Federal Laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs.

Robert A. Bohrer & John T. Prince, *A Tale of Two Proteins: The FDA's Uncertain Interpretation of the Orphan Drug Act*, 12 HARV. J .L. & TECH. 365, 366-68 (1999).

Under the ODA, a manufacturer of an orphan drug which obtains FDA approval in effect receives a seven-year exclusive right to commercialize the drug. *See id*. at 414. *See also* Genentech v. Bowen, 676 F. Supp. 301, 313 (D.D.C. 1987). The seven year period of exclusivity parallels the grant of patent protection under the doctrine of equivalents. Problems only arise in the orphan drug context when a "competitor seeks to serve the same population as an approved orphan drug." Bohrer & Prince, *supra*, at 403. The FDA makes the same type of determination regarding the second company's drug as would a court in determining patent infringement under the doctrine of equivalents. Courts initially applied a much narrower interpretation to the ODA protection than it would in patent law but later resolved the matter by interpreting ODA protection in a manner similar to the current patent system. *See id*. at 414. The initial difficulty was due in large part to the significant discretion given to FDA officials in determining appropriate protections under the ODA. *See id*. at 412.

[90] *See* Merges & Nelson, *supra* note 3, at 903.

[91] *See id*. This mirrors generally pioneer inventions, as an inventor may not always initially appreciate the full benefit of the pioneer invention.

[92] *Id*.

[93] *Id*. at 903. Merges and Nelson submit that it is the process, rather than the product, which the inventor discovered. *Id*. Where an inventor has discovered a new use for an existing product, some feel the general solution would be to award a process patent. *Id*. (citing Rohm & Haas Co. v. Roberts Chems., Inc., 245 F.2d 693, 699 (4th Cir. 1957)). In

fear will result in very broad patents.[94]

VI. PATENT LAW DOCTRINES

Patent law doctrines ultimately set the scope of a patent. Patent scope is determined in large part through a patentee's written description, as limited by existing prior art, novelty, and obviousness limitations.[95] It is imperative to determine the claimed subject matter, or the proverbial metes and bounds, of the patented invention in order to determine a patentee's rights under § 271(a).[96] As such, claim construction, the interpretation of patent claims and

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the chemical field, a common discovery is to improve the purity of a substance or to find a way to decrease the production costs by inventing synthetic versions of natural substances. *See id*. at 904.

[94] *See id*. Some view this as double patenting. In *In re Wands*, the Federal Circuit held that in order to claim a process, one must enable all of the elements and components to perform such a process. This prevents inventors from patenting both the process and the product itself. 858 F.2d 731, 733, 740 (Fed. Cir. 1988) (holding Wands did adequately enable and that the patent did not require undue experimentation).

[95] *See* 35 U.S.C. §§ 112, 102(b), 102(a), and 103 (2000). *See generally* Burk & Lemley, *supra* note 1, at 1182, 1185-86 (noting that "patent scope is a function of the obviousness and written description requirements and that a PHOSITA is used to "calibrat[e] the legal standard for patent disclosure").

[96] The United States patent laws provide a patent holder the right to exclude others from practicing the subject matter of the patentee's patent. Section 271(a) of the Patent Laws provides: "Except as otherwise provided . . . whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271 (2000). In other words, a patent holder has the right to prevent others from making, using, or selling the subject matter of the patent during the term of patent protection. Clearly, it is crucial that one know what the patentee's rights are in order to determine whether an accused product or process infringes such rights.

This mirrors the protections granted by section 106 of the Copyright Act. In particular, section 106(1) provides the copyright holder with the exclusive right to reproduce the copyrighted work. 17 U.S.C. § 106(1) (2000). As such, a copyright holder may prevent others from reproducing or selling such work without exclusive permission from the copyright holder. *Id*. ("[T]he owner of a copyright . . . has the exclusive right to reproduce [and authorize the reproduction of] the copyrighted work."). Though copyright and patent law mirror one another in this respect, they diverge greatly when it comes to using the protected subject matter. Patent law forbids the use of the patented invention without exclusive permission of the patentee, while under copyright law many people are free to use the copyrighted work.

Patents are interesting in that individuals play a role in declaring the breadth of their patent rights by drafting their own patent claims. Patents are "delegated rulemaking" and the scope and frequency of such rulemaking is constantly expanding and growing, now reaching previously untouched areas such as aesthetics, business skills, and one's talents. John R.

scope at trial by a judge, sets patent scope and influences the jury in its determination of infringement.[97] A patentee's rights may also be broadened by courts through the doctrine of equivalents or, in the case of biopharmaceuticals and generic drugs, by congressional mandate.

A. Written Description, Claim Construction, and Infringement

Patent claims are one of three major requirements of § 112 of the U.S. Patent Laws. Section 112 requires a written description, an enabling disclosure sufficient to enable a person having ordinary skill in the art ("PHOSITA") to make the invention, and claims defining the exact subject matter claimed by the patent.[98] One of the most obvious benefits of § 112 is the knowledge

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Thomas, *Liberty and Property in the Law*, 39 HOUS. L. REV. 69 (2002). According to Rai, the central question does not concern the subject matter of the patent, instead, the question is how should the scope of the patent be defined. *See* Rai, *supra* note 11, at 840.

[97] *See* Rai, *supra* note 14, at 1045 (noting that claim construction defines patent scope). Claim construction sets the standard by which literal infringement under 35 U.S.C. § 271(a) is determined. Patent infringement is a question of law and fact. The judge must first construct claims, and a jury then determines whether an accused device directly infringes upon the patent claims either literally or nonliterally under the doctrine of equivalents. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448 (Fed. Cir. 1998) (en banc).

Claim construction follows several canons, which include: claim terms should be afforded consistent meaning, a term should be given the same meaning in different patent claims, a claim cannot be given a narrow interpretation to distinguish a claimed invention from prior art then given a broader one to establish third party infringement, and it is presumed that each claim of a patent conveys a different meaning. *See Markman*, 517 U.S. at 373; CHISUM, *supra* note 11. Some prefer that courts consider bioethical factors in determinations of the appropriate scope of biotech patents, positing that courts should consider the specific scientific nature of the discovery as it does in an enablement analysis. *See* Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 307 (2000). In addition to claim construction, the court may also determine the breadth of a patent by employing the doctrine of equivalents to further broaden the scope and allow for nonliteral infringement of a patent. There are currently two exceptions to patent infringement: protection for FDA approval of generic drug equivalents of patented pharmaceuticals and an exemption for physicians practicing a medical method under patent. *See infra* notes 129-132 and 237 and accompanying text.

[98] Section 112 provides in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention (emphasis added).

gained through the enablement and disclosure requirements.[99] The United States Supreme Court has stated that:

> The aim of the patent laws is not only that members of the public shall be free to manufacture the product or employ the process disclosed by the expired patent, but also that the consuming public at large shall receive the benefits of the unrestricted exploitation, by others, of its disclosures.[100]

One must bear in mind that it is important to grant sufficient protection to motivate inventors to patent inventions and disclose discoveries, rather than opt to maintain secrecy and assume the risks of trade secret protection.[101] The public can learn the new technology through the enabling disclosure and is put on notice regarding rights of others in patented subject matter. This public disclosure is part of the hypothetical patent bargain, and once a patent expires the public may use and practice the patented product or process.[102]

The Federal Circuit in recent years has given enablement and written description a "rigorous interpretation in the context of biotechnology."[103] Generally, written description limits a patent holder's rights to the scope of the patented invention, while claim definiteness provides adequate notice to the public regarding the scope of the patented invention.[104] Enablement teaches the public how to make and use a patented invention. One can successfully enable an invention while failing to satisfy the written description requirement.[105] Enablement gives an inventor protection over more than just

35 U.S.C. § 112 (2000).

[99] The Federal Circuit has "tweaked the statute" in the written description area as it has in the obviousness area. This has resulted in high enablement/written description standards. *See* Burk, *supra* note 1, at 11-13. Some feel this high disclosure standard needs to be relaxed to allow for broader patents and would suggest raising the low obviousness standard, as discussed earlier. *See id.* at 14; *supra* note 62 and accompanying text.

[100] Scott Paper Co. v. Marcalus Mfg. Co., 326 U.S. 249, 255 (1945).

[101] *See* Meyer-Dulheuer, *supra* note 22.

[102] *See generally Scott Paper*, 326 U.S. at 255. Query whether the bargain now favors patentee by virtue of the doctrine of equivalents.

[103] Rai, *supra* note 11, at 840. "To be sure, for purposes of limiting patent scope, enablement has a longer doctrinal pedigree than written description. Nonetheless, the Federal Circuit has aggressively revived the role of the written description requirement in recent years." *Id.* at 840. *See* Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997). Some posit whether new technologies should be held to stricter enablement and written description requirements as than technologies in common, predictable fields. *See* Cantor, *supra* note 97, at 299.

[104] Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991) (citing Rengo v. Molins Mach., 657 F.2d 805, 810 (Fed. Cir. 1990)).

[105] *See Eli Lilly*, 119 F.3d at 1567 ("Whether or not it provides an enabling disclosure, it does not provide a written description.").

the literal invention, as literal protection alone could easily be circumvented by others. Some believe that biotechnology has come to have greater written description and enablement requirements, and patents in this field have been required to strictly comply with these requirements.[106] Federal Circuit case law supports this position.[107]

In *Regents of the Univ. of Cal. v. Eli Lilly & Co.*,[108] the Federal Circuit applied the § 112 written description requirement to limit the scope of the University of California (UCal) patent, finding a claim invalid for failing to meet the written description requirement.[109] The Federal Circuit held the written description requirement was not satisfied as the patentee failed to provide a specific sequence or structure.[110] As such, the court narrowed the patent scope and limited the University of California to only those cDNA sequences which it had in fact isolated and specifically provided.[111] The court stated that "[w]hether or not it provides an enabling disclosure, it does not provide [an adequate] written description."[112]

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[106] *See* Burk, *supra* note 1, at 11-13. The Federal Circuit has required patentees to describe with particularity and specificity the claimed invention. For example, in the realm of nucleic acids, the court has been adamant that the inventor specifically describe the "structure, formula, chemical name or physical properties" rather than providing a broad, general disclosure. *Eli Lilly*, 119 F.3d at 1566; Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

[107] This is also evident in the non-biotech world. For a general discussion of the Federal Circuit's relatively strict approach to written description, *see infra* notes 124 and 279.

[108] 119 F.3d 1559 (Fed. Cir. 1997).

[109] *See id*. at 1566.

[110] In a patent claiming a protein or DNA, the court held a patentee must provide a specific sequence or a chemical structure. *Eli Lilly*, 119 F.3d at 1566. The mouse homologue was fairly similar to that of humans. Nevertheless, UCal was not allowed to claim the human insulin encoding DNA simply because it found a way to use rat DNA to isolate human cDNA. CDNA, or "complimentary DNA," is not found in humans in isolation but is the coding portion of human DNA. In *Fujikawa v. Wattanasin*, the court held that a specific DNA sequence must be provided and that function is insufficient disclosure. 93 F.3d at 1571. Though Wattanasin maintained rights in the genus, Fujikawa did obtain rights in a particular subset or species because Wattanasin did not originally appreciate or identify significant properties of the subset. These types of overlapping patents demonstrate the difficulty subsequent researchers may face in obtaining multiple approvals or licenses for research in this patented area.

[111] The court also did not allow the university to extend its patent to other species. *Eli Lilly*, 119 F.3d at 1568.

[112] *Id*. at 1567. As such, Lilly's claim of all "vertebrate insulin genes" did not meet the section 112 written description requirements, particularly since the specifications described only rat insulin. *See id.* at 1568-69 (holding that in claiming a gene patent for human insulin, "a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA" is required). *See* Antony L. Ryan & Roger G. Brooks,

In *Enzo Biochem, Inc. v. Gen-Probe, Inc.*[113] the Federal Circuit reaffirmed its standard in *Lilly* and extended the *Lilly* standard from cDNA to gene patents.[114] In the context of cDNA and genes, the Federal Circuit thus established actual structure as the benchmark to determine whether § 112 written description requirements have been met. Query whether the *Lilly* decision is an outright roadblock. Some believe this decision is a mistake and that the Federal Circuit "goes too far" in narrowing claim scope in the context of cDNA.[115] Others find the *Lilly* decision "a warning signal to biotech patentees who might be tempted to claim their inventions too broadly,"[116] which the PTO written description guidelines specifically caution against.[117]

Enablement has a longer history and background than does the written description requirement of patent law.[118] A patent must enable, or teach, a PHOSITA to make and use the claimed subject of the patent without engaging in "undue experimentation."[119] Courts have used failure to enable as a way to restrict the trend toward expanding patent rights through broad claim language.

Innovation vs. Evasion: Clarifying Patent Rights in Second Generation Genes and Proteins, 17 BERKELEY TECH. L.J. 1265, 1272-73 (2002).

[113] 296 F.3d 1316 (Fed. Cir. 2002) (panel opinion on petition for rehearing).

[114] Though the Court reaffirmed the standard calling for specific structure, the court "applied [it] in a manner that renders uncertain when a person who discovers a gene may obtain claims to analog sequences." Ryan & Brooks, *supra* note 112, at 1268. The court in *Enzo* held that the description in the specifications met the written description requirement, but refrained from deciding whether the written description enabled the claim. *See Enzo*, 296 F.3d at 1327. As the enablement issue was not raised, the Federal Circuit ruled that issue was to be determined on remand as a question of fact. *See id*.

[115] Rai, *supra* note 11, at 841.

[116] *See id*.

[117] *See* U.S. PAT. & TRADEMARK OFF., PTO SYNOPSIS OF WRITTEN DESCRIPTION GUIDELINES 30-32 *available at* http://www.uspto.gov/web/menu/written.pdf (last visited Feb. 26, 2005) .

[118] *See* Rai, *supra* note 11, at 840. Some use enablement as the measure and propose that limited patents should be given to inventors only for what is specifically invented, disclosed, and claimed. *See* Gupta, *supra* note 25.

[119] *See In re* Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991) (citing *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)). Just because a specification requires some experimentation does not mean that the enablement requirement has not been met. What is important is that the experimentation involved not be "undue." *See* 35 U.S.C. § 112 (2000); Heim & Chorush, *supra* note 30, at 23; *In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (interpreting 35 U.S.C. § 112 (2000)). In *In re Wands*, the Federal Circuit articulated the factors to use in determining whether undue experimentation is needed: (1) quantity of experimentation needed, (2) amount of guidance or direction given, (3) existence (or lack thereof) of working examples, (4) the nature of the invention, (5) the existing prior art, (6) the skill of the PHOSITA. (7) predictability in the field, and (8) the breadth of the claims. *See* 858 F.2d at 737; *See* Heim & Chorush, *supra* note 30, at 22.

In *Amgen v. Chugai Pharm. Co.*,[120] the court used enablement, or rather lack thereof, to limit the scope of a DNA patent.[121] The impracticability of a patentee claiming the more than 3,000 variations of the DNA being claimed appears obvious, as does the ease with which another inventor could circumvent the patent by substituting as little as one amino acid. The court limited the scope to that which the patentee actually enabled, and held that the "sufficiently duplicative" language in the claims did not satisfy the enablement requirement.[122]

Claim drafting and interpretation are paramount to protecting a patentee's full rights in the invention.[123] An increasing problem, particularly with scientific patents, is the incursion of claims that attempt to cover a much greater area than the actual invention.[124] It has become a common practice for

[120] 927 F.2d 1200 (Fed. Cir. 1991).

[121] *See* Rai, *supra* note 11, at 840 n.113. In *Chugai*, the patentee had claimed "a DNA sequence . . . encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin [(EPO)] to allow possession of [a certain] biological property . . . ." *Chugai*, 927 F.2d at 1204.

[122] The Federal Circuit stated that "the number of claimed DNA encoding sequences that can produce an EPO-like product is potentially enormous" and Amgen provided "inadequate support for [its] desire to claim all EPO gene analogs." *Chugai*, 927 F.2d at 1213. Amgen has had extensive power vis a vis the EPO patent. *See* Randy Morin, Legal Update, *Recent Federal Circuit Decision Concerning Erythropoetin (EPO): Amgen v. TKT*, 9 B.U. J. SCI. & TECH. L. 490, 490 (2003).

[123] Patent claims have been described by United States Supreme Court as, "particularly if the invention [is] at all complicated, [ ] one of the most difficult legal instruments to draw with accuracy." Topliff v. Topliff, 145 U.S. 156, 171 (1892). *See also* Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917) (indicating that claim language determines the scope of a patent). It has been described "like an umbrella in that it has a clean zone underneath it and has a fuzzy zone at the edges." Williams, *supra* note 25. As the claims define the "metes and bounds" or scope of patent rights, they must clearly outline the invention, or property rights, covered by the patent. Heim & Chorush, *supra* note 30, at 28; Kitch, *supra* note 11; *see* Smithkline Diagnostics v. Helena Lab. Corp, 859 F.2d 878, 882 (Fed. Cir. 1988).

The importance of claiming can be seen in *Exxon Chem. Patents, Inc., v. Lubrizol Corp.*, 64 F.3d 1553 (Fed. Cir. 1995). The Federal Circuit interpreted Exxon's claims to an engine lubricating oil and found that Exxon did not claim a process or "recipe" as it intended to, but claimed a "product" or "chemical composition." *Lubrizol*, 64 F.3d at 1555. This difference determined, essentially, the outcome of the case. This approach to disclosure and claiming can also be seen in *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998). The Federal Circuit held that if *Gentry Gallery* possessed the technology that it later tried to claim in a continuation in part claim, it should have claimed it initially. 134 F.3d at 1479-80.

[124] Meyer-Dulheuer, *supra* note 22. "An obvious tendency is being observed of claiming too widely. Prominent examples [of this are] in the biotechnology and pharmaceutical chemistry fields." *Id*. Patentees and patent lawyers today are even advised to do so. *See*

patentees to claim more than they have actually enabled or reduced to practice.[125] Patent claims in the context of gene and protein patents have been limited by the Federal Circuit to the exact sequence that is actually described in the patent.[126] This aids in predictability of patents,[127] reduces the chilling

Joseph Yang & Rosanna Yang, *An Update on the Doctrine of Equivalents – Where do we Stand in 2003?* 749 PLI/PAT 521, 562 (2003) (advising that patentees "don't give up on broad claims before examination without a good reason . . . [W]hy resolve uncertainty against yourself? It's better to have broad literal coverage without DOE [instead of] narrow literal coverage with DOE . . . If you voluntarily sacrifice literal infringement for DOE, you're putting the cart before the horse!"). *But see id*. at 576 (advising patentees to "[m]ake good drafting and good prosecution a habit.").

Patents which claim too broadly have, historically, been invalidated. A famous example of this is the Sawyer and Mann light bulb patent. The Incandescent Lamp Patent, 159 U.S. 465 (1895) (noting the patent would not have been invalidated if it had claimed what had actually been invented); *see* Merges & Nelson, *supra* note 3, at 849, 882, 885 (stating the light bulb patent should never have been granted); *see also* O'Reilly v. Morse, 56 U.S. 62, 113 (1853) (holding the claims for communicating at a distance using electromagnetic waves "too broad, and not warranted by law" because it claims "a monopoly in its use, however developed"). In the biotechnology area, courts have been more stringent where enablement is concerned that they have with mechanical or other inventions. The novelty and nonobviousness requirements of sections 102 and 103 place limits on the broad claiming by patentees.

The Intellectual Property Commission's patent system recommendations to developing countries include in its description of the "elements of a pro-competitive model of patent law" a provision that a developing country "make use of strict patentability and disclosure requirements to prevent unduly broad claims in patent applications." *Final Report*, *supra* note 61, at 136.

[125] Claims in chemical and pharmaceutical patents often cover many different compounds yet the only thing they have in common is that they can be "described by one general formula."

[126] *See* Schering Corp. v. Amgen, Inc. 222 F.3d 1347, 1351-53 (Fed. Cir. 2000); Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed. Cir. 1994). *See also supra* note 125. In *Genentech*, the Federal Circuit confirmed its position in *Chugai* by holding that because the other definitions encompassed "an infinite number of permutations of natural-tPA" which were not enabled by the specifications. *Genentech*, 29 F.3d at 1564. The Federal Circuit rejected an infringement claim arguing that a modified natural protein (or a "second-generation natural protein") infringed the patent on the naturally occurring protein. *See id*.; Ryan & Brooks, *supra* note 112, at 1268. The court, in determining which of the four available definitions in Genentech's patent specifications to apply, decided that it would "avoid those definitions upon which the PTO could not reasonably have relied when it issued the patent." *Genentech*, 29 F.3d at 1564. The court determined that the narrow definition, that is limiting the definition to the natural amino acid (t-PA) sequence, should be used. *Id*. *See generally* Ryan & Brooks, *supra* note 112, at 1273-75 (providing a summary of the Federal Circuit's decision in *Genetech*).

Both *Amgen* and *Genentech* involved claims for modified structures or sequences which

effect of broad scope interpretation on subsequent inventors, and motivates patent holders to continue research "as competitors will be deterred from engaging in activities within the scope of patent protection."[128]

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resulted in the claim of "infinite" or "potentially enormous" scopes of products and, as such, were found invalid under section 112. *Genentech*, 29 F.3d at 1564. *See* Ryan & Brooks, *supra* note 112, at 1271 (explaining that "variant sequences not disclosed in the specification have generally been found invalid under the enablement and written description requirements"). The Federal Court echoed its previous decisions in *Schering*, holding that the original patent claim only enabled the "single, naturally occurring" protein and noting that "at the time of the application, neither [the patentee] nor [PHOSITA] knew of the existence of, let alone the identity of, the specific polypeptides[. As such,] those subtypes [could not] be within the scope of the claims." *Schering*, 222 F.3d at 1353-54; *see also id*. at 1351-53; Ryan & Brooks, *supra* note 112, at 1275-76.

[127] The need for predictability within a field was articulated by the Federal Circuit in *Festo*. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd, 234 F.3d 558, 577 (2000), *vacated by* 535 U.S. 722 (2002) (addressing the flexible bar approach to prosecution history estoppel in the context of the DOE); *see also supra* note 31 (addressing the need for predictability); *infra* notes 149, 250. The Federal Circuit stated that there is "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims [and which] discourage[s] invention only a little less than unequivocal foreclosure of the field." *Festo*, 234 F.3d at 577 (quoting United Carbon Co. v. Binney & Smith, Co. 317 U.S. 228, 236 (1942)). The Federal Circuit held, in declaring an absolute bar approach, that the "public will be free to improve on the patented technology and design around it without being inhibited by the threat of a lawsuit because the changes could possibly fall within the scope of equivalents left after a claim element has been narrowed by amendment for a reason related to patentability." *Id*.

[128] Meyer-Dulheuer, *supra* note 22 at 3. Infringement suits, often a result of broad patent scope or claims or the doctrine of equivalents, often chill future research as researchers fear being sued. *Id*.; Gupta, *supra* note 25. This is important to a patentee as well as other researchers given the costs of litigating infringement suits and the inability of small and independent inventors to bear such costs. *See* Gina Shaw, *Does the Gene Patenting Stampede Threaten Science?* 9 ASS'N OF AM. MED. C. REP No. 5, (Feb. 2000), *at* http://www.aamc.org/newsroom/reporter/feb2000/gene.htm ("[T]he threat of litigation is so expensive that cases aren't making it to court. They're letting the threat of lawyers rule: whoever has the most lawyers wins."). There has also been an increase in "patent mining," as companies are increasingly strict in their patent enforcement and infringement suits. *See* John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1021, Feb. 14, 2003 (noting that "aggressive assertions of IP . . . threaten scientific research"); Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. REV. 509 (2003) (noting that "[s]ome IP owners value their property rights chiefly as 'tickets' into court that give them a credible threat to sue vulnerable IP users"); Shapiro, *supra* note 88, at 3 (noting that suits are brought even against non-rivals). *But see supra* Walsh (indicating that patent holders indicated in interviews that they generally tolerate university infringement, "with the exception of patents on diagnostic tests used in clinical research, partly because it can increase the value of the patented technology") (citations omitted). The aggressive enforcement of patent rights is not limited to private industry, as

Patent infringement claims often arise in the context of generic pharmaceutical equivalents. Section 271(e) is particularly pertinent to allegations of patent infringement in the biopharmaceutical industry. Recent years have seen an increase in the number of companies manufacturing generic drug equivalents, many of these seeking entry to the market prior to the expiration of patents on the original drug.[129] This has resulted in an increase in patent infringement and patent validity suits. Section 271(e) was enacted in 1984 pursuant to the Hatch-Waxman Act.[130] The Hatch-Waxman Act sought to balance the important social benefit of generic drug alternatives with the need for strong patent protection to stimulate and encourage biopharmaceutical research.[131] Hatch-Waxman tried to achieve this balance and support generic

universities are also becoming more forceful in enforcement. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290 (2003).

One may question whether patent holders should only be allowed to bring patent infringement suits against direct competitors and those infringing in areas in which, akin to trademark law's *Polaroid* analysis, the patentee is likely to "bridge the gap." *See* Polaroid Corp. v. Polared Elec. Corp., 287 F.2d 492, 495 (2d Cir. 1961) (identifying the "likelihood of confusion" factors in the trademark context). This is also reminiscent of the concerns of a chilling effect in First Amendment jurisprudence relating to the overbreadth and vagueness of statutes. *See* NAACP v. Alabama ex rel. Patterson, 357 U.S. 449 (1958). One may ponder which is better for society, giving an original patent holder greater freedom to continue research sans competition, or encouraging research and development by others. It seems that infringement suits would best be used to protect the rights of patent holders against those who infringe their patent rights rather than to reserve them free license to quash future research in a patented or equivalent field.

[129] *See* MUELLER, *supra* note 2, at 262. As a result, Hatch-Waxman added section 271(e)(2) which provides that if a generic manufacturer attempts or desires to enter the commercial markets prior to the expiration of the patent of the original, equivalent drug, that the Abbreviated New Drug Application ("ANDA") and other actions will be deemed infringing. *See infra* note 130.

[130] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (also known as the "Hatch-Waxman Act"). *See* MUELLER, *supra* note 2, at 262.

[131] *See* Muris, *supra* note 22 (providing the need to "preserve the incentives to make the large, upfront, and risky expenditures necessary to develop new drugs successfully"); *see also supra* note 87 and accompanying text. *But see supra* note 75; *infra* notes 164-65 (indicating not that much is really invested in actual drug research). Generic drugs are regarded as socially useful. Research indicates that since the enactment of Hatch-Waxman, the price of pharmaceuticals has decreased. *See* Congressional Budget Office, *How Increased Competition from Generic Drugs has affected Prices and Returns in the Pharmaceutical Industry*, *at* http://www.cbo.gov/showdoc.cfm?index=655 (July 1998) (indicating 1994 figures estimating a savings of $8-10 billion for consumers). Some observers of pharmaceutical markets, however, say that the current framework does not effectively balance the needs of consumers, big pharma, and generic drug manufacturers.

manufacturers by enacting § 271(e)(1), which allows generic drug manufacturers to use a patented invention to seek FDA approval of a generic version of a drug previously approved by the FDA.[132]

MUELLER, *supra* note 2, at 264.

[132] *See* 35 U.S.C. § 271(e) (2000). *See* MUELLER, *supra* note 2, at 262. This provision came at the urging of generic manufacturers, who sought redress after Congress extended patent term of drug patents by the amount of time needed for FDA regulatory approval. *See supra* note 11 (noting patent term extension for pharmaceuticals). Without this provision, generic drug manufacturers could not begin testing of a generic drug equivalent until the original patent term expired, resulting in a de facto patent term extension, equal to the time it took the generic drug manufacturer to receive requisite regulatory approvals, to the original patentee of the time it took the generic drug manufacturer to receive requisite regulatory approvals. *See* MUELLER, *supra* note 2, at 264.

Generic manufacturers may obtain FDA approval under section 271(e) via an ANDA which is not deemed infringement of the existing patent. *See* Integra Lifesciences I, Ltd. v. Merck KGAA, *available at* 2003 U.S. App. LEXIS 11335 (Fed. Cir. 2003) (holding the section 271(e)(1) provision applicable to FDA-related procedures only). The Federal Circuit has stated that the Hatch-Waxman Act:

> strikes a balance between the interests of a party seeking approval of an ANDA and the owner of a drug patent. On the one hand, the manufacture, use or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation and submission of an ANDA. On the other hand, once it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent infringement suit. While it is pending, such a suit can have the effect of barring ANDA approval for two and a half years.

Bristol Myers Squibb v. Royce Labs, 69 F.3d 1130, 1132 (Fed. Cir. 1995); *See* MUELLER, *supra* note 2, at 264. Generic drug manufacturers submitting an ANDA must certify that: (1) that the drug is not patented, (2) that the patent on the drug has expired, (3) if it has not expired the date on which it will expire, or (4) that an existing, applicable drug patent is either invalid or will not be infringed. The bulk of ANDAs certify the last category. *See* 21 U.S.C. § 355(j)(2)(A)(vii) (I-IV) (2000); MUELLER, *supra* note 2, at 263.

Those certifying under this fourth category must provide the applicable patent owner with notice. Such notice provides the patent owner forty five days in which the patentee may bring a section 271(e)(2) infringement action against the generic drug manufacturer. If no infringement is found, ANDA approval can continue unimpeded. 21 U.S.C. § 355(j)(2)(A)(vii). *See* MUELLER, *supra* note 2, at 262. At the end of 2002, the government proposed changes for ANDA approval, seeking to limit patent owners to only one thirty month automatic stay for each ANDA. The government deemed this sufficient time to resolve patent infringement actions. *President Takes Action To Lower Prescription Drug Prices By Improving Access to Generic Drugs*, *at* http://www.whitehouse.gov/news/releases/2002/10/print/20021021-4.html (Oct. 21, 2002); *see* MUELLER, *supra* note 2, at 264.

Section 271(e) has been interpreted broadly, and the Supreme Court has allowed generic manufacturers to use not only regulatory data but also testing of medical devices. Eli Lilly & Co. v. Medtronic, 496 U.S. 661, 679 (1990); *See* MUELLER, *supra* note 2, at 262. To

B. Doctrine of Equivalents

Courts have utilized the doctrine of equivalents to expand the analysis of patent infringement beyond the literal claim language.[133] Learned Hand

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dissuade devious schemes by generic manufacturers, Hatch-Waxman added section 271(e)(2) which provides that if a generic manufacturer attempts or desires to enter the commercial markets prior to the expiration of the patent of the original, equivalent drug, that even the act of filing an ANDA with the FDA will constitute patent infringement. Hatch-Waxman Act, *supra* note 130; *See* MUELLER, *supra* note 2, at 263; Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339 (Fed. Cir. 2000).

There is an increase in attacks by generic manufacturers on the validity of patents held by big pharma. Heather Slowik, *The Battle for IP*, IN VIVO –BUS. & MED. REP. (June 2003), *available at* http://www.windhover.com (indicating attacks on large pharmaceutical companies such as Eli Lilly & Co., GlaxoSmithKline PLC, and Pfizer, Inc.); *see* Bill Alpert, *Whose Drugs? Big Pharma's Patents Draw Some Ugly Attacks*, BARRON'S, Mar. 17, 2003, at 26, *available at* 2003 WL-BARRONS 6977057 (noting recent attacks such as those on the Zyprexa patent by generic firms like Barr Laboratories, Mylan Laboratories, and Teva Pharmaceutical). This could serve problematic, as one of the reasons pharmaceutical companies are said to invest in drug research and development is the promise of strong patent protection. Cook-Deegan, *supra* note 87, at 280.

[133] *See* ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY – THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS 480 (2003). The doctrine of equivalents was first introduced in Winans v. Denmead 56 U.S. 330 (1853). It is described as a "turbulent river – full of treacherous shoals, a small number of safe harbors, and a lot of muddy water." *See* Yang & Yang, *supra* note 124, at 537. The doctrine of equivalents is complex and is characterized by fact-based application, differences in industries and technologies, activities of patentees and competitors, and the "complex nuances of competition at the edge of the products of others." *Festo*, 234 F.3d at 640 (Newman, J., concurring-in-part, dissenting-in-part); Ryan & Brooks, *supra* note 112, at 1294 (describing the doctrine as "fact-intensive"); Burk, *supra* note 1, at 12. Dan Burk says that the "equivalents in one industry [will come to] look different" in the biotech area than in other industries. *Id*.

There are four principal limitations on the doctrine of equivalents: prosecution history estoppel, prior art, public dedication, and the "all elements rule." *See* SCHECHTER & THOMAS, *supra* note 133, at 480-81. One of the threshold issues or "legal limitations [on the DOE]" is prosecution history estoppel. *Festo*, 234 F.3d at 630 (Newman, J., concurring-in-part, dissenting-in-part) (indicating the all elements rule is the other threshold question). Prosecution history estoppel has been one of the most controversial principles in patent law and prevents patent holders from receiving protection for that which they relinquished at the time of patent prosecution. "If the claims elements at issue were amended, the court first must determine whether the amendment narrowed the literal scope of the claim. If so, prosecution history estoppel will apply unless the patent holder establishes that the amendment was made for a purpose unrelated to patentability." *See* SCHECHTER & THOMAS, *supra* note 133, at 481. In the event that the doctrine of equivalents is not barred by prosecution history estoppel, then the court is to apply the "all elements" rule. Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 40-41 (1997). The objective PHOSITA standard is used in prosecution history estoppel. "Prosecution history estoppel

only applies where the court concluded that PHOSITA would reasonably believe that the patentee had surrendered subject matter during prosecution." SCHECHTER & THOMAS, *supra* note 133, at 394, 481. The *Festo* line of cases is seminal in the prosecution history estoppel doctrine.

Following the first Federal Circuit decision in *Festo*, the patent bar was in an uproar about the effect the complete bar announced by the court would have on the scope of patent protection, the rights of patent holders, and claim drafting. *See* Marc E. Brown, Festo *Alters Scope of Patent Protection – Again*, *at* http://marcebrown.com/publications /Festo%20again.htm (Sept. 29, 2003). Some described the decision as "draconian." Others describe the first Federal Circuit decision in *Festo* as having "dramatically changed the legal landscape for U.S. patents. The outcome is that patent holders should tremble and patent challengers should celebrate." Williams, *supra* note 25. Lawyers believed that the decision required the drafting of exact claims in order to avoid any arguments and amendments, and that such precise language would narrow the patent scope. *See* SCHECHTER & THOMAS, *supra* note 133, at 481. After the *Festo* line of cases, it is believed that it is crucial to secure claims of proper scope in an original patent application. *See* Brown, *supra*. Claim language should be selected carefully and that important words in claims should be provided "consistent, specific meanings that can later be relied upon to explain what the claim language means." *See* Williams, *supra* note 25.

In the biotechnology and biopharmaceutical area, claim amendments are commonplace and have been used to "win patent approval for coveted discover[ies]." *Id*. Williams poses the following example: The University of Rochester applied for a patent "on a method of treating inflammation with a non-steroidal prostaglandin inhibitor." The patent was issued after two infringing drugs, commonly and popularly known as Celebrex and Vioxx, were on the market. The University of Rochester had amended its claims during patent prosecution. Williams asks if this should prevent the university from bringing suit against the drug manufacturers, for two drugs which had sales hovering around $5 billion annually, due to a patent amendment. Williams notes the inherent lack of equity. *Id*. "Because it is virtually impossible to obtain a patent without changing the claim language, the *Festo* decision is one of the most powerful legal decisions ever rendered in patent law." *Id.* Many major pharmaceutical companies, including Amgen, Genentech, Scripps, Biogen, Novartis, and Gilead, have amended claims in obtaining what are commercially powerful patents. *See* Williams, *supra* note 25 (stating that the "revenue stream may now be threatened by the *Festo* decision").

Despite the *Festo* backlash, the question remains whether the Federal Circuit's attempt to reign in the doctrine of equivalents through a complete bar may have been the better choice. The Federal Circuit's *Festo* decision, it can be argued, encouraged competitive research and could spark "a new wave of innovation." *Id*. The controversial Federal Circuit decision in *Festo* was seen as weakening patents because patent claims could not be give, it was said, a broad interpretation. *Id*. As Festo's prosecution history estoppel only applies to the amended claim and not the entire patent, one may question whether the effect was as strong or "weakening" as some would have.

The United States Supreme Court later vacated the Federal Circuit's decision and held a flexible bar the more appropriate standard. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722 (2002); SCHECHTER & THOMAS, *supra* note 133, at 494. The Court held that the doctrine of equivalents could not be used to expand patent claims to

embrace products or processes that were presumably disclaimed. The patentee could rebut the presumption if the equivalent was not "foreseeable" to a PHOSITA at the time of application such that a PHOSITA "could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo*, 535 U.S. at 741. Specifically, a patentee is allowed to rebut by demonstrating that at the time the amendment was made, if patentee could show (1) at the time of amendment the equivalent was "unforeseeable," (2) "the rationale underlying the amendment" had only a "tangential relation to the equivalent in question," or (3) there existed "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 725. The case returned to the Federal Circuit, which articulated guidance on the Supreme Court's tests to rebut the presumption. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 344 F.3d 1359 (2003).

Determining the foreseeability of an equivalent, the court said, was to be done on a "case-by-case basis" but stated that the determination must be made from the view of a PHOSITA and considering what was known at the time of the amendment. *Festo*, 344 F.3d at 1368. In defining the "tangential relation" laid out by the Supreme Court, the court stated that this examines if the narrowing amendment was "peripheral, or not directly relevant, to the alleged equivalent," and that amending a claim to avoid prior art is not merely tangential. *Id*. at 1369. Further, the vague "some other reason" standard of the Supreme Court was described by the Federal Circuit as a "narrow" test. *Id*. at 1370 (stating that there must be "some reason, such as the shortcomings of language, why the patentee was prevented from describing the alleged equivalent when it narrowed the claim."). Finally, the Federal Circuit stated that "[q]uestions relating to the application and scope of prosecution history estoppel [are] within the exclusive province of the court." *Id*. at 1368. The question now seems "whether it was foreseeable to substitute the insubstantially different element in the invention, not merely whether the element was known to those in the field of the invention." *See* Brown, *supra*.

Mirroring the prosecution history estoppel doctrine, one should not be allowed to obtain protection for a discovery on which a patent would not originally have been granted because of existing prior art. The doctrine of equivalents is tested at the time of infringement. *See* Ryan & Brooks, *supra* note 112, at 1287. This also mirrors the section 112 ¶ 6 limitation that does not allow reissue of a patent on a discovery which would not have originally been allowed patent protection due to existing prior art. Following this concept, where later developed technology is concerned, another method the Federal Circuit has used is the "hypothetical patent claim" approach. Wilson Sporting Goods Co. v. David Geoffrey & Assocs., 904 F.2d 677, 684 (Fed. Cir. 1990), *vacated on other grounds* Cardinal Chem. Co. v. Morton Intern, Inc., 508 U.S. 83 (1993). The Federal Circuit stated that "it may be helpful to conceptualize the limitation on the scope of equivalents by visualizing a hypothetical patent claim, sufficient in scope to literally cover the accused product. The pertinent question then becomes whether that hypothetical claim could have been allowed by the PTO over the prior art." *Wilson Sporting Goods*, 904 F.2d at 684. Further, if a patentee discloses information within a patent but does not include it in the claim language, this information is considered to be dedicated to the public and the doctrine of equivalents can not be extended to cover this subject matter. In *Johnson & Johnston Assocs. Inc. v. R.E. Service Co., Inc*., the Federal Circuit indicated that reissue or continuation proceedings were available to prevent public dedication. 285 F.3d 1046 (Fed. Cir. 2002) (per curiam). Once

explained the doctrine of equivalents rather famously: "[A]fter all aids to interpretation have been exhausted, and the scope of the claims has been *enlarged as far as the words can be stretched*, on proper occasions courts make them *cover more than their meaning will bear*."[134]

The doctrine of equivalents attempts to protect a patent holder while granting notice to the public and potential competitors of the scope of the patent.[135] It helps a patentee when a subsequent party invents something so substantially similar to the patented invention that, though it does not directly infringe the claim language, it would warrant a finding of infringement.[136] The original test for the doctrine of equivalents was articulated in *Graver Tank & Mfg., Co. v. Linde Air Prods. Co.*,[137] namely if "two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape."[138] The test was examined by the Federal Circuit and the Supreme Court in *Warner Jenkinson*.[139] The Court stated that the important inquiry was whether "the

again, the desired outcome seems to be improving the quality and accuracy of patent claims and language. *See* SCHECHTER & THOMAS, *supra* note 133, at 481.

An alternative to the doctrine of equivalents, as noted by one of the dissenting opinions in the lower court case *Hilton Davis Chem. Co. v. Warner-Jenkinson Co., Inc.*, is that broader claims should be sought by the patentee through reissue proceedings rather than applied by the court via the doctrine of equivalents. 62 F.3d 1512, 1547 (1995) (en banc) (Lourie, J., dissenting). This mechanism, already built into the patent system, seems a natural alternative to the doctrine of equivalents and a straightforward solution to the ever-expanding concern with patent scope. *See id.*; SCHECHTER & THOMAS, *supra* note 133, at 482.

[134] Royal Typewriter Co. v. Remington Rand Inc., 168 F.2d 691, 692 (1948) (emphasis added).

[135] *See* SCHECHTER & THOMAS, *supra* note 133, at 480.

[136] *See* Bohrer & Prince, *supra* note 89 at 404. *See also* Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997). If the improvements or modifications made to a patented product are "minor, easy or relatively obvious changes," the doctrine of equivalents will prevent "what in essence is a pirating of the patentee's invention." Bohrer & Prince, *supra* note 89 at 404 (citing Hormone Res. Found. v. Genentech, 904 F.2d 1558(1990)); *see* Yang & Yang, *supra* note 124, at 577 (encouraging the habit of good claim drafting and prosecution, indicating a patentee will "not only decrease the chances of losing DOE, but also the chances of needing it in the first place").

[137] 339 U.S. 605 (1950).

[138] *Graver Tank*, 339 U.S. at 608; *see* Bohrer & Prince, *supra* note 89 at 405; Merges & Nelson, *supra* note 3, at 853.

[139] 520 U.S. 17 (1997). The Federal Circuit had said that the test should not be one of "substantial differences" between the original and accused process. Rather than the insubstantial difference or "function/means/result" tests, the Supreme Court stated the doctrine of equivalents should be applied as an "objective inquiry on an element by element basis." *Warner*, 520 U.S. at 39-40. *See also* Hilton Davis, 62 F.3d at 1518-19.

accused product or process contains elements identical or equivalent to each claimed element of the patented invention."[140] Some courts have subsequently interpreted the breadth of equivalents on the "degree of advance over the art the original patent represents."[141] In *Texas Instruments v. United States Int'l Trade Comm'n*,[142] the Federal Circuit emphasized the modifications and improvements in materials, elements, and efficiency, which alternatively, others think should serve as the standard for the grant of equivalents.

Given the importance of patent claims, both to put others on notice as to what is claimed and to establish the rights of a patentee under § 271, it seems a fair expectation that "[t]he patentee, as the author of the claim language, may be expected to draft claims encompassing readily known equivalents."[143] Yet the Supreme Court has acknowledged that the doctrine of equivalents "has

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[140] *Warner*, 520 U.S. at 40. As every single "element contained in a patent claim is deemed material to defining the scope of the patented invention . . . the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Id*. at 29. Every element in a claim is material and, to find nonliteral infringement under the doctrine of equivalents, each element must be equivalent. *See* SCHECHTER & THOMAS, *supra* note 133, at 481. The all elements rule, together with prosecution history estoppel, is a threshold matter for the application of the doctrine of equivalents.

Some believe that this may mean each nucleotide or amino acid in a gene or protein patent, respectively, constitutes a separate claim. This argument seems to fail since the individual nucleotides or amino acids do not perform a function independently but only do so in the context of the larger structure which is necessary to functioning. For a general discussion, *see* Lawrence S. Graham, Note and Comment, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After Warner-Jenkinson Co. v. Hilton Davis Chemical Co*., 6 J.L. & POL'Y 741, 783 (1998); Ryan & Brooks, *supra* note 112, at 1284-85 (noting that this would "lead to absurd results" highlighting that this type of claim language would have prevented the patent holder from receiving doctrine of equivalents protection in *Amgen v. TKT* as the 166th amino acid would have been considered a claim element in its own right). Were this approach to claiming to be used in that case, the all elements rule of *Warner* would not have been satisfied. As such, this approach would have prevented the grant of extended protection to the patent holder where the original patent is a perfect candidate for doctrine of equivalents protection as the accused product nonliterally infringed.

[141] Merges & Nelson, *supra* note 3, at 854.

[142] 805 F.2d 1558 (Fed. Cir. 1986).

[143] *Festo*, 535 U.S. at 740. *See* Jeffrey P. Kushan & David L. Fitzgerald, *The Written Description Requirement Post-Festo*, 725 PLI/PAT 223, 257 (2002) (indicating that "for inventions in unpredictable fields (e.g. biotechnology, pharmaceuticals, etc.), the challenge for an applicant seeking a comprehensive scope of protection is to prepare a disclosure that anticipates and meets the requirements that will be imposed first by the PTO and later by the courts."). For example, in genus claims, patentees must properly define the genus, set forth characteristics of the compounds within that genus, transmit an understanding of the interaction among species within the genus, and take into consideration the utility of the genus. *See id*. at 257-258.

taken on a life of its own, unbounded by the patent claims."[144] The doctrine of equivalents parallels and exacerbates patentees' increasingly common practice of broadening scope by claiming more than they have enabled or reduced to practice.[145] One rationale for the doctrine of equivalents, that such equivalents may not be foreseeable to the patentee and that claims would easily be circumvented if patentees did not have protection, is tolerable.[146] This comports with Judge Linn's position in *Festo* that patentees are not linguists.[147] To allow expansive application of the doctrine of equivalents, however, thoroughly undermines "the policy for rewarding inventors in proportion to the contribution to the public through disclosure of the invention."[148] It also risks undermining the certainty, as well as the notice function, of the patent claiming system.[149]

Granting robust doctrine of equivalents protection in unpredictable or undeveloped fields, some believe, will grant patentees needed benefits while keeping the enablement standards relatively intact. Especially in biopharmaceutical-related areas in which strong patent protection is paramount, a generous application of the doctrine of equivalents will allow

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[144] *Warner*, 520 U.S. at 28-29.

[145] Patent applicants may receive broad patent scope first by claiming broader than their enabling disclosures, and then through the courts' generous use of the doctrine of equivalents. The difference between the two is that the patentee accomplishes the expansion of claims during patent prosecution, while the court accomplishes broad scope at the time of infringement and trial. Sections 102 and 112 do attempt to serve as limits on this practice. *See* 35 U.S.C. §§ 102 and 112 (2000).

[146] *See generally Festo*, 535 U.S. at 740 ("There are some cases . . . where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of application."). In many cases, allegedly infringing devices may lie outside the literal scope of the claims yet a court will find that it falls so close to this scope as to justify inclusion as an equivalent. *See generally* Merges & Nelson, *supra* note 3.

[147] *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 620 (Fed. Cir. 2000) (Linn, J., concurring in part, dissenting in part) (warning on placing "greater emphasis on literary skill than on an inventor's ingenuity").

[148] Toshiko Takenaka, *The Best Patent Practice or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal for a "First to Invent" Exception for Domestic Applicants*, 11 TEX. INTELL. PROP. L.J. 259, 325 (2003) (quoting CHISUM, *supra* note 11, at § 18.04[2][a][i]). How then does this comport than with the court's requirement in *Gentry Gallery* that it claim what it actually possessed? *See generally supra* notes 125-126. The reconciliation of these two doctrines is tentative, at best.

[149] *See* Paul R. Michel, *A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Introduction: The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1237 (1994).

patent applicants to draft specific and narrow claims without the fear of weakened patent protection. It would also prevent claiming variations that have not yet been tested and avoid possible findings of insufficient enablement.[150] As we see, "the doctrine of equivalents renders the scope of patents less certain."[151] How far the courts will extend a patent claim through the doctrine of equivalents remains one of the most contentious and important issues in current patent law.[152]

It bears noting that just as the doctrine of equivalents is used to broaden the scope of a patent to find nonliteral infringement and give the patentee rights beyond the literal claims of a patent, the reverse doctrine of equivalents has been used to narrow patent rights and grant improver rights to a patent that were clearly not included or envisioned by the original patentee.[153]

VII. BIOPHARMACEUTICAL PATENTS AND PATENT SCOPE

Who is best served by broad patent scope in the biopharmaceutical industry?[154] According to Merges and Nelson, control of technology by a few creates dead weight losses resulting in the inefficient use and development of

[150] *See* Takenaka, *supra* note 148, at 325. The goals of disclosure and public notice will still be met. In effect, however, this use of the doctrine of equivalents instead of broad patent claiming would likely be a distinction without difference in a world where the patent claim system and the doctrine of equivalents are "at war." Baker, *supra* note 22, at 447.

[151] *Festo*, 535 U.S. at 732. Merges and Nelson have criticized the doctrine of equivalents. *See* Merges & Nelson, *supra* note 3, at 857. Merges and Nelson do acknowledge the role of the doctrine of equivalents in promoting "leapfrogging" improvements rather than copying on the fringes of existing patent claims. *See id.*; *see also Graver Tank*, 339 U.S. at 607 (indicating that copying deprives holders of patents the full benefit of their invention and may result in inventors opting for secrecy).

[152] *See* Brown, *supra* note 133.

[153] In *Westinghouse*, the Supreme Court held that a patent, though literally infringing, did not give rise to a finding of infringement because the "new design featured substantial improvements." Westinghouse v. Boyden Power Brake Co., 170 U.S. 537 (1898); Chang, *supra* note 11, at 36. Notably, a reverse doctrine of equivalents analysis, of sorts, is performed by the FDA in an orphan drug context. *See* Bohrer & Prince, *supra* note 89 at 407-409 (noting that when "the FDA makes a finding that a second, similar drug is different from a prior orphan drug because it is clinically superior to the first, it is very much like a court determining that a second [invention] is not infringing under the reverse doctrine of equivalents."). *See generally supra* note 89 (describing orphan drugs generally).

[154] Broad patent scope encourages first discovery and discourages improvements because the patentee may require or deny licensing, while narrow patent scope encourages further follow-on or stepping-stone innovations by limiting the ability to block or collect royalties. *See* Merges & Nelson, *supra* note 3, at 907; Gilson, *supra* note 19 (summarizing Merges and Nelson's view).

technology.[155] A modern view focuses on the utilitarian aspects of the law and sees patenting as a tool to incentivize and commercialize new products and services.[156] The premise for this argument is that the foundation of the United States patent system is purely economic, and a strong patent system will stimulate the economy.[157] This is especially true in the pharmaceutical area, where "research and development historically have focused on development of products likely to attract significant commercial interest."[158]

A. Actual Investment and the Bayh-Dole Act

Biopharmaceutical research and development is a lengthy, expensive and risky process.[159] The need for incentives for a company to undertake this type of research and to commercialize discoveries in the biological sciences industry is "uncommonly strong."[160] Rai acknowledges the need for broad

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[155] *See* Merges & Nelson, *supra* note 3, at 871-74.

[156] *See generally* Kieff, *supra* note 12, at 717-53; *Final Report*, *supra* note 61 ("The patent system is designed as a tool to provide an incentive to technological progress."). The increase in domestic expenditures and the number of patents granted do not necessarily correlate. *See Final Report*, *supra* note 61 (indicating that in the 1990s, investments in research and development increased 41%, yet patents granted increased by more than 72%).

[157] *See* Kieff, *supra* note 12, at 699.

[158] John Dodge, *Big Pharmas are Dinosaurs, Conversation with Nathan Myhrvold*, *at* http://www.bio-itworld.com/archive/050702/horizons_dinosaurs.html (May 7, 2002) (indicating that pharmaceutical patents are desirable because they serve as an incentive for hundreds of millions of dollars of investments in drug research and regulatory approval). *See* Cook-Deegan, *supra* note 87, at 280; Biodefense Readiness, Statement before the Committee on Senate Health, Education, Labor and Pensions to Congress, July 24, 2003, *available at* 2003 WL 56336710 (statement of Mark B. McClellan, Commissioner of Food and Drugs Committee on Senate Health, Education, Labor and Pensions) (explaining why countermeasures to terrorism have no market and why government interest and subsidies are needed to develop vaccines). Senator Joseph Lieberman has sponsored legislation to further the development of drugs, tests, and vaccines. Lieberman, together with Senator Orrin Hatch, introduced a bill in March of 2003 which would grant private companies financial motives to develop counterterrorism measures. *See* S. 666 Biological, Chemical, and Radiological Weapons Countermeasures Research Act (introduced in response to insufficiencies in the Bioshield legislation). *See also Lieberman Statement on the Importance of Medical Research*, *at* http://lieberman.senate.gov/newsroom /release.cfm?id=215074 (outlining Senator Lieberman's efforts to increase NIH funding). In *Brenner v. Manson*, the U.S. Supreme Court stated that patents are not a "reward for the search, but compensation for its successful conclusion." 383 U.S. 519, 536 (1966).

[159] *See supra* note 87.

[160] According to Kieff's commercialization theory, "it is precisely this combination of high initial commercialization costs and risks facing the first mover and low marginal costs facing a second mover that makes the biotechnology industry a particularly strong candidate for patent protection." *See* Kieff, *supra* note 12, at 725; *see also* Cook-Deegan, *supra* note

patent rights to provide incentives for investments in the biopharmaceutical industry.[161] One must compensate a pharmaceutical company for the time and resources invested in research, obtaining regulatory approvals, and commercializing a drug.[162] According to Kieff, the time and money needed to complete the FDA regulatory approval process, the low probability of success, and other associated costs make the ability to recapture investment in a new drug questionable.[163] Some believe this inability to recoup investment costs is appropriate, as the financial investment of pharmaceutical companies in actual research and development is small. For example, Burk and Lemley contend that the real expense in drug development lies not in the research but in mass production, marketing, and the like.[164] Large pharmaceutical companies conduct very little, if any, research, and only a minority of important drug discoveries are the result of commercial research.[165] This is due, in large part, to the passage of the Patent and Trademark Law Amendment Act of 1980, P.L. 96-517, commonly known as the "Bayh-Dole Act." The Bayh-Dole Act changed the research culture and allowed universities[166] and private inventors

87, at 280 (indicating that the reason pharmaceutical companies invest the time and capital in drugs is strong and durable patent protection).

[161] Rai recognizes that in the "biopharm sector[, realizing] the importance of broad, monopoly-conferring patent rights in incentivizing the [research and development] process by allowing appropriation of its full value [seems best]." Rai, *supra* note 11, at 822; *see also* Hollis, *supra* note 28 (positing that the patent system provides an effective incentive for development). At the same time, Rai and Eisenberg believe "[t]he time is ripe to fine-tune the Bayh-Dole Act to give funding agencies more latitude in guiding the patenting and licensing activities of their grantees." Rai & Eisenberg, *supra* note 128, at 310.

[162] *See* Kieff, *supra* note 12, at 702, 705. Those who disagree with this view hold that cash rewards, patent buyouts, and the like will stimulate the economy and spur commercialization.

[163] *See id.* at 725. Pharmaceutical companies often do not recover the costs of research and development associated with bringing a new drug to market. H.G. Grabowski & J.M. Vernon, *A New Look at the Return and Risks to Pharmaceutical R&D*, 36 MGMT. SCI. 804, 804-21 (1990).

[164] *See* Burk & Lemley, *supra* note 9, at 1581 (indicating that pharmaceutical research, development, and regulatory approval costs hundreds of millions of dollars but that exact figures are uncertain because pharmaceutical companies often include marketing costs in these figures).

[165] While big pharmaceutical labs are viewed as researching giants, the underwriting of a great deal of research is actually publicly funded. Private biopharmaceutical companies spend "extraordinary sums of money on marketing." *See* Ludwig, *supra* note 82 (noting the various marketing and promotional tactics used); Tom Clarke & Helen Pearson, *Goliath Befriends David*, 414 NATURE 482, 482-83 (2001).

[166] More than 3000 patents were granted to American universities in 2000, as compared with less than 350 in the 1970s. *See Final Report*, *supra* note 61. During the debates leading to the enactment of the Bayh-Dole Act, the importance of strong patent rights for

to patent drug discoveries made using public funds, and to retain exclusive rights to make and sell such discoveries.[167] Thus, public funding is seen as a

universities was emphasized. Strong patent rights lead private companies to enter licensing agreements with the universities and commercialize the product. *See generally* Shreefal Mehta, *The Emerging Role of Academia in Commercializing Innovation*, 22 NATURE BIOTECHNOLOGY 21, 21-22. For a general discussion of the change in the research ethos, see Seth Shulman, TROUBLE ON "THE ENDLESS FRONTIER": SCIENCE, INVENTION AND THE EROSION OF THE TECHNOLOGICAL COMMONS (2002).

[167] The Government Patent Policy Act of 1980, better known as the Bayh-Dole Act, was passed to promote the economic development of federally funded research, thereby benefiting the public through commercialization of advances in research and technology. Government Patent Policy Act of 1980, Pub. L. No.96-517 (1980) (amending Title 35 of the United States Code by adding chapter 18, §§ 200-212); *see* Howard K. Schachman, *Secrecy in Science and Access to Scientific Data* 304, *at* http://www.aaas.org/spp/rd /yrbk00/Part7.pdf. Under Bayh-Dole, recipients of government funds may keep title to inventions so long as they promote utilization, commercialization, and access to the public. *See id*. As many universities, and even private firms, are recipients of NIH grants and other federal funds for research, Bayh-Dole has relatively broad application. *See id*. The Bayh-Dole Act has been deemed successful. *See id*.; Iain Cockburn & Rebecca Henderson, *Public-Private Interaction in Pharmaceutical Research*, 93 PROC. NAT'L ACAD. SCI. USA 12725, 12726 (1994) (determining that publicly funded research was critical to the discovery of almost all of the 25 most important drugs from 1970 to 1995); Francis Narin et al., *The Increasing Linkage Between U.S. Technology and Public Science*, 26 RES. POL'Y 317, 318 (1997) (noting that 50% of the scientific research cited in drug and medicine patents was funded by the United States Government). *But see* Judith Gorman, *Paper Cuts: The Golden Fleece*, *at* http://www.alternet.org/story/9290 (last visited Feb. 26, 2005) (noting that the Bayh Dole Act has caused the current crisis in our nation's health care).

Bayh-Dole has, undeniably, contributed a shift in scientific norms, a change in research culture, and the demise of academic use of information. Heller and Eisenberg note that a researcher who may previously have looked to coauthorship or journal citation, now seeks patent listing as coinventor or seeks receipt of a portion of the licensing agreement revenues. *See* Heller & Eisenberg, *supra* note 50; Rai & Eisenberg, *supra* note 128, at 310 (discussing the university research setting in general and indicating that "[a]s patenting by universities gains momentum, the normative baseline in the academic community concerning free exchange appears to have shifted"). *But see* Walsh et al., *supra* note 128 (indicating the results of a study showing that patent holders generally look the other way when universities infringe their patents because they do not want to "upset the norms of open access," or risk bad publicity or losing goodwill).

The experimental use defense was created by more than a century ago by Justice Story in Whittemore v. Cutter, 29 F. Cas. 1120 (D. Mass. 1813). If applicable, research created and covered by Bayh-Dole would be available to other academic, non-commercial researchers for experimental use. *See id.* Prior to Bayh-Dole, the scientific research community viewed patent infringement suits as applicable only when patented information was used commercially. *See* Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018, 1019 (2003). The tides turned when a university was held to infringe a patent even though the use was purely academic. *See* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).

Though the experimental use defense still exists, it is largely "eviscerated . . . to the point that it is essentially useless to research universities." Eisenberg, *supra* note 167 at 1018. Once the Federal Circuit rejected the experimental use defense in the patent infringement suit against Duke University, the bells of cultural change in the academic community began to ring. This culture change is attributable to the Bayh-Dole Act; by granting universities the right to patent their discoveries, universities changed from being purely research oriented to "players in the patent system . . . aggressive about enforcing their patents in court." Eisenberg, *supra* note 167, at 1018; Rai & Eisenberg, *supra* note 128, at 290 (indicating that universities are now "major players" in the biopharmaceutical industry).

This is the complete opposite of the view Justice Story described in 1813, when he wrote "it could never have been the intention of the legislature to punish a man, who constructed [a patented] machine *merely for philosophical experiments*, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Whittemore*, 29 F. Cas. at 1120 (emphasis added); *see* Eisenberg, *supra* at 1018. Yet, interviews with university researchers and technology transfer offices personnel indicate that many researchers are simply using research tools and infringing. *See* Walsh, *supra* note 128 (indicating that universities take this risk because such infringement is hard to detect, hoping the statute of limitations expires prior to detection). The use of the experimental use doctrine with regards to research tools is troubling to some, as it provides an exception for the very use of research tools: experimentation. *See* Philippe Ducor, *Research Tool Patents and the Experimental Use Exemption – a No-Win Situation?* 17 NATURE BIOTECHNOLOGY 1027, 1027 (1999).

With the passage of the Bayh-Dole Act, the character of research transformed from academic-and research-oriented to commercially and financially driven. *See id*. at 1019. The Bayh-Dole Act has been described as "the fruits of academic research [being] passed from taxpayer funded laboratories directly to the wallets of the pharmaceutical manufacturers." Gorman, *supra*. Whereas parties would have openly shared the information before the act, they now patent their discoveries. *See* Schachman, *supra* at 305 ("Prior to the passage of the Bayh-Dole Act, patent laws strictly separated academic research from corporate profit. If a scientist took even one dime of money from the government, then the rights to his or her discovery remained in the public domain."); Gorman, *supra*. The shift from sharing information to a race to the patent office may seem justified given the investment and time involved in biopharmaceutical research. It creates obstacles, however, to further research since other inventors must obtain licenses to use and benefit from such research, which prior to Bayh-Dole would have been published. Further, this increase in patents also poses a potentially great anticommons problem. *See* Heller & Eisenberg, *supra* note 50, at 699. S*ee also* Schachman, *supra* at 304-06. Bayh-Dole provides several avenues which have not really been used, including "march-in" rights for public health or government interest clause. These rights quickly call to mind a regulatory taking.

Bayh-Dole is not solely responsible for the shift in research culture. Rai notes that though pharmaceutical companies have historically focused on small-molecule drugs and research, they now focus on research involving genes and proteins. *See* Rai, *supra* note 11, at 816. As this information is owned by biotechnology companies, we are seeing an increased relationship and collaboration between the two sectors. *See id*. This includes both collaboration and vertical integration, either with biotechnology firms moving downstream, or pharmaceutical companies moving upstream. This was the case with Novartis and the

successful method to spark private investment in research and also "leaves open [the] possibility of multiple development paths for the research."[168]

How much spark is truly needed to patent?[169] In light of the Bayh-Dole Act

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Genomics Institute, Human Genome Sciences and Millennium. *See id*. at 817-18 (noting that this serves the companies in establishing joint institutions, reducing licensing costs, and the like); Clarke & Pearson, *supra* note 165, at 482-83 (noting that large companies are increasingly outsourcing research to smaller companies and start-ups).

Yet, the relationship of large companies with start-ups is not fully altruistic. More and more large companies are licensing research tools and patented information to start-ups in exchange for equity. Robert Kneller, *Technology Transfer: A Review for Biomedical Researchers*, 7 AM. ASS'N FOR CANCER RES. 761, 769 (2001), *available at* http://clincancerres.aacrjournals.org/cgi/content/full/7/4/. Some companies are taking the initiative to make information public. This is likely partially self-motivated, to avoid the need to enter licensing agreements as well as any possible anticommons which result from numerous patents. *See* Walsh, *supra* note 128 (noting the GenBank and SNPs Consortium databases of genomic information); Rai & Eisenberg, *supra* note 128, at 298 (noting that "when stakeholders in the biopharmaceutical industry have seen the potential for an anticommons, they have reacted not by forming patent pools but, rather, by enhancing the public domain"). Universities themselves are also attempting to maintain the previously existing culture by making publication conditional upon authors making sequences available via such public databases. *See* Walsh, *supra* note 128.

[168] Rai, *supra* note 11, at 819 n.24. *But see* Rep. of the Nat'l Inst. of Health (NIH) Working Group on Research Tools (June 4, 1998), *available at* http://www.nih.gov/news/researchtools/#backgrnd (highlighting a DOJ statement that, "[i]f there was one point on which virtually every private firm that we spoke to was in agreement, it was that universities take inconsistent positions on fair terms of access to research tools depending on whether they were importing tools or exporting them."). "Universities want it both ways. They want to be commercial institutes when it comes to licensing their technology, but to be academic environments when it comes to accessing technology that others have developed . . . ." *See id*. (quoting an anonymous lawyer from a small biotechnology firm).

"Research tools" are defined by the NIH as the "full range of resources that scientists use in the laboratory [including] cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software." *Id*. There is a "frustration in biotechnology, pharmaceutical, and academic research sectors with the high transaction costs of licensing negotiations over research tools." Rai, *supra* note 11, at 832. The Association of American Medical Colleges has emphasized the importance of granting access to biomedical research tools. *See* David Korn & Stephen Heinig, *Public Versus Private Ownership of Scientific Discovery: Legal and Economic Analyses of the Implications of Human Gene Patents*, 77 ACAD. MED. 1301, 1302 (2002).

[169] *See* Bessen & Maskin, *supra* note 35, at 2 (indicating that "some of the most innovative industries today" are those to which patent protection is less available or weaker, such as computers and semiconductors); Coale, *supra* note 33 (noting the original purpose of patent laws was to spark innovation by encouraging disclosure of inventions).

and the availability of public funding, how much additional motivation is needed vis a vis the patent system?[170] Given the effectiveness of the Bayh-Dole Act, the question remains whether broader patent scope is actually needed to motivate research.[171] The biopharmaceutical industry is characterized by rapid discovery and invention: one needs only "fiddle" with chemical structure to come upon a new discovery.[172] At the same time, commercializing these products requires significant financial resources and surviving a lengthy approval process.[173] The Department of Justice recognizes the economic incentive that patents provide to engage in "risky and costly research and development."[174] The promise of full patent rights for successful

Interestingly, in the context of computers, a series of 1980s judicial decisions granting greater patent protection in the software industry actually led to a time of inactivity, and even a decrease, in research and innovation. *See id*.

[170] Many inventions are born in private universities who in turn license the invention to the commercial sector. *See* Faith S. Fillman, Comment, *Doctrine of Equivalents: Is* Festo *the Right Decision for the Biomedical Industry?* 33 ST. MARY'S L.J. 493, 494 (2002); *Final Report*, *supra* note 61 (noting the stimulus Bayh-Dole gave university inventions and the fact that some see the commercialization of such inventions as a societal benefit); Cook-Deegan, *supra* note 87. Increasingly in the biomedical area, research is taking place in academic institutions and being commercialized through licensing agreements. *See infra* notes 199-207 and accompanying text; Fillman, *supra* at 494. Perhaps patents should be reserved only in those fields it is "necessary to grant a patent to get an invention." *See* Nelson & Mazzoleni, *supra* note 32.

[171] Some may even question the "effectiveness" of the Bayh-Dole Act. Concerns have been raised about limitations on research data and obstacles to research, the distortion of the traditional university research agenda, and whether increased patenting truly reflects the licensing and transfer of patented technologies. *See Final Report*, *supra* note 61.

[172] *See* Rai, *supra* note 11. In the pharmaceutical industry, the chemical structure of a drug is both the invention and the product. *Id*.

[173] *Id*. As discussed above, Kitch believes that granting broad monopoly rights on research, both upstream and downstream, is necessary to motivate research and development, to allow inventors to successfully recoup the benefits they are due, and to coordinate future development, i.e. through licensing. *See id.*

[174] The Department of Justice has indicated that it will not challenge a property owner taking advantage of the full value of its patent. *See* United States Department of Justice, *Antitrust Enforcement Guidelines*, § 3.62 (Nov. 10, 1988). An aspect of property ownership in the U.S. is the right to contract away such rights as one desires. *See* John W. Schlicher, *The Law and Economics of Licensing Biotechnology Patent and Related Property Rights in the United States*, 235 PLI/PAT 333, 361 (1987). "Allowing the owner of intellectual property to use license restrictions in order to reserve some exclusive use of the licensed property to itself . . . may encourage efficient licensing of technology where the owner of intellectual property otherwise might choose not to license its property at all." *See* ANTITRUST GUIDELINES, *supra* at § 3.61. *See* Dickinson, *supra* note 37. Moreover, antitrust and intellectual property laws are seen as being wholly complementary to, and sharing the same goals of, innovation, development and competition. *See* Atari Games Corp. v.

discovery is important motivation for inventors entering the unpredictable, competitive biopharmaceutical area.

B. Competition and Innovation

Many researchers and pharmaceutical companies compete to discover new drugs. Where new technology or an invention is expected to lead to improvements or follow-on discoveries, a broad patent may provide intense incentive for initial discovery, whereas a narrow patent on such initial discovery will reduce costs and minimize the obstacles for subsequent researchers.[175] Does the presence of a strong patent with broad scope[176] actually serve as a productive incentive, attracting inventors and investors to biopharmaceutical research and resulting in useful inventions, or does it simply result in too much investment in the drug market? Many posit the latter.[177] One must also question whether, once attracted, the actors will "stay in the inventing competition over time and [engage in an efficient and successful]

Nintendo of America, Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990).

[175] *See* Gilson, *supra* note 19. Regarding improvements on patented technology, Merges and Nelson emphasize that:

> [E]very potential inventor is also a potential infringer. Thus, a "strengthening" of property rights will not always increase incentives to invent; it may do so for some pioneers, but it will also greatly increase an improver's chances of becoming enmeshed in litigation . . . . When a broad patent is granted . . . its scope diminishes incentives for others to stay in the invention game, compared again with a patent whose claims are trimmed more closely to the inventor's actual results. This would not be desirable if the evidence indicated that control of subsequent developments by one party made subsequent inventive effort more effective. But the evidence, we think, points the other way.

Merges & Nelson, *supra* note 3, at 916.

[176] Though broad scope may be granted through claim interpretation, scope may also be broadened through the use of the doctrine of equivalents. This can have a direct impact upon competition and innovation, as noted by the United States Supreme Court:

> [The DOE] renders the scope of patents less certain. It may be difficult to determine what is . . . an equivalent to a particular element of an invention. If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 732 (2002); *see also* Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17 (1997).

[177] *See* Nelson & Mazzoleni, *supra* note 32. Several "patent race models" have been put forth, including those by Loury, Dasgupta and Stiglitz, and Barzel. *See id.* Nelson and Mazzoleni describe the models, summarizing that when there are increases in "total inventive effort exerted at any one time or in the number of persons engaged in inventive activity," the benefit becomes less clear. The increase in inventive effort in one area heightens the consequences of a "winner-take-all system" and may result in overinvestment of resources. *See id.*

inventive effort over the long run."[178] Kenneth Arrow believes that "competition is essential to invention."[179] Such competition, according to Arrow, may lead to inefficiency and duplicative research in the ever-present quest to be the first to the patent office.[180]

Merges and Nelson take the "[s]imple [view] . . . that when it comes to invention and innovation, faster is better."[181] Further, they contend that the sooner improvements on patented products can be placed on the market, the sooner the benefit to society, both in meeting current consumer need as well as in developing subsequent, future improvements.[182] Merges and Nelson's view appears superior to Kitch's in the biopharmaceutical area.

Rai takes the position that broad patent rights, particularly upstream rights, usurp and challenge the important role of competition in biopharmaceuticals.[183] History has shown that in those industries in which cumulative innovation plays an important role, "broad patents on initial invention could not be licensed effectively and hence hindered subsequent development."[184] Though waste and inefficiency are indeed concerns,

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[178] Merges & Nelson, *supra* note 3, at 869. Inventors know that as another finds a new discovery or creates a new drug, there remains less to reap. The greater the number of inventors, the lower the probability of success, i.e. winning the race to invent and patent, for each. Some inventors may avoid crowded fields of research or may abandon their efforts after a short time. *See* Merges & Nelson, *supra* note 3, at 870 (discussing "over fishing" and indicating that many competitive inventors "fish" from the same "pool" and each inventor knows that as others "catch" or invent, less remains to be "caught"); Kieff, *supra* note 12, at 710 (discussing the resulting problem "when the lure of a reward causes too many individuals to engage in the rewarded activity"); Bessen & Maskin, *supra* note 35, at 1. Given the broad scope of the patent reward awaiting the successful inventor, particularly in the biopharmaceutical arena, this is likely improbable.

[179] Rai, *supra* note 11, at 819. Arrow believes this is particularly true in fields like biopharmaceuticals where patent rights are available downstream and would lead to substitute products on the market. *See id.*

[180] *See* Merges & Nelson, *supra* note 3, at 870. The races to the patent office have seen an increase in frequency. The number of U.S. patents granted increased 159% from 1981 to 2001. The bulk of this increase came in the years 1996-2001. The increase does not reflect a greater number of inventions, simply a greater number of patents. *See Final Report*, *supra* note 61.

[181] Merges & Nelson, *supra* note 3, at 878. They base their statement on a study of the relationship between research, development, invention and increase in productivity. *See id*. The study shows, generally, that the more money that is spent on research and development, the more inventions will result; the more inventions that result, the better the effect on increase in productivity, and the better the productivity, the better the economy. *See id*.

[182] *See id*. at 879.

[183] *See* Rai, *supra* note 11.

[184] *Id*. at 831. *See* Merges & Nelson, *supra* note 3, at 886-87, 890-91. Thomas Edison's broad patent on his improvement to the light bulb forced competitors who had made

competition is better than leaving discovery in the hands of a few, evidenced, for example, by the increased speed of technological advancements when competition plays a role.[185] Though a patentee indeed has a legitimate legal right to exclude others from practicing one's patented invention, such right can also block future innovation.[186] Balancing the need for adequate incentives to develop new inventions and research tools with the need for these tools to be readily available in the field for subsequent improvement and development is a prevailing conflict in biopharmaceuticals.[187]

In the biopharmaceutical industry most cumulative innovation occurs in the "pre-commercial" stage.[188] The increase in upstream patents is particularly troublesome because it takes only one upstream patent to block downstream research and innovation.[189] This is an exceptional concern in fields with

subsequent improvements out of business and hindered innovation. *See* Rai, *supra* note 11, at 831; Merges & Nelson, *supra* note 3, at 849-50, 885-87. Agreements to license the Wright brothers' patent on the airplane were reached only because of the pressures of World War. *See* Rai, *supra* note 11, at 831. According to Merges and Nelson, "[t]he exact nature of failure to license differed by industry." *Id.* Yet, many agree that strong patent rights result in lower licensing costs. *See* Nelson & Mazzoleni, *supra* note 32.

[185] *See* Merges & Nelson, *supra* note 3, at 908; Rai, *supra* note 11, at 819.

[186] Rai reports that Bristol Meyers, a leading U.S. pharmaceutical company, concedes the inability of the company to complete projects because of broad upstream patents which successfully blocked such research. *See* Rai, *supra* note 11, at 831-32 (citing Peter Ringrose in R&D at Bristol Myers, who said there were dozens of projects the company could not do because it could not get requisite licensing agreements with upstream patent holders). *But see* Walsh, *supra* note 128 (noting study results that indicate no "worthwhile projects being stopped because of issues of access to IP rights to research tools"). This is because researchers are entering into licensing agreements, conducting the research outside of the United States, circumventing patents, launching patent validity challenges, or simply deciding to infringe existing patents. *See id.*

[187] *See* Koo & Wright, *supra* note 11 (discussing the important role research tools such as cell lines, cloning tools, and the like, play in improvement and innovation); Walsh, *supra* note 128 (noting that though biomedical advances are encouraged by patents, "by raising the costs of access, growing numbers of patents on research tools may now be retarding the pace of biomedical discovery").

[188] Rai, *supra* note 11, at 815 n.4 (indicating that most cumulative drug innovation happens prior to the production of the end product, namely the drug). Rai indicates that end-stage drugs are not generally improved; the greater competition comes from generic drug equivalents or "me-too" drugs. *Id.* "Me-too" drugs "perform the same function as the patented drug but do so without infringing the original drug patent." *Id.* Rai notes an exception to this position, namely, "where the patented drug is not a traditional small molecule chemical but, rather a biologic (e.g., a protein or other macromolecule) and the improver has come up with a dramatically different method for producing the biologic." *Id.*

[189] Heller & Eisenberg, *supra* note 50, at 698 (noting that the "proliferation of intellectual property rights upstream may be stifling life-saving innovations further

constantly developing scientific advances.[190] Broad patents, however, are not the only concern in this area. A proliferation of narrow rights may likewise prevent needed research and development.[191] Too many patent rights and too much competition can invariably result in what is known as the tragedy of the anticommons.[192] The anticommons tragedy can be characterized as "property

downstream in the course of [biomedical] research and product development"); Rai & Eisenberg, *supra* note 128, at 290 (noting the courts have not resisted the influx of upstream patents). *See generally* Merges & Nelson, *supra* note 3. For example, a pharmaceutical company desiring to develop a drug to treat Alzheimer's requires access to associated genes and gene fragments. Rai, *supra* note 11, at 816. Securing such genes requires negotiations with several biotech companies who may own these applicable genes. *See* Rai, *supra* note 11, at 816. This has also been a concern in the past in non-pharmaceutical fields. *See* Merges & Nelson, *supra* note 3, at 882 (noting the Selden automotive patent and the Edison light bulb patent). Rai proposes that narrow patent rights on upstream research still "may create sufficient research incentives . . .because [such] research is inexpensive or, at least in part, publicly funded." Rai, *supra* note 11, at 838. Lee Bendekgey and Dr. Diana Hamlet-Cox of Incyte Genomics contend there is no concrete evidence that, in the context of gene research, patenting has thwarted research. *See* Korn & Heinig, *supra* note 168, at 1305 (noting his "pessimis[m] that the diversity of participants in biotechnology will provide a 'sufficient community of interest to organize comprehensive low-royalty cross-licensing' regimes").

[190] Merges and Nelson note:

> [T]echnologies whose advance is predominantly driven by recent developments in science, while rare, warrant special recognition. In these [areas] . . . research and development efforts attempt to exploit recent scientific developments[, which] tend to narrow and focus perceived technological opportunities and concentrate the attention of inventors on the same thing. [This deserves] distinction for several reasons: given the inventive race, the first too apply a scientific finding will get a patent of considerable scope; new scientific and tech developments in the air open the possibility of a major advance over prior practice, and the contribution made by the individual or firm who first makes these possibilities operational may be relatively small. Also the invention may diverge from prior art and sweep the market yet still be only a successful application of knowledge that is apparent to the scientifically sophisticated. Where this is possible the patent system should be careful in awarding broad scope patents. Finally, there is a real danger that allowing patent scope to be overbroad may enable the individual or firm that first come up with a particular practical application to control a broad array of improvements and applications.

Merges & Nelson, *supra* note 3, at 883-84.

[191] *See* Barton, *supra* note 22, at 1933 ("[T]hose who wish to introduce a new pharmaceutical product must negotiate an unwieldy number of license with firms that have patents on various steps in the research. [As such,] it has become necessary to negotiate complex cross-licenses and agreements to maintain freedom of access to broadly useful information and technology.")

[192] *See* Heller, *supra* note 51, at 622 (defining the tragedy of the anticommons as the situation where "multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use. When there are too many

rights [divided] so small [that one has] to negotiate with too many people to do

owners holding rights of exclusion, the resource is prone to underuse – a tragedy of the anticommons.") (citations omitted); s*ee also* Heller & Eisenberg, *supra* note 50, at 698. Heller's anticommons theory is an adaptation of Garrett Hardin's tragedy of the commons, which Hardin used to explain overutilization of resources and has been used in economic, legal and scientific analyses. *See id*. at 698. Heller and Eisenberg emphasized the corollary, the underutilization of a resource when too many rights are granted in a resource. *See id*. at 699. Heller looked at post-socialist Russia to describe the anticommons tragedy: so many "fragmented rights" were granted in the privatized storefronts that it was too cumbersome or impossible to obtain the numerous need approvals. In response, store owners set up kiosks on the street in front of the stores. *See* Heller, *supra* note 51, at 622-24, 633-59 (comparing the storefronts to komunalkas, a type of communal-living apartment prevalent in the former Soviet Union). The tragedy can arise whenever the government creates new property rights. *See id*. at 624. There is indeed potential for an anticommons tragedy in the biotechnology and biomedical areas, where many upstream patents are being granted.

Some pay particular attention to ensuring that the development of therapeutic discoveries is not inhibited by countless patent rights. *See* Korn & Heinig, *supra* note 168, at 1305 (noting Scherer's "pessimis[m] that the diversity of participants in biotechnology will provide a 'sufficient community of interest to organize comprehensive low-royalty cross-licensing' regimes"). This is highlighted in the Myriad Genetics infringement dispute with Institute Curie. Institute Curie developed an improved diagnostic test. Because it infringed the Myriad patent, however, the test could not be made available to the public. JoAnn Lee, *Policy Court: Hardin vs. Heller & Eisenberg*, at 3. These social costs are often warned of. *See* Chang, *supra* note 11, at 35; Nelson & Mazzoleni, *supra* note 32.

Rai and Scherer agree that, in the biopharmaceutical industry, the likelihood of pooling patents is low. Korn & Heinig, *supra* note 168, at 1305; *see* Rai & Eisenberg, *supra* note 128, at 297-98 (noting that disseminating information publicly, not patent pools, has been the solution of choice in the biopharmaceutical industry). Yet, others suggest that it benefits institutions that interact with one another to together develop institutions and reduce licensing transaction costs. *See* Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1328 (1996). Rai acknowledges the increasing, significant, horizontal mergers within the biopharmaceutical industry. *See* Rai, *supra* note 11, at 818, 822. This industry standard-setting, a self-regulation of sorts, has been seen in other areas where anticommons tragedies exist, such as the semiconductor industry. Christopher Stadnick, *Standard Setting Organizations: Answer to the Tragedy of the Anticommons?* 4, *at* http://www.law.upenn.edu /fac/pwagner/ideas/stadnick_paper.pdf (Nov. 12, 2002) (noting generally that under certain circumstances industry standard setting is a solution to the anticommons tragedy and indicating the ability of the semiconductor industry to reduce transaction costs and facilitate licensing). Industry standard setting can also be seen in the music industry in the copyright context. *See* Heller & Eisenberg, *supra* note 50, at 700.

This also leads to a real fear that our patent system is "imposing an unnecessary drag on innovation by enabling multiple rights owners to "tax" new products [and] processes." Shapiro, *supra* note 88, at 121. An area where this is apparent, which has a direct effect on biopharmaceuticals, is gene patenting. *See supra* note 88 and accompanying text; *infra* note 280 and accompanying text (discussing gene patenting).

anything meaningful and the transaction cost prevents you from doing important or large products."[193] This is particularly troubling in any upstream research and even more in biotechnology,[194] which by its nature easily lends itself to an anticommons tragedy.[195] Patents are often granted on upstream research in the biotechnology sector.[196] Federal Circuit decisions and PTO policies afford upstream patents a relatively narrow scope, as the Federal Circuit has imposed a low obviousness standard but a very high disclosure standard.[197] Though this may prevent broad upstream patent rights, the resulting plethora of narrow patents may still result in an anticommons tragedy, reducing access to needed research tools and requiring a researcher to

[193] Burk, *supra* note 1, at 14. The anticommons concern in this situation is evident. The number of subsequent licenses and licensing fees a researcher must obtain not only hinders research and development but also compromises health care. *See* College of American Pathologists, *Genes Patents Detrimental to Care, Training, Research at* http://www.cap.org /apps/docs/advocacy/advocacy_issues/Issue_Genepat.html (last visited Feb. 26, 2005). This anticommons tragedy has also arisen in the computer and software industry as well as in the telecommunications industry, where the problem is said to "abound." *See* Thomas Hazlett, *Tragedies of the Tele-commons*, FIN. TIMES, Apr. 18, 2003, *available at* 2003 WL 15525117; Reback, *supra* note 32.

[194] Compared to downstream research and innovation, upstream research is often subsidized or not particularly expensive to conduct. *See* Rai, *supra* note 11, at 838. Rai says this is especially true with upstream research on gene fragments or SNPs. *See id*.

Dan Burk explains the recent approach of the Federal Circuit to interpret and impose a very low obviousness standard in the biotechnology area. Burk, *supra* note 1, at 13. If the exact sequence of DNA, for example, cannot be found in the prior art, then the sequence is considered nonobvious and a patent may be granted. *Id*. This results in the grant of many patents which are narrow and limited in scope. *Id*. This situation easily lends itself to an anticommons tragedy, where we will have "numerous probably overlapping patents or numerous adjacent patents, all of which are very, very narrow." *Id*. The exact opposite prosecution history estoppel occurrence is observed in the software field. *Id*. People do not have to disclose codes but because of the high obviousness standard the prior art often makes such code obvious. *Id*. This results in the grant of few patents, which are broad in nature if actually issued. *See id*.

[195] Research in this area often depends on using patented research tools. *See* Rai, *supra* note 11, at 832. This is particularly true when gene or receptor patents are involved, as they are difficult to invent around. *See id*. at 842. This may appear to have little effect on biopharmaceutical research, which tends to be less cumulative than other areas. *See id*. at 828-31. Given, however, the increasing importance of genes, proteins and the like in biopharmaceutical development, cumulative innovation and use of patented research tools will likely play a more important role in drug research in the future. *See id*. at 831-32.

[196] *See* Rai & Eisenberg, *supra* note 128, at 290 (indicating the judiciary's willingness to allow patentability on upstream research).

[197] Rai, *supra* note 11, at 838. This has resulted in narrow rights. *Id*.

obtain numerous approvals or licenses prior to research efforts.[198]

Query whether broad scope inherently limits access to research tools. It is interesting to look at the patents held by Myriad Genetics on the BRCA breast cancer genes and those held by the Wisconsin Alumni Research Foundation (WARF) on embryonic stem cells (ESCs). The BRCA patents claim approximately eighty human gene segments, diagnostic techniques, and the right to use the genes for pharmaceutical and therapeutic uses.[199] Though the Myriad patents cover only two breast cancer genes, BRCA1 and BRCA2, and related gene segments, the effects are far-reaching and preclusive.[200] Myriad has successfully prevented other companies from developing diagnostic tests and performing research which involve BRCA genes in any way.[201]

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[198] Downstream inventors may not be able to, or it may be cumbersome to, obtain patent rights or licenses on all of the upstream patent rights, resulting in a standstill in downstream research and commercialization. *See supra* note 186 and accompanying text.

[199] *See* Greenpeace, *The True Cost: The Economic and Social Consequences of Patenting Genes and Living Organisms*, http://weblog.greenpeace.org/ge/archives /1Study_True_Costs_Gene_Patents.pdf (last visited Feb. 26, 2005). Some have criticized the grant of the BRCA patents itself, as Myriad engaged in "slight technical performance" and before discovery by Myriad, "it was already known on which chromosome and in which chromosome segment the mutations" were located. *Id.* The grant of patent protection, however, doesn't seem alarming or unfair, as the promise of patents, akin to Dr. Thomson's research with the ESCs, motivated companies like Myriad to continue research. There is a difference between having a general idea as to the location of mutations and actually locating the mutations, as only the latter are important in diagnosis, therapy, and research.

[200] *See* Donald J. Willison & Stuart M. MacLeod**,** *Patenting of Genetic Material: Are the Benefits to Society Being Realized?*, *at* http://www.cmaj.ca/cgi/content/full/167/3/259 (Aug. 6, 2003); Lee, *supra* note 192, at 3 (noting Myriad's aggressive defense has "alarmed the biomedical research community."); David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?* 3 J. PHIL, SCI. & LAW (2003), *at* http://www.psljournal.com /archives/papers/biotechPatent.cfm (noting the detrimental impact of Myriad's strict patent enforcement on women's health); Nat'l Human Genome Res. Inst., *Questions About the BRCA1 and BRCA2 Gene and Cancer Test*, *at* http://www.genome.gov/10000940 (last visited Feb. 26, 2005) (indicating that a woman's family history is the most important indicator of propensity for breast cancer and highlighting the importance of the BRCA genes in diagnosing this type of cancer). *But see* MSN Money Central, *Myriad Genetics, Inc. Will Provide its BRACAnalysis Genetic Test of the BRCA1 and BRCA2 Breast Cancer Genes as a Research Service to the National Institutes of Health*, *at* http://news.moneycentral.msn.com/ticker/sigdev.asp?Symbol=MYGN&PageNum=1 (Feb. 3, 2000) (noting Myriad's agreement to provide the National Institutes of Health its BRACAnalysis genetic test of the BRCA genes "as a research service to scientists and grantees of the [NIH]" and that the agreement "will help NIH and NIH-supported scientists to aggressively pursue several fundamental research questions involving the BRCA genes, which are a major cause of inherited breast and ovarian cancer"). BRCA genes are "genetic sequences indicating a predisposition to breast cancer." *Id.*

[201] The Commission on Intellectual Property rights recommended that developing

The WARF ESC patents, on the other hand, are literally broader than the BRCA patents.[202] Some feared that the broad scope of the ESC patents would have expansive and preclusive effects, as ESCs serve as a "springboard" for research in a great number of biomedical areas.[203] Though the Myriad patents are narrower than the WARF patents, both effect upstream research and the development of new diagnostics, treatment and therapies.[204] Unlike Myriad, and reminiscent of the Cohen-Boyer patent, the fears of access to ESCs, despite the broad scope of the WARF patents, appear unfounded because WARF has made ESCs readily available to researchers.[205] One might question whether the scope of a patent actually plays a definitive role in the actual breadth of patent rights or thwarting of research.[206] It seems that the exercise

countries completely exclude human diagnostic therapeutic and surgical methods for patentability. *Final Report*, *supra* note 61.

[202] The claims are so broad that they include all stem cells, whether or not funded by the federal government. *See* Carroll, *supra* note 32, at 441. The patent includes methods for isolating and transplanting ESCs. *Id*. Broad patents on "research platforms" such as the WARF ESC patent, "may outweigh the usual benefits of stimulating invention and development." Korn & Heinig, *supra* note 168, at 1305.

[203] *Stem Cell Research: Hearing Before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies*, 105th Cong. 83 (1999) [hereinafter *Stem Cell Research Hearings*] (statement of Maria C. Freire, Director of The Office of Technology Transfer at NIH). Stem cells serve as a "springboard" for potential discoveries in human physiology, developmental abnormalities, abnormal cellular growth, and illness. Sheryl Gay Stolberg, *Patent on Stem Cell Puts U.S. Officials in a Bind*, N.Y. TIMES, Aug. 17, 2001, at A1. Research is unmistakably paramount to the scientific innovation and advancement, and ESCs are a requisite tool for such research. *See Stem Cell Research Hearings*, *supra* at 84 (statement of Maria C. Freire, Director of The Office of Technology Transfer at NIH). It is crucial for researchers to have access to ESCs. *See id*. at 83.

[204] The concern with the Myriad patents focuses on preclusion of use in diagnosing breast cancer, whereas the concern with the WARF patents focuses on the availability of ESCs for future research. *See* Resnik, *supra* note 200; *supra* note 203 and accompanying text.

[205] Some had feared that WARF's expansive patent rights and lucrative edge defeat the purpose of the patent system, which is not to provide companies an advantage but to protect inventors and allow them to recover research and development costs. Zerega, *supra* note 23; *see* John Miller, Comment, *A Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market*, 13 ALB. L.J. SCI. & TECH. 555, 575 (2003).

[206] WARF, though it holds a patent with broad scope, freely licenses and makes easily available the ESCs needed for research. Quite the contrary, one may have initially overlooked Myriad's comparatively simple patent on the BRCA genes and gene segments; yet, the effect of Myriad's strict enforcement of its patent rights, however narrow such rights may be, seems to have had the far greater effect. Carroll, *supra* note 32, at 442. This comports with Kitch's view that a patentee has the right to control the licensing and innovation of a patented discovery. *See* Gupta, *supra* note 25.

of control by the patentees over the patented technology, primarily the licensing of the technology and enforcement of patent rights rather than the actual patent scope granted, may actually have a direct effect on future research.[207]

C. *Doctrine of Equivalents in the Biotechnology and Biopharmaceutical Fields*

The granting of narrow patents does not end these concerns and may additionally raise anticommons concerns. Further, even if patent claims are construed narrowly, the patent scope may still be generously expanded vis a vis the doctrine of equivalents. The application of the doctrine of equivalents in the realm of gene and protein patents, which appear to be the foundation of new medical breakthroughs, is highly significant, particularly given the strict § 112 written description and enablement standards being imposed by the courts.[208] Thus there is debate over its applicability.[209] Here, too, there is no bright line rule. Given the strict written description requirements, the use of the doctrine of equivalents "will be critical to pharmaceutical companies' continuing ability to invest in the development of recombinant DNA

[207] A strong policy of experimental use would perhaps have alleviated this problem. *See generally supra* note 167 and accompanying text; *infra* note 247 and accompanying text (describing the experimental use). Merges & Nelson would likely frown upon Myriad's strict enforcement of its patent on the BRCA gene, particularly in connection with research and in providing new and substitute treatments and diagnostics. *See supra* note 190 and accompanying text.

[208] "Biotechnology inventions are particularly susceptible to section 112, first paragraph rejections, as they are held to heightened enablement and written description requirements." Sheila R. Arriola, *Biotechnology Patents After* Festo*: Rethinking the Heightened Enablement and Written Description Requirements*, 11 FED. CIR. B.J. 919, 922 (2002). "[M]edical breakthroughs will require the identification and characterization of the proteins expressed by human genes." Ryan & Brooks, *supra* note 112, at 1266. Protein engineering, in particular, involves scientists improving upon naturally occurring proteins by modifying them. *See id*. at 1266. The courts are already requiring that researchers identify specific structures in order to fulfill section 112 requirements. *See supra* notes 108-10 and accompanying text.

In the area of gene patenting, the scope of protection has been constantly upstaged by ethical debates over the patenting of human genes. *See* Ryan & Brooks, *supra* note 112, at 1267. This area is pervaded with uncertainty as to what is actually covered by gene patents. Will "gene and protein patents, once issued . . . cover variant genes and proteins that differ slightly in their nucleotide or amino acid sequence[?]" *Id*.; *see also* Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200 (Fed. Cir. 1991).

[209] The tension has real consequences. Granting broad rights over variant genes may impede future improvements and developments. At the same time narrow, patent scope over the exact sequence and structure claimed in the original patent may easily be circumvented by making small modifications to gene or amino acid sequences.

products."[210]

While the doctrine of equivalents serves useful purposes, its use should be limited in the context of biopharmaceuticals, gene and DNA patents.[211] In *Genentech v. Wellcome*,[212] the Federal Circuit took this view and held that the doctrine of equivalents should not be applied to expand the scope of Genentech's original patent on the natural human amino acid, t-PA.[213] Likewise, the doctrine of equivalents should be the rare exception for a patentee whose patent is being unjustly circumvented, not a generous grant of judicially-determined, unsubstantiated broader scope. This is not to say that courts should never apply the doctrine of equivalents.[214]

It is said that patent holders are inventors, not drafters of language.[215] Yet, together with skilled patent attorneys, inventors should generally be able to disclose their invention and specifically claim the metes and bounds of their invention to fulfill the notice function of a patent. The doctrine of equivalents should, appropriately, be applied to allow the patent holder some narrow protection from unscrupulous copiers and from those who attempt to circumvent patents with minimal change. At the same time, patent holders should not be given free license over all subsequent inventions simply because

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[210] Ryan & Brooks, *supra* note 112, at 1267.

[211] If "progress" is the constitutional concern, then the patent system should operate to ensure that the work of an improver is, indeed, "progress." *See* Bohrer & Prince, *supra* note 89, at 402. In the pharmaceutical context, the concern is magnified as pharmaceutical companies can simply compare their product to one already patented or one in the FDA approval process. There are also benefits, however, as inventors can better judge the value of an improvement based on the availability of such information. *See id.* at 403. The concern for "progress" and innovation does not apply, however, in the context of an orphan drug. *See id.* (noting that orphan drugs "treat a rare disease and have a useful scientific rationale, but need not be a new or nonobvious chemical entity or even a nonobvious use of an existing chemical entity"); *see also supra* note 89 (discussing orphan drugs).

[212] 29 F.3d 1555 (1994).

[213] *See id.* at 1567-69. The court applied the traditional three-part "function, way, result" test of *Graver Tank* and determined that since the accused product "possess[ed] dramatically different properties[,] structure, [and] mode of binding [and] behave[d] significantly differently than human t-PA in the human body," it was not an equivalent of the natural t-PA that was the subject of Genentech's patent. *Id.* at 1568. This is fitting as the new Supreme Court standard in the *Warner-Jenkinson* decision was not articulated until 1997. Presumably, as equivalence was not found under the equivalent "function, way, result" test, it likely would not satisfy the all elements test articulated in *Warner Jenkinson*. *See id.* at 1567-69.

[214] *See* Ryan & Brooks, *supra* note 112, at 1267-77; *supra* note 208-09 and accompanying text.

[215] *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd, 234 F.3d 558, 620 (Fed. Cir. 2000) (Linn, J., concurring in part, dissenting in part) (indicating that literary skill should not be the focus).

such discoveries involve the patented discovery in some remote or tangential manner.

D. Does Utility Serve as an Effective Limit on Patent Scope?

Academic researchers, who generally engage in upstream research rather than downstream research or commercialization, are directly affected by patent rights and licenses. The utility requirement may be a way to limit these concerns by denying patents to certain discoveries or by excluding upstream research from patentable subject matter.[216] Rai believes that utility is the best way to categorize a discovery as upstream or downstream research.[217] The 2001 PTO utility guidelines were put forth after great pressure and criticism by the academic research community opposed to broad upstream research patents.[218] The guidelines seemingly remove much upstream research from

[216] Some propose the government ask itself "in what subject matter areas [it wants] to encourage innovation [and] in what areas it is willing to grant limited monopolies." Heim & Chorush, *supra* note 30, at 4-5. The PTO could, theoretically, refuse to grant patent protection to isolated genes and proteins, ESCs, and the like. This hypothesis, in light of the Supreme Court's decision in *Diamond v. Chakrabarty*, seems relatively unlikely. *See* 447 U.S. 303 (1979); *see also supra* note 189 (discussing how courts have generally accepted and allowed patents on upstream research and tools). Courts have applied utility stringently in the biotech industry. This was seen in the pharmaceutical context when the PTO, in its Proposed Utility Guidelines, required a showing of proof of therapeutic efficacy. Request for Comments on Proposed Utility Examination Guidelines, 60 Fed. Reg. 97, 98 (Jan. 3, 1995). The Federal Circuit later weakened this requirement and held that indicators, rather than proof, of efficacy were sufficient to satisfy utility. *In re* Brana, 51 F.3d 1560, 1567 (Fed. Cir. 1995).

Utility, however, may not the best factor in determining or limiting patent scope. Though utility may be useful as distinguishing between upstream and downstream research or designating when a patent is "patentable," it does not do much to actually limit or broaden patent "scope" in particular. For example, in *Eli Lilly*, the Federal Circuit used the section 112 written description requirement as a quasi-utility standard, akin to the utility standard used in *Brenner v. Manson*, in determining whether a new and useful invention had been discovered. When determining the actual breadth of scope once a patent has issued, however, one is likely better served employing other sections and doctrines of patent law. *See* Brenner v. Manson, 383 U.S. 519 (1966); Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); 35 U.S.C. § 112 (2000).

[217] Of course, drawing the line between upstream and downstream research poses another challenge. Rai believes that utility can at least serve to distinguish upstream and downstream research for purposes of patentability. *See* Rai, *supra* note 11, at 838-39 ("Acquisition of broad power can be thwarted by ensuring that the most upstream research remains outside the bounds of patentability."); 35 U.S.C. §§ 101, 112 (2000). This can in turn limit patent scope. Heim & Chorush, *supra* note 30, at 14-15. Section 101 of the patent laws requires that an invention be "new and useful." 35 U.S.C. § 101.

[218] *See* PTO Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092-93 (Jan. 5, 2001);

patentability by requiring that a "specific, substantial and credible utility" be demonstrated.[219] Requiring such a showing "exist[ed] at the time the patent application [wa]s filed may serve as a limit on the scope of the patent" and may limit the grant of patent rights on upstream research.[220] Conversely,

Rai, *supra* note 11, at 840 n.111. The PTO guidelines were issued with the gene research context in mind. Conversely, Rai believes the PTO standard of "any credible assertion of any research use" was also sufficient to demonstrate utility and is too far the other extreme. *See supra* Utility Examination Guidelines at 1098; Rai, *supra* note 11, at 839; Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 106-07 (1999). It should be noted that the 2001 PTO guidelines were issued with the gene utility in mind. *See* PTO Utility Examination Guidelines, *supra* at 1092-93.

[219] *See* Utility Examination Guidelines, *supra* note 218; Rai, *supra* note 11, at 840. Mirroring *Brenner*, "specific" utility is utility that is particular to the subject matter being claimed. Substantial is generally viewed as having a "real world" utility. Again paralleling *Brenner*, "credible" is interpreted as one skilled in the art would believe that the invention is "currently available" for use. *See id*.; *Brenner*, 383 U.S. at 519.

[220] Heim & Chorush, *supra* note 30, at 14-15. It is uncertain whether the PTO utility guidelines, or future judicial decisions, will invalidate patents currently issued or prevent the issue of future patents. Rai posits that using the utility standard may invalidate the patents currently issued on DNA, genes, proteins, and SNPs. *See* Rai, *supra* note 11, at 840 (citing PTO Revised Interim Utility Guidelines Training Material 50-53 (2000), *available at* http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf). If these patents are still granted and not invalidated, Rai believes they will be "quite narrow in scope and 'will not' have blocking power with respect to later-isolated full genes." *See* Rai, *supra* note 11; *PTO Synopsis*, *supra* note 117. *But see supra* notes 192-95 and accompanying text (indicating an anticommons tragedy is likely when numerous patents are granted).

This appears to not apply in the ESC context. *See* Stacy Kincaid, Comment, *Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research*, 30 PEPP. L. REV. 553, 588 (2003). As the Court in *Brenner* required, ESCs can indeed be said to have a "specific benefit exists in currently available form," namely as a research tool. *Brenner*, 383 U.S. at 534-35. Given the insight ESCs provide into "complex cellular events," drug development, tissue engineering and cell therapy, the ESC patent has several "specific, substantial and credible" utilities. *See* Miller, *supra* note 205, at 560-61, 584. It is true, however, that concerns with the ESC patents differ from those suggested by Rai with gene patents, as the latter are generally more undesirable due to gene fragmentation. *See* Coale, *supra* note 33. The overall concern with gene patents is with the lack of collective ownership rights. Inventors have isolated and patented various gene fragments over the past ten to fifteen years. Even today, all of the major life sciences companies are scouring the planet looking for rare genes with value that may be patentable. *See* Zerega, *supra* note 23. This has resulted in a "mosaic" of rights to fragments of genes and has created a potential "litigation minefield" for scientists when determining which fragments are owned and which can freely be developed. *See* Coale, *supra* note 33 (likening the situation with gene patents with the anticommons problem with real property in the Soviet Union post-socialism); Cook-Deegan, *supra* note 87, at 282; *supra* note 88 and accompanying text

others feel that the use of utility or limitations on the doctrine of equivalents is unnecessary and that given "the relatively small size of the academic science community[,] informal norms may evolve to manage any anticommons concerns that do exist."[221]

E. Is Licensing a Solution?

A patentee has the right to make use of its intellectual property in an effective and efficient manner.[222] Licensing reduces commercialization risks and increases revenue intake.[223] Kitch contends that the holder of patent rights has the right to a broad scope of patent protection and the right to share the patented invention via licensing, which, in Kitch's mind, fosters efficiency. Licensing plays an important role and is a customary practice in the

(noting the development of gene patent thickets).

[221] Kieff takes a relaxed view of the need to limit the number of patents and patent scope, assuming that the research community will address the problem. *See* Kieff, *supra* note 12, at 726-27. Some of these norms may already be addressing the concerns of researchers in the scientific community by proverbially "outsmarting" the patent system and patent holders. Several organizations and companies are acting to place into the public domain as much information as possible regarding gene research. This ironic situation is described as:

> a surprising reversal of roles, it was industry (represented by major pharmaceutical companies) that initiated or helped enable the project to ensure open and unencumbered access to information, the type of access that has historically been the provenance of academia and the raison d^etre of academic research.

Korn & Heinig, *supra* note 168, at 1308. This is being done to "thwart the novelty and nonobviousness requirements of the patent statute and the ability of upstream developers to obtain patents on the information," or in other words to prevent others who are working to get broad patent scope protection. *See* Rai, *supra* note 11, at 832-33; 35 U.S.C. §§ 102(a), 103 (2000). Though this goes against the recent current produced by the Bayh-Dole Act, it will help both the private pharmaceutical industry and academic researchers as both will have the unfettered ability to use such gene-related discoveries in the public domain in further research, developing products for commercialization.

[222] *See* Schlicher, *supra* note 174, at 363. "Licenses of patents and other forms of intellectual property are contracts transferring to the licensees a right to use intellectual property." *See* ANTITRUST GUIDELINES, *supra* note 174, at § 3.61.

[223] *See* Kieff, *supra* note 12, at 725. "Indeed, the use of joint ventures and other licensing strategies to reduce commercialization risk in the biotechnology industry is well recognized." *Id.* This is particularly important as the biopharmaceutical industry faces large risks when bringing a product to market. *See id.* Given how resource intensive such commercialization is, there is a natural incentive for patent holders in the biopharmaceutical area to license to others. *See id;* Teece, *supra* note 32, at page number (indicating a concern that patent holders "negotiate in a socially efficient fashion"). Licensing is generally considered to be "procompetitive." *See* Pate, *supra* note 32. Private parties have control over licensing arrangements. *See Stem Cell Research Hearings*, *supra* note 203, at 84 (statement of Maria C. Freire, Director of The Office of Technology Transfer at NIH).

pharmaceutical industry.[224] "Licensing . . . increases the expected economic returns from intellectual property and thereby increases the incentive to invest in creating such property in the first place."[225]

Situations where one company holds great control raise the fear that the patentee will refuse to license, grant exclusive licenses, prohibit sublicenses, attempt to extract high royalty payments, and generally exercise its patent rights and license in a way that does not promote research and development.[226]

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[224] *See* Walsh, *supra* note 128, at 1021.

[225] Schlicher, *supra* note 174, at 363. It is exactly this desire to win the proverbial race to invent and race to the patent office that likely motivated Dr. Thomson and the University of Wisconsin and led to WARF's strong patent rights on ESCs. This is both acceptable and even desirable. The Antitrust Enforcement Guidelines reflect this notion, and provide:

> Market power or even a monopoly that is the result of superior effort, acumen, foresight, or luck [is acceptable]. The owner of intellectual property is entitled to enjoy whatever market power the property itself may confer. Indeed, respecting the rights of the creator of intellectual property to enjoy the full value of that property provides incentive for the innovative effort required to create the property. And the results of that innovative effort both increase productive efficiency and expand society's knowledge and wealth.

ANTITRUST GUIDELINES, *supra* note 174, at § 3.6.

[226] This was the fear with the WARF patents on ESCs and is the criticism with Myriad's rigorous patent enforcement. Similar speculation was raised approximately twenty years ago when Stanford University was granted the Cohen-Boyer patent. *See* Dickinson, *supra* note 37. The Cohen-Boyer patent was a patent on a "method covering basic recombinant DNA technology." *Id.* Concerns were raised at the time that this patent would inhibit research and that Stanford would limit the dissemination of information and require excessive royalty payments. *See id.* This never happened. To the contrary, Stanford developed a licensing program and offered the licenses at reasonable rates. *See id.* The reason, some believe, Stanford was not challenged was that it provided the technology at no financial cost for academic use and it kept royalties low for other uses. *See* Cook-Deegan, *supra* note 87, at 288.

The Cohen-Boyer patent example lends support to the NIH position on patents and licensing, namely that patents in science are useful and have led to significant scientific and medical advancements. Neither the NIH nor the research community opposes broad, upstream patents. *See* Rai, *supra* note 11, at 841; Jack Spiegel, NIH, *Comment 64 on the Interim Utility Guidelines* 10-11 (Mar. 22, 2000), *available at* http://www.uspto.gov/web/offices/com/sol/comments/utilitywd/nihjs.pdf. For example, the Director of the Office of Technology Transfer of the National Institutes of Health (NIH) has addressed patent and licensing considerations in the context of stem cell research. *See Stem Cell Research Hearings*, *supra* note 203, at 81 (statement of Maria C. Freire, Director of The Office of Technology Transfer at NIH). Of primary concern to the NIH is the availability of technology for development of products for public benefit. *See id.* Dr. Bernadine Healy, the Director of the NIH, has put forth the agency's position that advancements in medicine and technology would not have been developed if not for patents. *See id.* Since October 2001, the NIH has also been working to establish licensing agreements for the stem cell

Cross-licensing may be desirable in the biopharmaceutical area, which is characterized by uncertain patent scope and a burgeoning number of patents.[227] Others see compulsory licensing as the solution when upstream patent holders, such as Myriad Genetics, refuse to license patented discoveries.[228] Compulsory licensing may be deemed effective in areas where a single entity controls the market.[229] Rai disagrees, however, positing that because the biopharmaceutical industry is so heavily dependent on patents, compulsory licensing is not ideal.[230] This is truer when patent scope is viewed narrowly, as

technology and working to create a stem cell registry. Wendy Baldwin, *Statement Before the Senate Appropriations Subcomm. On Labor, Health & Human Services, Educ. And Related Agencies* (2001) *available at* 2001 WL 1336419. The NIH position ignores the view of researchers that obstacles created by numerous upstream research patents stunt research. *See supra* note 186 and accompanying text. The European Union biotech advisory panel similarly maintains that eliminating patenting will slow research and decrease incentives for progress and innovation. *See EU Biotech Panel Backs Human Stem Cell Patents, But Also Compulsory Licenses*, MARKETLETTER, Feb. 20, 2002, *available at* 2002 WL 7179266 (2002). Yet another concern of this new environment is that inventors and researchers will be inclined to engage in defensive patenting. *See* Teece, *supra* note 32.

[227] *See* Teece, *supra* note 32. (describing cross-licensing of patents which are complementary as "unambiguously good"); Merges & Nelson, *supra* note 3, at 890. For example, though many patents exist in the automobile industry, a procedure has been developed for patents to be automatically cross licensed. "While formal agreements to cross license all new patents no longer exist, the practice of relatively automatic cross licensing has endured to the present." *Id*. The computer and aircraft industries are also described as this type of "cumulative system technologies." *See* Nelson & Mazzoleni, *supra* note 32. *But see* Korn & Heinig, *supra* note 168, at 1305 (doubting that biotech players will freely engage in low-royalty cross licenses). Granting broad patents in these industries is "counterproductive" and makes "technological advance difficult and costly." *See* Nelson & Mazzoleni, *supra* note 32; Merges & Nelson, *supra* note 3, at 907 (noting that unless licensing is readily available, the limitations on access will hinder innovation).

[228] *See* Harvey E. Bale, *Patents and Public Health: A Good or Bad Mix?*, *at* http://www.cnehealth.org/pubs/bale_patents_and_public_health.htm (last visited Feb. 26, 2005) (stating compulsory licensing has been "touted as a solution to the access issue"); Hollis, *supra* note 28. *But see* Kirby W. Lee, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175 (2003). For a general discussion presenting arguments in favor of and opposed to compulsory licensing in the biomedical arena, see Lee, *supra* note 192.

[229] *See* Rai, *supra* note 11, at 843.

[230] *See id*. at 842-43 (noting the importance of patents as incentives for drug companies to invest the arduous time and capital in research and development). The push for compulsory licensing in the biopharmaceutical industry has been at the forefront of domestic and international news. Though the lobbies of the large pharmaceutical companies have been successful to date, states are trying to secure prescription drug programs for senior and low-income citizens. *See* Gorman, *supra* note 167 ("the well-off and the well educated . . . are most likely to take advantage of the many drugs available"); Wayne M.

the freedom to license then becomes even more important.[231] Given the

O'Leary, *The Real Drug Lords*, *at* http://www.alternet.org/story/13831 (Aug. 13, 2002) (noting that retail drug prices have been especially difficult for the elderly). It is interesting to consider whether the inability of domestic citizens to obtain pharmaceuticals is a violation of Fourteenth Amendment Equal Protection, given that the government is increasingly funding related research. The results of this research are privately commercialized and are, effectively, only available to that segment of the population able to afford the drugs. It is hardly surprising that elderly and low-income citizens are not part of this segment of the population and are the ones potentially discriminated against.

Compulsory licensing is urged globally in order to get needed medicine to those in dire need – in Latin America, Africa, and elsewhere. *See* 2003 Rep. of Médecins Sans Frontières/Doctors Without Borders, *Trading Away the Health of Millions: Top Ten Most Underreported Humanitarian Stories of 2003*, *at* http://www.doctorswithoutborders.org /publications/reports/2003/top10.html. This is one of the leading human rights issues of our time. *Id*. MSF stated in the report that:

> [T]he US and its powerful pharmaceutical industry have made it harder by pushing for more stringent intellectual property requirements in regional trade agreements . . . that restrict generic competition, [generics being] the only factor that has resulted in sustainable price reductions for essential medicines. Such provisions undermine the 2001 Doha Declaration, an agreement adopted by all World Trade Organization (WTO) members which reaffirmed the right of countries to make full use of existing flexibilities in international trade treaties in order to "protect public health and promote access to medicines for all." These proposals threaten to trade away the lives of millions for commercial profit and make lifesaving treatment a luxury few people like Carmen can afford.

Id. The European Union's European Group on Ethics in Science and New Technology has embraced the use of compulsory licenses when access to health care diagnoses and treatments is blocked and when "unreasonable fees" are charged for inventions and technology. Società Italiana Brevetti, *Biotechnology Patents in Europe: Patenting of Inventions Involving Human Stem Cells: European Group on Ethics Publishes Opinion*, *at* http://www.sib.it/engsib/novita/pat/140502.htm (last visited Feb. 26, 2005) (summarizing Opinion No. 16, the group's report to the President of the European Commission. The group also opined that only modified stem cell lines should be patentable); *see EU Biotech Panel*, *supra* note 227. The biotech advisory panel has recommended that member states establish legal procedures for the delivery of such compulsory licenses as well as a system of overview to assess the situation and to determine whether such licenses are required and appropriate. *See id*.

[231] *See* Rai, *supra* note 11, at 843. Compulsory licensing has many downfalls. "The competition benefits [of compulsory licensing] are small . . . and the long term damage of widespread use [is] likely to be significant." Bale, *supra* note 228. Compulsory licensing is seen as a breach of the bargain made between an inventor and the government, and as nothing more than a taking by the government under eminent domain rights. Further, as is a problem with eminent domain regulatory taking of real property, the compulsory licensing scheme is inadequate and unable to adequately predict and determine a royalty rate as would the competitive market. *See* Rai, *supra* note 11, at 842. This inability to determine "reasonable and entire compensation" is a serious concern. *See* 28 U.S.C. § 1498

important role of licensing, compulsory licensing should be used infrequently in patent law, and only rarely in the context of biopharmaceutical patents.[232]

(establishing the right of patent owners to receive "reasonable and entire compensation" when its patent is infringed). Intellectual property "cannot be effectively managed or efficiently transferred without adequate means to value them." Ted Hagelin, *A New Method to Value Intellectual Property*, 30 AIPLA Q. J. 353, 402 (2000). It is difficult to determine reasonable royalties for a new discovery for which a market does not exist. *See* Carroll, *supra* note 32, at 464. In these areas, there are no "finished products" or commercial applications, nor are there ways to anticipate regulatory costs and reflect these in a royalty structure. *See id.* Courts should not be placed in the "awkward" position of determining appropriate royalties. *See* Rai, *supra* note 11, at 842-43. It is difficult to balance royalties together with future rights before development of these rights, and is difficult to anticipate such regulatory costs and development expenses. *See* Schlicher, *supra* note 174, at 375. This may result in inventors opting for the risk in electing secrecy rather than patenting.

[232] Rai holds one view, that compulsory licensing should only be allowed when an inventor is blocked from getting a needed patent and such inventor can demonstrate that "a market transaction was thwarted by highly strategic behavior by the patentee," such as a patent holder demanding large sums of money, etc. *See* Rai, *supra* note 11, at 842-43. Query, however, the sufficiency of this justification for compulsory licensing. It is well demonstrated and accepted that patent laws provide the right to exclude others from practicing one's patented discovery, and that one who wishes to use the patented technology must enter into a license with, and acceptable to, the patent holder.

Though compulsory licensing is a common remedy in antitrust law, it is generally disfavored in patent law. *See* Chang, *supra* note 11, at 43; *Final Report*, *supra* note 61 (indicating that in the United States compulsory licensing was used in over one hundred antitrust cases) (quoting F.M. Scherer, *The Patent System and Innovation in Pharmaceuticals*, REVUE INTERNATIONALE DE DROIT ECONOMIQUE SPECIAL EDITION: PHARMACEUTICAL PATENTS, INNOVATIONS AND PUBLIC HEALTH 199).

Compulsory licensing would probably be deemed best applied, from an idealistic and human rights standpoint, to solve the world's growing health crises. *See* U.N. Comm'n on Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, (June 27, 2001), *available at* http://www.unhchr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa0238025668700518ca4/590516104e92e87bc1256aa8004a8191/$FILE/G0114345.pdf; John Donnelly, *Deal Paves Way for Generic HIV Drugs*, BOSTON GLOBE, Dec. 11 2003, at A8, *available at* LEXIS, News Library, Bglobe File (summarizing agreements with GlaxoSmithKline and Boehringer Ingelheim); A. Attaran and L. Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatments in Africa?*, 286 J. AM. MED. ASS'N 1886 1886-92 (2001); Bebe Loff and Mark Heywood, *Patents on Drugs: Manufacturing Scarcity or Advancing Health?*, 30 J. LAW, MED. AND ETHICS 621-31 (2002).

The United Kingdom, comparatively, employs compulsory licensing when the demand for patented goods cannot be reasonably met, when the use of another patented discovery involving an "important technical advance of considerable economic significance" is prevented, or if the formation or growth of commercial or industrial activities is unjustly prejudiced. *See Final Report*, *supra* note 61.

Collusive licensing has also drawn considerable attention. Collusive licensing may take place, for example, where an improvement is a substitute for an original product.[233] Scotchmer suggests that competing patent holders should be allowed to enter into collusive licensing agreements.[234] Others suggest that this would create additional incentives for subsequent inventors or improvers to circumvent an original patent.[235] Chang believes, in the context of cumulative innovation, that only patentees holding patents with little social value should be allowed to enter collusive agreements with those who would subsequently produce or invent valuable improvements to such patent.[236]

VIII. PROPOSED SOLUTIONS TO LIMIT PATENT SCOPE

While strong patent protection is needed in the biopharmaceutical industry, certain limitations on patent scope are likewise necessary to encourage and promote biopharmaceutical research and development. In addition to solutions already proposed in this article, such as compulsory licensing and experimental use, the following proposals seek to prevent the negative effects of excessively broad patent scope and rights, and to increase the notice function of patent law.

A. Judicial Limitations of Patent Scope.

Some may be troubled that courts are dictating the subject matter and scope of patent protection in the United States, when the Constitutional power to

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[233] *See* Rai, *supra* note 11, at 815; *See* Scotchmer, *supra* note 62 at 33-34. (giving limited endorsement of such collusion on the theory that it would allow the first innovator to profit from the externality conferred on later inventors); Chang, *supra* note 11, at 49 (saying collusion is unnecessary and should not be permitted).

[234] *See* Scotchmer, *supra* note 62 at 34.

[235] *See id*. at 35 (quoting Kaplow who believes this would result in "excessive social cost").

[236] *See id.* As a general proposition, horizontal agreements of any sort pose an antitrust problem as there exists a great risk of collusion and price fixing amongst firms with cross-licensing agreements. "Though price restrictions in patent law are not illegal per se, licenses may not fix prices if the licenses cover substantial parts of the market and thus cartelize an industry through these price preferences." *See id.* at 36.

Burk and Lemley suggest that an important instrument in the pharmaceutical industry, given the increasing attempts by biopharmaceutical companies to expand their patent scope and rights by entering collusive agreements with generic drug manufacturers, is the revival of the patent misuse doctrine. "The patent misuse doctrine can play a powerful role in deterring anticompetitive efforts to extend patent rights beyond the scope a rational pharmaceutical patent policy would give." Burk & Lemley, *supra* note 9, at 1681-82, 1687 (noting that companies are increasingly entering into collusive agreements, delaying patent prosecution, and obtaining patents on obvious or previously patented inventions). *See generally* Dawson Chem. Co. v. Rohm and Haas Co., 448 U.S. 917 (1980).

create the patent system is granted not to the courts but to Congress.[237] However, the Court in *Chakrabarty* accentuated the notion that one patent law is sufficient to apply to all technologies and the courts may interpret such law as needed to make it applicable to the various industries.[238] Given the role patent law plays in various industries and its important role in biopharmaceuticals, Rai believes the courts are the appropriate interpreters and "should develop a federal common law of patents that is tailored to the economic realities of different industries."[239] Burk agrees that the courts are best suited to apply the patent law as needed,[240] stating that it is unrealistic to expect legislative action each time a new technology is at issue.[241]

The Federal Circuit has attempted to send a much needed signal indicating its inclination to limit the scope of patent claims and to fulfill the disclosure and enablement requirements of § 112.[242] The PTO Written Description Guidelines highlight this by allowing "functional characteristics" to be claimed "when coupled with a known or disclosed correlation between function and structure."[243] Yet, despite the stringent written disclosure requirements and the

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[237] Congress has exercised this power in other instances. Congress, in enacting section 287(c), determined it was appropriate and necessary to prohibit the grant of monetary or equitable remedies in infringement actions against medical practitioners who infringed a patent when engaging in certain "medical activity." *See* 35 U.S.C. § 287(c) (2000); SCHECHTER & THOMAS, *supra* note 133, at 301. Congress exempted medical methods and explicitly limited the scope of these patents so that these activities are not considered to infringe upon a patent holder's rights. *See id*. Although pharmaceuticals may appear to have the same justifications for an exemption as medical methods, such express congressional exemption may not be desirable because, given the considerations of time, risk and length of investment involved in pharmaceutical research and development, pharmaceutical companies will want infringement suits available for aggressive enforcement of their important patent rights. *See* Rai, *supra* note 11, at 822.

[238] *See* Burk, *supra* note 1, at 6. ("We have courts and other institutions that can shape it to the needs of specific industries.").

[239] Rai, *supra* note 11, at 837. *See supra* notes 61-62 and accompanying text.

[240] *See supra* note 62 (noting how courts have already done this with obviousness and enablement standards); Burk & Lemley, *supra* note 1, at 1170 (noting that though many software patents will be deemed obvious by the court, those that receive patent protection will receive broad protection); *id*. at 1183-84 (comparing the different standards applied in the software and biotechnology industries).

[241] *See* Burk, *supra* note 1, at 10 (stating "it takes a lot of political capital and political will" to have the legislature address this issue). Through the use of the PHOSITA standard, judges can make fact- and industry-specific decisions. *See* Burk, *supra* note 1, at 11; Rai, *supra* note 14, at 1129-30 (noting the inefficiency, exorbitant time, and politics involved in legislative, rather than judicial, response). Congress appears uninspired by this debate as it shows no signs that it will address the patent scope issue. *See* Thomas, *supra* note 6, at 619.

[242] *See* 35 U.S.C. § 112 (2000).

[243] Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1,

PTO guidelines, the practice of broad claiming continues in this area.[244] The converse risk is that the narrow claims will be greatly broadened by the courts through the doctrine of equivalents.[245] An alternative to clarify the situation and increase certainty in this area would be to limit claims to the actual descriptions in the specifications.[246] Finally, the Federal Circuit could revive and strengthen the experimental use doctrine.[247] Given the fast-paced

"Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2001).

[244] A common practice is to claim broadly, assuming that the patentee will have to cede a portion of patent breadth to the PTO examiner during patent prosecution. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd, 234 F.3d 558, 592 (Fed. Cir. 2000) (Plager, J., concurring) ("Patent counsels . . . may start claiming narrowly . . . That itself may be to the good, since much of current patent litigation involves claim construction issues resulting from the vague, sometimes almost incomprehensible, manner in which claims have been drafted.").

[245] *See id.* ("An unintended consequence [of patent claims being drafted narrowly] may be that patent litigation will lean ever more heavily on the doctrine of equivalents, especially in those cases in which the patent application, containing narrowly drawn claims, was approved without any amendment in the area that affects the accused product."). *Compare Festo*, 234 F.3d at 598 (Michel, J., concurring in part, dissenting in part) ("Today's majority upsets the balance" between "the competing needs of meaningful patent prosecution and adequate public notice" by "holding that the public notice function of patents can *only* be fulfilled by limiting the effective scope of patents with amended limitations to the literal wording of such limitations.").

[246] *See* Gupta, *supra* note 25. This parallels the section 112 ¶ 6 analysis for direct infringement in means plus function claims. The doctrine of equivalents must also be curbed if patent scope is seriously going to be limited. The author suggests a doctrine of equivalents interpretation that mirrors the section 112 ¶ 6 analysis. The doctrine of equivalents was not used expansively in the enablement cases above. The Federal Circuit in *Genentech, Inc. v. Wellcome Found., Ltd.*, however, did not find nonliteral infringement through the doctrine of equivalents, holding that the accused product was not an equivalent of the patented one. *See Genentech*, 29 F.3d 1555, 1567 (Fed. Cir. 1994). In *Schering Corp. v. Amgen*, Schering did not seek a finding under the doctrine of equivalents, so it was not considered by the court. *See* Schering Corp. v. Amgen Inc., 35 F. Supp. 2d 375 (D. Del. 1999); *affirmed by* Schering Corp. v. Amgen, Inc. 222 F.3d 1347 (Fed. Cir. 2000).

[247] *See* Beth E. Arnold, *Navigating Gene Patent Minefields*, *at* http://www.bio-itworld.com/archive/111202/insights_mine.html (Nov. 12, 2002) (indicating that though a court has not recognized the exception, the experimental use doctrine should apply to academic research). Others argue that scientists should be able to use patented research tools without approval or licensing, but that the patentee receive an ex post facto royalty payment. Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 1 (2001) (noting the royalty payment should be determined by the commercial success of products or pharmaceuticals developed by using the research tool). Others believe that unless patent infringement results in commercialization or profit, a patentee would likely not sue. *See id. But see supra* note 128 (noting the increase in strict patent enforcement by patentees).

innovation in pharmaceuticals, genes, and proteins, the court is sure to be "confronted with [even] harder cases in the coming years."[248] As Congress has not given any indication that it will address the problem of broad claiming and proliferating patent scope,[249] the Federal Circuit must continue in its course of jurisprudence to reign in the already overbroad scope of patents.[250]

B. Limit the Application of the Doctrine of Equivalents by Incorporating Principles from Section 112 ¶ 6

The application of the doctrine of equivalents in the biopharmaceutical and biotechnology fields expands patents that receive already-broad patent constructions.[251] The number of equivalents that may be applied to such patents are numerous.[252] Section 112 ¶ 6 of the patent law embodies many concepts which may appropriately be applied to limit the application of the doctrine of equivalents to biopharmaceutical patents.[253] This author proposes

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[248] Ryan & Brooks, *supra* note 112, at 1276.

[249] *See* Michel, *supra* note 149, at 1243.

[250] The Federal Circuit may increase predictability in patent claims if it heard a greater number of cases en banc. *Id.* at 1244. The Federal Circuit however has decided it would not do so, and in 1993 announced it would hear no more than ten cases en banc. *Id*. at 1255. A federal circuit decision to hear more cases en banc may address controversial issues in patent law including claim interpretation and the doctrine of equivalents and, hopefully, increase predictability. *See id*.; *supra* notes 240-241 (describing such determinations are appropriate for the courts).

[251] For example, the Harvard oncomouse patent was broad in scope and covered not only the method used to produce transgenic mice that were carcinogen-sensitive, but on all "non-human transgenic animals" produced by their technique. *See* Gupta, *supra* note 25; Shayana Kadidal, *Digestion as Infringement: The Problem of Pro-Drugs*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 241, 245-48 (1996) (noting that the various ways chemical compounds may be claimed). Broad, generic claims may be made in the context of DNA or proteins so long as the claim scope adequately discloses and enables the genus. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1214 (Fed. Cir. 1991); *supra* Kadidal at 245-63 (concluding that "[p]atent laws should be changed so as to allow claims only on specific manufacturing processes and specific uses of chemical structures, but never on the chemical structures themselves."). This also parallels the need to limit the application of the doctrine of equivalents in pioneer invention patents. *See generally* Graham, *supra* note 140.

[252] *See* Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d. 1553 (Fed. Cir. 1996) (involving a patent on human growth hormone); Kadidal, *supra* note 251, at 245-48 (discussing the Bio-Technology v. Genentech decision and noting the high number of equivalents includable in the broad method patent in that case). It should be noted that in Bio-Technology General, equivalents were determined under the former function-means-result test rather than the all elements rule.

[253] *See* 35 U.S.C. § 112 ¶ 6 (2000). Section 112 ¶ 6 requires that if the claim is a means plus function claim covered by section 112 ¶ 6, patentees will not only have to meet section 112 ¶ 6 but may also have to amend claims to meet the definiteness requirement. *See*

that the doctrine of equivalents should only apply to equivalents, foreseeable to a PHOSITA, in the same field and substantially equal to that which is disclosed in the patent specification, at the time of application. This will serve to apply the doctrine of equivalents in a manageable and just manner, allowing greater predictability to future innovators and preventing the uncertainty of scarecrow patents from deterring competition and innovation.[254] At the same time, this standard supports inventors whose claim language is lacking or has been easily circumvented.[255]

The primary limitation that should be adopted from § 112 ¶ 6 in the application of the doctrine of equivalents is the notion that claims be interpreted to cover the "corresponding structure, material or acts described in the specifications and equivalents thereof."[256] This is a dependable avenue to follow when interpreting patent claims and determining the breadth of patent

SCHECHTER & THOMAS, *supra* note 133, at 497-98. The need for a narrower application of the doctrine of equivalents is not particular to the biopharmaceutical industry. *See* Cohen & Lemley, *supra* note 12, at 3 (urging a narrower application of the doctrine in the software industry given the industry's "culture of reuse and incremental improvement, a lack of reliance on systems of formal documentation used in other fields, the short effective life of software innovations, and the inherent plasticity of code").

[254] *See supra* note 32.

[255] In the spirit of the notion that a patent holder is not a linguist, one can understand extending the patent scope through the doctrine of equivalents to cover those discoveries which are substantially equivalent to that which is claimed or disclosed in the specification. Graver Tank & Mfg. Co. v. Linde Air Prods., Co., 339 U.S. 605, 607 (1950) (noting the doctrine of equivalents protects patentees from being at "the mercy of verbalism"). One can also tolerate granting patent rights to that which a PHOSITA would view as a foreseeable substantial equivalent. The use of the objective PHOSITA standard would serve the purpose of providing fair notice to others. Extending scope to completely unrelated fields, however, improperly gives a patent holder much greater rights than those articulated in the proverbial metes and bounds of the patent. While copying must be prevented, it is important that subsequent innovators be rewarded for novel and inventive improvements. This includes protection for taking a patented discovery and applying it in a completely unrelated field, i.e. to solve a long-felt need or problem in that field.

[256] SCHECHTER & THOMAS, *supra* note 133, at 497-98. The Federal Circuit effectively limited the claims to the specification in *In re Wright*. *In re Wright* involved the use and creation of vaccines which were not pathogenic to treat RNA viruses which were. 999 F.2d 1557, 1559 (Fed. Cir. 1993). The specifications of the patent provided one example, while the remainder was a generic description. *Wright*, 999 F.2d at 1559. The court limited the patent to the example in the specification, particularly given the complexity of the science and the breadth of the claim. *Id*. at 1560. Though the ease of circumvention is obvious when limiting scope specifically to the patent specifications, granting a patentee protection only for this type of infringement, as well as for those that are foreseeable at the time of patent and in the same field, remedies the risk that others will invent around the patent.

scope.[257] It guarantees a narrower scope of protection based on the literal claim language and information disclosed in the patent specifications. The timing of § 112 ¶ 6 should also be incorporated into the application of the doctrine of equivalents to biopharmaceutical patents. Section 112 ¶ 6 determinations of equivalents are made at the time of patent application.[258] The doctrine of equivalents is currently generally applied at the time of the infringement. The former is a better choice.[259]

Additionally, comparable to the § 103 analogous arts requirement,[260]

[257] *See supra* note 133. Generally, claims are not limited to the embodiments in the specifications. *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316 (Fed. Cir. 2002); Genentech, Inc. v. Wellcome Found. Ltd., 29 F.3d 1555 (Fed. Cir. 1994). Section 112 ¶ 6, however, limits equivalents to the embodiments in the specifications.

[258] *See* Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1320 (Fed. Cir. 1999) (noting the difference in timing when examining an equivalent structure or act under section 112 and under the doctrine of equivalents).

[259] Equivalence should be determined not at the time of infringement, as the doctrine of equivalents is currently applied, but at the time of patent application as in section 112 ¶ 6. An integral notion in patent law is that one may lay claim to what one possesses. The patent specification "must be enabling at the time the inventor filed his application." SCHECHTER & THOMAS, *supra* note 133, at 396. Ryan & Brooks, *supra* note 112, at 1291-94. A patent specification must "convey with reasonable clarity" that the patentee was "in possession of" the subject matter of the claims at the time the patent was filed. Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991); Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re* Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). It is impossible for a patent holder to satisfy the section 112 written description and enablement requirements for a discovery which is not known or foreseeable at the time of patent application. *See Genentech*, 29 F.3d at 1569 (holding that claims for proteins beyond the sequences disclosed invalid for failure to enable and unpredictability). *See* Ryan & Brooks, *supra* note 112, at 1287-88 (discussing hypothetical and "expanded hypothetical" claiming). *See also* Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1212-13 (Fed. Cir. 1991). Further, in *Gould v. Hellwarth*, the CCPA stated that since the patentee, nor anyone else, could construct the claimed device, the disclosure was not enabling. 472 F.2d 1383, 1384 (C.C.P.A. 1973). Like the theory in *Gould*, something that is later developed cannot be constructed by the enabling disclosure of a patent and should not be protected. *See id*. at 1383, 1385. The Federal Circuit has stated that progress in the art made post-application should not be considered when deciding whether an application or patent satisfy section 112 enablement. *See* SCHECHTER & THOMAS, *supra* note 133, at 396.

[260] *See* 35 U.S.C. § 103 (2000). Under a section 103 obviousness analysis, one must determine whether the references are in the same field as the inventor's endeavor, or whether the reference is "reasonably pertinent" to the problem the inventor was attempting to solve. *Id*. The Federal Circuit has defined "reasonably pertinent" as an invention which:

> may be in a different field from that of the inventor's endeavor, [but] is one which, because of the matter with which it deals, logically would have commanded itself to an

equivalents should be limited to the same field. Further still, this should be limited to substantial equivalents in the same field as the patented discovery which are foreseeable to a PHOSITA.[261] The patentee should have an opportunity to rebut attempts by copyists to evade the original patent by demonstrating that the accused product is an "insubstantial variation" on the

> inventor's attention in considering his problem. Thus the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports the use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention. If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

In re Clay, 966 F.2d 656, 659 (Fed. Cir. 1992). Courts should apply only the "same field" test of the analogous arts, and not the "reasonably pertinent" standard, analysis in the context of the doctrine of equivalents. *Id*.

Some have likened the FDA's analysis of "sameness" in the orphan drug context to the section 103 nonobvoiusness analysis. *See* Phillipe Ducor, *supra* note 167.

[261] *See* Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co., Inc.**,** 285 F.3d 1046 (Fed. Cir. 2002) (per curiam). Judge Rader stated in concurrence in *Johnson* that when a PHOSITA would foresee coverage of an invention, the patent drafter has an obligation to claim those foreseeable inventions. *See id.* at 1057 (Rader, J., concurring). Foreseeability, in the view of Judge Rader and as explained in Rader's concurring opinion, serves a notice function. *See id*. "When [a PHOSITA] would foresee coverage of an invention, a patent drafter has an obligation to claim those foreseeable limits. This rule enhances the notice function of claims by making them the sole determination of invention scope in all foreseeable circumstances." *Id*.

The courts have not provided much assistance in defining "foreseeability" in patent law. L. Scott Burwell, *Biotechnology Law 2003*, 760 PLI/Pat 11, 35 (2003). Burwell notes that several issues remain unresolved, including: (1) Who must foresee? The inventor or PHOSITA? and (2) When should foreseeability be determined? As of the date of application or date of amendment? *See id*. In *Johnson*, the court acknowledge foreseeability in the doctrine of equivalents. 285 F.3d at 1059. *Johnson* involved an application which disclosed certain information in the patent specification but failed to include the disclosed matter in its claims; as the information was included in the specification, it was obvious that the matter was foreseeable. *See id*. The court held that anything that is disclosed but not claimed in the patent may not be used for doctrine of equivalents purposes. *See id*. at 1052, 1054.

Some propose the opposite, that a patentee be required to claim all foreseeable subject matter and relinquish anything foreseeable that is not claimed. *See* Michael John Gulliford, Comment, *Much Ado About Gene Patents*, 34 SETON HALL L. REV. 711, 742 (2004). This position was emphasized by Judge Rader in *Johnson*. *See Johnson*, 285 F.3d at 1056 (Rader, J., concurring) (indicating that the doctrine of equivalents should not extend to provide protection for foreseeable subject matter that a patentee could have reasonably included in the claims). Query whether this actually obviates the desire to support patentees who have made errors in patent claiming or disclosure.

existing, patented product[262] or is interchangeable with it.[263] Finally, despite Judge Rader's position in *Festo*,[264] a blanket application of the doctrine of equivalents to later developed technology is unreasonable. True, a patentee should be protected from unforeseeable gaps in patent protection due to drafting or "out-dated terms"[265] through the proposed "substantial (or interchangeable) equivalents in the same field" test.[266] At the same time, it is

[262] *Johnson*, 285 F.3d at 1056 (Rader, J., concurring). "When the skilled artisan cannot have foreseen a variation that copyists employ to evade the literal text of the claims, the rule permits the patentee to attempt to prove that an 'insubstantial variation' warrants a finding of non-textual infringement." *Id*. at 1057. As such, anything that is foreseeable must be claimed and disclosed by the patent applicant and shared with the world. Though notice is certainly served by the requirement that all that is foreseeable be claimed or relinquished, Judge Rader's view leads to the possibility that patent applications will be packed with numerous claims, broad and narrow, many of which may fail the enablement or written description requirements, simply so that an inventor may protect him or herself from relinquishing patent protection over a foreseeable equivalent that was not included due to errors in drafting.

The notion of allowing an original patentee protection against insubstantial variations is somewhat mirrored in the Intellectual Property Commission's patent system recommendations to developing countries, in which they recommend that new uses of known products not be patentable. *See Final Report*, *supra* note 61.

[263] A mirror notion was first articulated in doctrine of equivalents jurisprudence in *Graver Tank & Mfg. Co., Inc. v. Linde Air Prods. Co*. 339 U.S. 605, 609 (1950) (holding the interchangeability test was an "important factor" to be considered). The interchangeability test is "whether [a PHOSITA] would have known of the interchangeability of an ingredient not contained in the patent with one that was." *Id*. This test has also been employed by the Federal Circuit. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed. Cir. 1995) (en banc). The Federal Circuit followed the Supreme Court's interchangeability test when it was reviewing the Warner-Jenkinson decision on other grounds. *See id*. at 1518-19. The Federal Circuit has at times failed to follow the decisions or jurisprudence of the Supreme Court. *See generally* Ryan, *supra* note 112. The use of the interchangeability test allows for the extension of the doctrine of equivalents to discoveries with "substantially improved or new properties" while keeping original patents from being circumvented. *See id*. at 1294. This also takes into consideration limitations or errors in drafting. *See id*. The interchangeability test provide for a "clear, sensible outcome." *Id*.

[264] "A primary justification for the [DOE] is to accommodate after-arising technology. Without a [DOE], any claim drafted in current technological terms could be easily circumvented after the advent of an advance in technology." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 619 (Fed. Cir. 2000) (Rader, J., concurring-in-part, dissenting-in-part).

[265] *Id*.

[266] As such, Judge Rader's concern in *Festo* over the use of the terms "anode" and "cathode" in a claim in tube technology and the inability to extend these terms to transistor technology is without warrant. If these are deemed to be "substantial equivalents" and deemed to be the same field, then the patentee may receive protection. *Id*. If, on the other

key in the biopharmaceutical area that the application of the doctrine of equivalents be limited in order to promote predictability and notice, and to encourage future development and investment by both the original inventor and competitors. This will promote certainty of patents, which is crucial in the biopharmaceutical industry given the inherent risks and investments in this area.

This proposed test will encourage thoughtful, precise patent claims.[267] Acknowledging that a patentee is an inventor and likely not a linguist,[268] it is more reasonable to grant doctrine of equivalents protection to a discovery that was a foreseeable equivalent in the same field at the time of application but was simply unclaimed due to an error in drafting, as opposed to an unforeseeable, later developed discovery in a completely different art.

C. Litigation

Some suggest that litigation attacking the validity of a patent is a mechanism to contest patents with extremely broad scope.[269] Many will argue that the costs of litigation are exorbitant and an obstacle to small inventors who are unable to afford such a legal challenge.[270] Yet, it is possible that the actual threat of litigation is important enough to keep patent owners and potential infringers in check and to promote fair license agreements.[271]

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hand, the improvements and innovation are so complex that equivalence is insubstantial, the subsequent inventor should have the benefit of patenting their new discovery. *See id*.

[267] The patent claims in *Eli Lilly* were found to fail the section 112 written description requirement because the patentee did not foresee nor give an adequate description of the structure of sequences within a genus. *See* Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1569 (Fed. Cir. 1997); Burwell, *supra* note 261, at 36 (2003). Others suggest patent scope can be limited by making distinctions amongst the organisms being patented. *See* Cantor, *supra* note 97, at 288-89.

[268] *See Festo*, 234 F.3d at 620 (Linn, J., concurring in part, dissenting in part) (warning on placing "greater emphasis on literary skill than on an inventor's ingenuity"). This further assumes that if a patentee has an attorney, that neither the attorney nor the inventor are linguists.

[269] *See* Teece, *supra* note 32, at 6. Many suits, however, end up in settlement. *See* Rai, *supra* note 11, at 814. Notably, settlements of patent infringement suits between drug manufacturers and potential generic competitors often raise antitrust concerns. *Id*. (noting these settlements are seen as preventing competition).

[270] *See supra* note 128 (indicating that litigation is most available to those who can financially afford it, usually large companies).

[271] *See* Teece, *supra* note 32, at 7 (citing Lemley's notion that "the 'threat' of litigation is needed to encourage negotiated agreements") (quotations omitted).

D. Should Pioneer Inventors Be Given Special Consideration?

Pioneer innovations and patent scope go hand in hand.[272] It is proposed that pioneer inventions be afforded broader protection because of their high social value.[273] Chang posits that broad patents should serve as rewards for pioneer inventions where an invention has greater social than commercial value.[274] The social value, according to Chang, calls for a subsidy of invention in pioneer fields via broad patent scope.[275]

Kitch's Prospect Theory centers on the notion that a patent gives the holder "the exclusive right to develop further the 'prospect' that the invention represents."[276] Kitch holds that the U.S. patent system should allow broad patent scope to incite pioneer investors in undeveloped fields of technology to invest in and develop such fields.[277] Merges and Nelson, conversely, believe

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[272] *See* R. Polk Wagner, *Reconsidering Estoppel: Patent Administration and the Failure of* Festo, U. PA. L. REV. 159, 202 (2002).

[273] *See* BF Goodrich Flight Sys. Inc. v. Insight Instruments Corp., 22 U.S.P.Q. 2d 1832, 1837 (S.D. Ohio 1992); CHISUM, *supra* note 11, at § 18.04[2][a]. Such broad protection, however, is not to go unbridled. A specific area of concern with pioneer drugs is that pioneer patentees enter into agreements to deter or delay the manufacture of generic alternatives. Muris, *supra* note 22. This was the case in *Abbott Lab. v. Geneva Pharm.*, where a generic manufacturer was paid to forego entry into the generic market. 182 F.3d 1315 (Fed. Cir. 1999). These agreements cause unreasonable delay in getting a generic drug to market, which costs consumers hundreds of millions of dollars annually. *See supra* note 131 (indicating the savings to consumers).

[274] *See* Chang, *supra* note 11, at 48-49. Incentive to invent is a primary factor in Chang's position. Some believe infringement of certain "meritorious" patents, namely those covering pioneer inventions, should result in greater damages. It is argued that this will provide pioneer inventors the extra incentives they need and deserve. *See* Baker, *supra* note 22, at 446. It is natural that as development in a pioneer field progresses, however, at some point others will attempt to compete and improve upon the pioneer patent.

[275] Broad patent scope will motivate pioneer inventors to engage in, and reap the benefits of, such socially valuable research. *See* Chang, *supra* note 11, at 49. An inventor in an undeveloped field may not invest the necessary investment of time or money to engage in research and development given the unpredictable outcome. "The innovator takes the risk of commercial success or failure of new things in new markets – the risk of unfulfilled expectations, obsolescence, regulation, [and] technologic failure." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd, 234 F.3d 558, 640 (Fed. Cir. 2000) (Newman, J., concurring in part, dissenting in part).

[276] *See* Chang, *supra* note 11, at 48. Kitch distinguishes his "prospect" theory from the "reward" theory of patents, "which focuses on the incentives offered to the patent holder to encourage the invention." *See id.*

[277] *See* Gupta, *supra* note 25. "Kitch proposes this theory keeping in mind the waste and inefficiency associated with rivalrous development of technology." *See id.* This, presumably, allows pioneer inventive activity to take place without competition and wasteful rivalry and duplication of research and development efforts. *See id.*

that the grant of a great monopoly through broad patent scope will impede development of the technology rather than promote and incentivize it.[278]

Pioneer inventions are allowed broader scope in § 112 written description and permitted to cover areas beyond the knowledge and disclosure of the inventor.[279] The reason for such weak enablement standards where pioneer inventions are concerned is "that any other rule would leave claim scope too much in the hands of individual examiners and their technological forecasting abilities."[280] Further, the difficulty in drafting claims in a pioneer field is often

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[278] *See* Merges & Nelson, *supra* note 3, at 909; Hugh McTavish, Note, *Enabling Genus Patent Claims to DNA*, 2 MINN. INTELL. PROP. REV. 121 (2001) (noting that broad patent rights should slow future innovation within the patented pioneer field). Nelson does, however, agree that the "societal value of encouraging invention is worth the societal costs associated with the resulting monopolies." *See* Baker, *supra* note 22, at 452 (citing Richard R. Nelson, *The Economics of Invention: A Survey of the Literature*, 32 J. BUS. 101 (1959)).

[279] *See* Merges & Nelson, *supra* note 3, at 848-49; *In re* Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977) ("[P]ioneers . . . deserve broad claims to the broad concept"). A strict enablement standard and strict limitations of the patent scope of a pioneer invention would provide inventors little incentive and would grant weak protection to potentially valuable inventions. *See id*. The PTO examiner bears the burden of showing that an inventor has not, in fact, sufficiently met the disclosure, and enablement requirements. *See* Merges & Nelson, *supra* note 3, at 849.

Broad patent protection can be granted pioneer inventors not by the PTO through weaker enablement and written description standards but through the courts use of the DOE. *See* Takenaka, *supra* note 148, at 325. *See also* John R. Thomas, *The Question Concerning Patent Law and Pioneer Inventions*, 10 HIGH TECH. L.J. 35, 43 (1995). Courts have held that pioneer inventions should be allowed a broad range of equivalents. Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532 (Fed. Cir. 1987) ("A pioneer invention is entitled to a broad range of equivalents."); Baker, *supra* note 22, at 448-49. "[A] greater degree of liberality and a wider range of equivalents are permitted where the patent is of a pioneer character than when the invention is simply an improvement, may be the last and successful step, in the art theretofore partially developed by other inventors in the same field." Cimiotti Unhairing Co. v. Am. Fur Refining Co., 198 U.S. 399, 406 (1905). Likewise, the doctrine of equivalents cannot be read so broadly that it would encompass prior known art. *See* SCHECHTER & THOMAS, *supra* note 133, at 481; *see e.g.* 35 U.S.C. § 102(a)-(f) (2000). Given the limited to nonexistent prior art in pioneer fields, those inventions considered pioneer inventions naturally enjoy a less limited and broader range of equivalents.

[280] Merges & Nelson, *supra* note 3, at 849. *But see* Thomas, *supra* note 279, at 43 (discussing the possibility that an examiner might read a claim more broadly than the inventor intended). Should such determination of claim scope be left to examiners, it follows that we will be left with unpredictable and unknowledgeable patent claim review which is likely to result in a complete lack of clarity and uniformity of standards. Patents should initially be given broad scope, it is argued, and the narrowing of claims should remain the duty of the courts in particular infringement suits. *Cf*. Michel, *supra* notes 149 and 250 (highlighting the importance that predictability result from such judicial decision

noted.[281] Construction and drafting "of the disclosure and claims for a pioneer patent is a difficult task [due to the] new scientific ground being broken" by the pioneer invention.[282] Yet, this view is not universally embraced.[283] Though broad patent rights often favor a pioneer inventor and are important incentives for a pioneer inventor to foray into an unknown field, particularly in the biopharmaceutical area, one must remain equally cognizant of the effect,[284] and the inherent limit such broad scope places on other deserving inventors or improvers.[285]

Nevertheless, one must consider, particularly in a resource-intensive, quick-developing area such as biopharmaceutical research, whether the pioneer

making) .

[281] *See* Baker, *supra* note 22, at 451.

[282] Moore v. United States, 211 U.S.P.Q. 800, 806 (Ct. C. 1981). It is difficult for a pioneer patent applicant to anticipate the potential uses of new technology and competitors should not be allowed to take advantage of oversights in drafting due to the novelty of the field. *See* Baker, *supra* note 22, at 451.

[283] Some question the validity of the claim that pioneers have particular challenges when drafting claim language. Given the minimal prior art existing in pioneer fields, pioneer inventors, it is proposed, actually have an easier task drafting claim language and disclosures as they do not have to circumvent applicable prior art. *See* Texas Instruments v. U.S. Int'l Trade Comm'n, 846 F.2d 1369, 1370 (Fed. Cir. 1988); SCHECHTER & THOMAS, *supra* note 133, at 491.

[284] The United States Supreme Court in *Westinghouse v. Boyden Power Brake Co*, stated that "[t]o say that the patentee of a pioneer invention for a new mechanism is entitled to every mechanical device which produces the same result is to hold, in other language, that he is entitled to patent his function." 170 U.S. 537, 569 (1898); *In re* Certain Stabilized Hull Units, 218 U.S.P.Q. 752, 766 (U.S. ITC 1982) (holding that though the accused products fell within literal claim language, the different mechanisms used showed that "substantially different means [were used] to perform the same function").

[285] *See generally* Merges & Nelson, *supra* note 3, at 848 (warning that though pioneer protection is needed, one should not "go too far"); McTavish, *supra* note 278, at 144. Improvements are generally not afforded broad equivalents. *See* Hughes Aircraft Co. v. U.S., 717 F.2d 1351, 1362 (Fed. Cir. 1983) (stating that that even though the Hughes invention is "not of such 'pioneer' status as to entitle the invention to the very broad range of equivalents to which pioneer inventions are normally entitled," the invention is still entitled to some range of equivalents, possibly greater than the "very narrow range of equivalents applicable to improvement patents in a crowded art"). *But see* Kinzenbaw, 741 F.2d 383, 389 (Fed. Cir. 1984) (stating that it was "inappropriate" to "enlarge the literal scope . . . patent claims," given that the invention was an improvement in a crowded art). The incentives for improvement are said to reduce the incentive to create a pioneer invention in the first place." Merges & Nelson, *supra* note 3, at 878. It follows that the earlier improvements are available the faster others will attempt to improve upon such improvements. *See id*. at 879.

inventor doctrine is desired.[286] Given the speed of development in these areas, would broad patent rights, as Merges and Nelson contend, merely impede the pace of development? Are broader patent rights needed to stimulate pioneer invention in uncharted waters, particularly given the existing incentive of the great race to the patent office and the benefits of the Bayh-Dole Act, or are market rewards sufficient? Given the limited prior art and the propensity towards granting strong patent rights in the biopharmaceutical industry, the freedom that pioneers are already afforded likely suffices in incentivizing research. In the case of nonliteral infringement, the proposed doctrine of equivalents standard should apply. Were the PTO to grant pioneers broad scope initially, only to have courts further broaden the patent scope later in time vis a vis the doctrine of equivalents, the § 112 requirements of patent law would be, in essence, obliterated.

IX. CONCLUSION

Given the growth of the pharmaceutical industry in the United States, patent rights in this area take center stage. The need for strong patent protection in the biopharmaceutical industry, particularly given the risk, time, and financial investment involved in the research and development of drugs, is well established. In the realm of biopharmaceuticals, patent law must encourage research and foster development. This can best be accomplished through competition and strong, predictable patent protection within the scope of patent claims.

Biopharmaceutical patents are not the appropriate area for courts to exercise beneficence and generosity toward patentees. As such, extensive use of the doctrine of equivalents and expansively broad claim interpretation in this field is undesirable. Patentees should be allowed reasonable protections through the application of the doctrine of equivalents but, as this author proposes, only for foreseeable equivalents in the same field existing at the time of patent application. The Federal Circuit should continue to uphold strict written description and enablement requirements in the biopharmaceutical and related areas. Once granted, however, it is imperative in this field that these patents be given full force and effect.

The effects of patent scope are far-reaching indeed. Given the changing landscape in biopharmaceutical research and its growing dependence on genes, proteins, and the like, it important that patents provide accurate notice of claims and scope, so as not to deter or dissuade research and investment. Curbing and clarifying the breadth of patent scope will avoid "scarecrow" patents and oppressive licensing while guaranteeing patentees durable rights in their discoveries. The resulting increase in predictability will undoubtedly

[286] This is particularly true given the little cumulative innovation that takes place in this field.

have positive effects on competition, research and development in the biopharmaceutical industry.