

Note

Patents and Patients: Who Is the Tragedy of the Anticommons Impacting and Who Is Bearing the Cost of High-Priced Biotechnological Research?

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I. INTRODUCTION

As the scientific and medical worlds continue to research and develop new therapeutic theories, drugs, diagnostics, and treatments, the legal world must address concurrent questions stemming from such research and covering issues of ownership, privacy, morality, and public policy. One key issue involves biotechnology patents, a topic of not only national debate, but also the subject of extensive legal literature and case law, as well as recent congressional action aimed at enacting new patent laws. In the ongoing debate, which has focused on the research roles of major universities, large pharmaceutical firms, and small, start-up biotech research firms, a group of America's most important medical research facilities—private, non-profit research hospitals, like the Mayo Clinic in Rochester, MN—have been ignored.

These private non-profit research hospitals are hybrids of businesses and academic centers and, because of this, they are negatively impacted by patent laws in ways that institutions which have been the focus of recent patent debates are not. For example, pharmaceutical companies make money—their sole focus—through high-quality research and patient test results distributed by the private institutions. Start-up firms keep development and research costs down by utilizing the private institutions' research. Universities, which would seem most analogous to the private institutions, have fewer financial concerns than the non-profit private research centers, since they have a continual stream of revenue from state appropriations,

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federal grants, and large endowments. In addition, sovereign immunity protects state universities from patent lawsuits. The non-profit private institutions, by contrast, are stuck in the middle. These institutions enjoy few research or financial advantages, but, through their business arms, must patent all of their discoveries to protect themselves, much as any pharmaceutical or start-up biotech company would. Most importantly, these institutions focus primarily on patient care.

Because of the patent problem, private institutions have been forced to (1) apply for patents on all of their medical research breakthroughs, whether major or minor, preventing physicians and researchers from changing experimental procedures quickly for individual patients; (2) incur costs in physician time, legal expenses, and business administration to apply for and process patents; (3) incur costs to defend against unwitting patent violations; (4) incur costs of monitoring and suing violators of their own patents; and (5) pay high prices for the use of patented material not developed in-house. Meanwhile, the Mayo Clinic and its counterparts, for example the Cleveland Clinic, ARUP Laboratories, and Johns Hopkins Health and Medicine Center,¹ remain critical to the delivery of medical research and patient care in the United States. These private research institutions may individually treat more than 520,000 patients annually² as well as using and developing patentable biotech processes.³ By ignoring the needs of

¹ . "The Johns Hopkins Health System Corporation (JHHS) is a not-for-profit organization dedicated to providing the highest quality patient health care in the treatment and prevention of human illness." About Johns Hopkins Medicine, (last visited Feb. 9, 2008).

² . See, e.g., MAYO CLINIC, ANSWERS: MAYO CLINIC 2006 ANNUAL REPORT, 20 (2007), available at <http://www.mayoclinic.org/annualreport/>.

³ . *Id.* at 51. Mayo Clinic invests significant resources in educational and research programs:

Overall funding for Mayo research and education programs was \$634 million in 2006, an increase of \$67 million over 2005. Government, foundations and industry sources provided \$319 million of the total amount—a 1.9 percent increase over 2005. Mayo invested \$315 million in research and education in 2006. This includes Mayo funds and benefactor gifts.

Mayo will continue to partner with foundations, benefactors, government and industry with mutual aims to support education programs that train the next generation of medical professionals and research programs that identify tomorrow's medical breakthroughs.

private research institutions that provide both patient care and develop and utilize emerging medical processes and procedures, current patent policy places patients throughout the United States, including patients not actually treated at the non-profit institutions, at risk, since all patients ultimately will incur the increased costs and time delays caused by the legalities of medically related patents.

To that end, this Note argues that non-profit research institutions, although they are leading centers of medical care and therapy development, are fundamentally different from other biotechnology research institutions and are being overlooked in the current attempts by the courts to interpret patent law and the current attempts by Congress to enact new laws. The background of this note discusses the history of patent law; analyzes the debate over the impact on research of current patent practices in biotechnology; suggests reasons non-profit, private, research institutions have been ignored, and reviews current case law and the patent legislation approved by the U.S. House of Representatives in the fall of 2007. The Note then analyzes whether the proposed "tragedy of the anticommons" actually exists, particularly from the perspective of patients at non-profit, research institutions, and suggests possible reforms and areas for further research that would possibly impact both congressional and judicial decision-making as they interpret patent law or enact new patent legislation. This note concludes that in the narrow sector of non-profit, private, research hospitals, it seems that current theories and research may not be exhaustive indicators of the entire "tragedy of the anticommons" scenario. Since medical research and testing is a societal mechanism for advancing knowledge, health, and community development, and since it is unclear whether the increased use of patents in biotechnology is impeding or advancing scientific research, the actual effect, as seen at non-profit, private, research hospitals, may be harm to the patients. Therefore, the current use of patents in biotechnology needs to be reassessed, as current practices are likely to be against public policy. A thorough understanding of the impact of patents on non-profit institutions should enable Congress and the courts to promote effective drug and diagnostic test

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development and patient care without raising prices or
discouraging development in other areas of biotech
research.

II. DEVELOPMENT OF PATENT USE IN BIOTECHNOLOGY

Patent law, historically, is designed to protect society from a type of "market failure."⁴ To encourage the creation and disclosure of inventions, patents protect inventors in a market economy from free-riders by "provid[ing] a right to exclude others from making, using, selling, offering to sell, or importing the patented invention Patents also provide an incentive for capitalists to invest in the commercialization, including the further innovation, of patented technology."⁵ Ideally, patent law creates incentives to invent, incentives to disclose and an incentive to innovate.⁶ In fact, because this capitalist idea was fundamental to the nation's founding, the Constitution expressly grants Congress the right to protect these incentives:

"The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."⁷ "By granting inventors a limited monopoly over the use of their discoveries, [generally 20 years from the date of filing,⁸] patent holders will be able to receive a return on investment from their creations."⁹ Title 35 of the U.S. Code provides further guidance for current patent law.¹⁰ To be patented an invention must be novel, useful, and of a nonobvious nature,¹¹ and "[i]f a defendant is found guilty of patent infringement in a civil lawsuit . . . the remedies available to

⁴ . Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 144 (2004).

⁵ . *Id.*

⁶ . *Id.* at 150.

⁷ . U.S. CONST. art. I, § 8, cl. 8.

⁸ . 35 U.S.C. § 154 (2000).

⁹ . BRIAN T. YEH, CONG. RESEARCH SERV., *INFLUENZA ANTIVIRAL DRUGS AND PATENT LAW ISSUES 6* (2005) (internal citations omitted) [hereinafter YEH, *INFLUENZA*].

¹⁰ . See 35 U.S.C §§ 101-376 (2000).

¹¹ . See 35 U.S.C §§ 101-103 (2000).

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the plaintiff include an injunction to cease and prohibit the offending activity by the defendant, damages to compensate for the infringement, and even attorney fees."¹²

A. CONGRESS HELPS PATENTS FLOURISH IN BIOTECHNOLOGY

Beginning in the early 1980s, in an effort to promote medical research and product development in biotechnology, both the courts and the federal government encouraged privatization of medical research and patent protection of new discoveries and treatment methods. In 1980 the Supreme Court decided in *Diamond v. Chakrabarty* that biotechnological processes and products are patentable.¹³ Also in 1980 Congress passed the Bayh-Dole Act, which allowed universities and small companies to patent and retain the property rights in inventions developed using federal funds.¹⁴ The passage of this Act increased joint ventures between the public and the private sectors.¹⁵ Consequently, the number of patent filings in biotechnology

¹² . YEH, INFLUENZA, *supra* note 9, at 7 (internal citations omitted).

¹³ . *Diamond v. Chakrabarty*, 447 U.S. 303, 307-09 (1980) (holding that a live, human-made microorganism is patentable subject matter under 35 U.S.C. § 101, which provides for issuance of a patent to a person who invents or discovers "any" new or useful "manufacture" or "composition of matter").

¹⁴ . See Patent and Trademark Act Amendments of 1980, Pub. L. No. 96-517, (1980); Ass'n of Univ. Tech. Managers, *Bayh-Dole Act*, http://www.autm.net/aboutTT/aboutTT_bayhDoleAct.cfm (last visited Nov. 4, 2007).

[T]he Bayh-Dole Act . . . created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs. This legislation was co-sponsored by Senators Birch Bayh of Indiana and Robert Dole of Kansas.

Id. See also Mireles, *supra* note 4, at 155.

¹⁵ . Mireles, *supra* note 4, at 155-56. Discussing the importance of the Bayh-Dole Act, Mireles finds that

because the federal government is the largest source of funding for research and development in the United States for universities The government spends almost sixty percent of all funding for research and development in universities in the United States. Private industry funds about seventy-six percent of [total] research and development in the United States. Prior to the passage of the Bayh-Dole Act, less than four percent of all government funded research was commercialized.

Id. (internal citations omitted).

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health-care spending throughout the industrial world. Second, biomedical innovation in the U.S., long considered the global leader, has slowed markedly in the past half decade. Despite escalating research spending in the public and private sectors, the number of new drugs and biologics recently approved by the U.S. Food and Drug Administration (FDA) has fallen below previous eras. . . . And those new therapies that have been approved tend to have less significance than medical advances of the past.²¹

To address the issue the House of Representatives passed "the most comprehensive patent reform in half a century" on September 7, 2007.²² The legislation will supposedly (1) make patents harder to obtain; (2) easier to challenge, and (3) curtail litigation by limiting where patent owners can file suit (venue) and how much they can collect in damages.²³ According to one of the legislation's co-sponsors, Rep. Lamar Smith (R-TX), "Too many patents of questionable integrity have been approved, and owners of these patents have found a unique way to make money."²⁴ While Congress passed this legislation to address the efficacy of the current patent system, the impact of the new legislation might not have the desired result. While supporters of the legislation, primarily biotech and pharmaceutical firms, agree with Congressman Smith and argue that "[a] proliferation of low-quality patents, skyrocketing litigation costs and potentially ruinous damages for patent infringement have . . . combined to undermine the foundations of inventive-ness,"²⁵ others caution against sweeping legislation.²⁶ For example, dissenters note that past reforms led to such major changes as the 1982 creation of the Court of Appeals for the Federal Circuit, a court committed solely to intellectual property issues. This led to "strengthened patent protection, lowered the bar for

²¹ . *Id.* at 611-12.

²² . Catherine Rampell, *House Approves Comprehensive Patent Overhaul*, WASH. POST, Sept. 8, 2007, at D1.

²³ . Bloomberg News, *House Passes Bill to Curb Suits by Patent Owners*, N.Y. TIMES, Sept. 8, 2007, at C4 (The House legislation will limit the damages awarded in patent litigation to the value of the specific small item or part that was infringed rather than the value of the entire product, which simply uses the smaller idea as one component in a larger good); see Patent Reform Act of 2007, H.R. 1908, 110th Cong. (1st Sess. 2007).

²⁴ . Bloomberg News, *supra* note 23, at C4.

²⁵ . Claude Barfield & John E. Calfee, *Congress's Patent Mistakes*, WALL ST. J., Oct. 29, 2007, at A18.

²⁶ . *Id.*

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inventiveness ('non-obviousness' in patent-law jargon), and paved the way for large damages against alleged patent infringers."²⁷ The centralized decisions of the new court instinctively supported patent holders.²⁸ Therefore, opponents of the House legislation argue that as Congress considers reforming patent law,²⁹ "[i]ncremental reform is a better idea than radical change."³⁰

B. "TRAGEDY OF THE ANTICOMMONS" THEORY

In 1998 Michel Heller and Rebecca Eisenberg³¹ published an article suggesting that the increase of patents might have distinct negative consequences on future research opportunities.³² Heller and Eisenberg agree with Garrett Hardin,³³ who popularized the original theory of the "tragedy of the commons,"³⁴ which argues that society will overuse common resources because there is no incentive to conserve the resources.³⁵ Yet, Heller and Eisenberg argue that too much privatization may be detrimental, rather than beneficial, in

²⁷ . *Id.*

²⁸ . *See id.*

²⁹ . *See* H.R. 1908, 110th Cong. (1st Sess. 2007); S. 1145, 110th Cong., (2d Sess. 2008).

³⁰ . Barfield & Calfee, *supra* note 25.

³¹ . "One motivation for patent reform is a concern that the over-proliferation of patents, instead of encouraging innovation, is stifling it. This argument achieved prominence in an influential 1998 article published in *Science* by two University of Michigan law professors, Michael A. Heller and Rebecca S. Eisenberg." Ronald Bailey, *The Tragedy of the Anticommons: Do Patents Actually Impede Innovation?*, REASONONLINE, Oct. 2, 2007, <http://www.reason.com/news/show/122785.html>.

³² . Michael Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998).

³³ . "Trained as an ecologist and microbiologist and a Professor of Human Ecology at the University of California for more than thirty years, he is best known for his 1968 essay, 'The Tragedy of the Commons.'" The Garrett Hardin Society, <http://www.garretthardinsociety.org/> (last visited Nov. 4, 2007). The phrase, "tragedy of the commons," derives originally from a comparison of medieval village land holding noticed by [William Forster Lloyd](#) in his 1833 book on population. WILLIAM FORSTER LLOYD, *TWO LECTURES ON THE CHECKS TO POPULATION* (Oxford, England: Oxford University Press, 1833). The theory itself dates to Thucydides and Aristotle. William Forster Lloyd, 1795-1852, <http://cepa.newschool.edu/het/profiles/lloyd.htm> (last visited Feb. 10, 2008).

³⁴ . Heller & Eisenberg, *supra* note 32, at 698.

³⁵ . *Id.*

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the realm of biomedical research.³⁶ Heller and Eisenberg posit:

The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovations.³⁷

In other words, having to spend the time and money to buy many different patented elements necessary to create a new drug or therapy inhibits biomedical advances and research. Later literature addressed other problems that might result from this proposed overuse of patents. For example, if multiple research tools are necessary in product development, it might be difficult to negotiate a license agreement with each of the patent holders.³⁸ Further, if the license agreements include a reach-through provision, which allows the patent holder to profit if the research tool ultimately contributes to a successful final product, the agreements might "erode profit potential, creating a disincentive for companies that require a number of research tools to develop specific commercial products or services."³⁹

As a result of the 1998 Heller and Eisenberg study and its progeny, suggesting that privatization needs to be "more carefully deployed if it is to serve the public goals of biomedical research,"⁴⁰ varying policies and theories have attempted to find a balance by encouraging the development of beneficial products and treatments without strangling experimental research.

C. THE DOMINANT POLICY ARGUMENTS

Patent protection has encouraged certain developments because patent holders, both public and private, reap financial benefits for their work.⁴¹ This monetary incentive

³⁶ . *Id.*

³⁷ . *Id.* at 699.

³⁸ . Mireles, *supra* note 4, at 165.

³⁹ . *See id.* at 165 (describing different possible problems with increased patent use, such as blocking patents, complementary patents, and increased transaction costs).

⁴⁰ . Heller & Eisenberg, *supra* note 32, at 701.

⁴¹ . "[P]atents facilitate innovation by rationalizing the allocation of resources necessary to develop a particular invention Whereas a single patent holder can orchestrate exploitation of a technological prospect,

likely changed the overall dynamic and widely held belief in "open research" previously adhered to among research institutions, pharmaceutical companies, small start-up groups, and hospitals.⁴² For example, with guaranteed patent protection providing security for financial windfalls of new discoveries, venture capitalist firms have become increasingly willing to support small biotech start-up firms.⁴³ These small, start-up businesses are arguably fundamental for diversity in research, which might be lost without patent protection.⁴⁴ Mayo physicians, on the other hand, note that historically this might have been true, when the individuals "starting up" the companies were actually the people making the discoveries. Now, though, most start-ups are just businesses that make no contribution to the research itself and provide no diversity of research. Today's start-up firms tend to depend on academic centers for expertise and guidance in validation of their products. If they do not, their products are usually inadequate and die out.⁴⁵

Meanwhile, as patent laws evolved, universities and private industry began collaborating, most likely because pharmaceutical companies envisioned increased financial rewards in both marketing and production of the new technologies.

The [pharmaceutical] companies do not have the access to patients and assays required to validate their products. They have to collaborate with medical centers to get the data and medical expertise they need to get their products past the regulatory agencies and to the market. They have managed to get the expertise for free, because the people they get it from generally lack business savvy and the legal support that protects them from giving their time and information away for essentially nothing. Dangle the chance of publication in front of researchers in an academic institution, and they will have their lab employees work night and day to generate data for nothing.⁴⁶

allowing all parties free access to that prospect may produce 'chaotic, duplication, and wasteful' effort." Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 670 (2004).

⁴² . "These scholars observe a fundamental tension between the proprietary development of end-product pharmaceuticals and the research community's tradition of open, communal science. Privatization and commercialization 'threaten to undermine certain cornerstones of our scientific infrastructure.'" *Id.* at 672.

⁴³ . Mireles, *supra* note 4, at 162-63.

⁴⁴ . *Id.* at 157.

⁴⁵ . McClure, *supra* note 18.

⁴⁶ . *Id.*

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While universities might have freely disseminated the information in order to advance educational research, privatization insulated them from costly competition, again, arguably encouraging research and innovation.⁴⁷ Yet, patents discourage "the wide sharing of information [which] helps to place information in the possession of the people who can best use it, even if these people are not the original discoverer or inventor."⁴⁸ As a result, these collaborative efforts might be preventing the most efficient use of resources. Again, the ultimate effect of increased patent protection in biotech-nological research is unclear, but, as discussed below, the courts seem willing to uphold traditional patent law in this innovative arena.

D. THE CURRENT ROLE OF THE COURTS IN BIOTECHNOLOGY AND PATENTS

Although Congress may listen to policy arguments and amend legislation in efforts to remedy "perceived deficiencies,"⁴⁹ the courts of the United States also play a major role in patent interpretation, litigation and law.

While the Supreme Court has left the Federal Circuit's opinions undisturbed in the vast majority of patent cases since the creation of the specialized patent court in 1982, the Court has shown, over the past three terms, an increased willingness to hear cases that raise patent law issues. The Supreme Court Justices' apparent newfound interest in patent cases perhaps stems from a recognition of the growing importance of intellectual property to the nation's informed-based economy, as well as the need to correct perceived errors in the lower courts' interpretation and application of patent law.⁵⁰

⁴⁷ . Mireles, *supra* note 4, at 161-62.

An outside technology transfer firm, a university foundation, or an 'in house' technology transfer office typically do the administration and transfer of a university's property rights University patent policies often require that the university researcher assign her rights in an invention to the university [T]he university will reserve the right to acquire title in any invention the inventor wishes to commercialize.

Id.

⁴⁸ . *Id.* at 187; see Lee, *supra* note 41, at 671 ("[S]tudies debunked the popular conception of the solitary scientist toiling alone in his laboratory. [Studies] showed instead that scientists work in communities, where [freely] sharing information, theories, and even materials fundamentally facilitates basic research.").

⁴⁹ . BRIAN T. YEH, CONG. RESEARCH SERV., AN OVERVIEW OF RECENT U.S. SUPREME COURT JURISPRUDENCE IN PATENT LAW 1 (2007).

⁵⁰ . *Id.*

In fact, the Supreme Court, in the past five years, has granted certiorari in eight patent cases.⁵¹ A few of these recent patent decisions, combined with earlier rulings, have significantly shaped and will continue to shape patent law application in biomedical research, as discussed below.

1. The Utility Requirement

In order to be awarded a patent, the inventor must show, among other requirements, that the patent fulfills the utility requirement.⁵² "The utility requirement ensures that the public receives an invention that is useful in exchange for the limited right to exclude others from practicing the invention. An invention is useful if it performs some function of positive benefit to society."⁵³

Initially, the Supreme Court decided in *Brenner v. Manson*,⁵⁴ a case involving a new chemical process, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."⁵⁵

⁵¹ . *Id.*

⁵² . "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C § 101 (2000).

⁵³ . Mireles, *supra* note 4, at 195.

⁵⁴ . 383 U.S. 519 (1965).

In December 1957, Howard Ringold and George Rosenkranz applied for a patent on an allegedly novel process for making certain known steroids Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Id. at 520-35.

⁵⁵ . *Id.* at 536.

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However, the Federal Circuit Court in *In re Brana* stated in a biotechnology patent case, "[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans."⁵⁶ The courts seem to favor finding utility in most biotechnology research tools,⁵⁷ making the patent easy to get.

There are other limits on patentability. For example, the Patent Act states that one who "invents or discovers any new and useful process, machine, manufacture, or any composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."⁵⁸ The Supreme Court originally interpreted the Act as limited to processes, machines, manufactures, and compositions of matter and not "laws of nature, natural phenomena, and abstract ideas," which may not be patented.⁵⁹ A doctor from Mayo points out that, "If this were really followed, much of our current biotechnology mess would vanish."⁶⁰

In a dispute between Laboratory Corporation and Metabolite Laboratories, Metabolite filed a patent infringement lawsuit against Laboratory, which had encouraged doctors to administer a test based on a Laboratory patent for a research method that correlated elevated levels of amino acid with vitamin deficiencies.⁶¹ The Federal Circuit held that Laboratory's actions were a "direct infringement of the patent."⁶² The Supreme Court granted certiorari to decide the question whether:

[A] method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.⁶³

⁵⁶ . *In Re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

⁵⁷ . Mireles, *supra* note 4, at 201.

⁵⁸ . 35 U.S.C § 101.

⁵⁹ . *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

⁶⁰ . McClure, *supra* note 18.

⁶¹ . *Id.*

⁶² . *Id.* at 1364-65.

⁶³ . Petition for Writ of Certiorari, *Metabolite Labs v. Lab. Corp. of Am.*

The Court ultimately dismissed the case on a technicality and stated that the writ of certiorari was "improvidently granted."⁶⁴ This decision affirmed the infringement liability. Justice Stephen Breyer dissented. "Those who engage in medical research, who practice medicine, and who as patients depend upon proper health care, might well benefit from this Court's authoritative answer."⁶⁵ He also went on to state that the patent should not have been validated because "[t]here can be little doubt that the correlation between homocysteine and vitamin deficiency . . . is a 'natural phenomenon'" that is not patentable.⁶⁶ Thus, the Court allowed for possibly low-quality patents, which Congress is now railing against. Because it can decide what constitutes "natural phenomenon," the Court makes it easier to obtain biomedical patents. The problems with this lenient definition are amplified in the non-profit sector of medicine:

Although I am not entirely clear whether the whole genome has been patented at this point, I can tell you that every mutation found in every disease today is. This leads to all of the problems one could imagine we would have had if Newton had been able to patent gravity. This means that whoever holds the patent essentially controls the entire United States with respect to anything done with that gene/mutation. In my world, where a clinical test for the mutation may be useful or necessary for clinical care, this can range from licensing/royalty fees of unlimited amount to excluding anyone or everyone of the patent holder's choosing from testing, to forcing the testing to be done at their designated location or with their designated kit, at their designated price for their sole profit. Not only does this have obvious implications for the increased cost of medical care single center testing is really dangerous for medical care. All genetic tests are in a constant state of flux and require unlimited "peer review" to make sure they are running appropriately, being interpreted appropriately, and open to modification using better methods over time. In almost all instances, the more removed clinical testing is from the physicians using it, the less likely it is to be optimally monitored and interpreted. Many of the tests used must be interpreted in the clinical context and in conjunction with other tests. This can not be done effectively by companies with no medical affiliations. The mistakes/inconveniences/ waste that accumulate when pure businesses try to monopolize medical testing are costly to all. If we could enforce the Supreme Court's

Holdings, 126 S. Ct. 543 (No. 04-607), 2004 WL 2505526.

⁶⁴ . Lab. Corp. of Am. Holdings v. Metabolite Labs, 126 S. Ct. 2921, 2921 (2006) (per curiam).

⁶⁵ . *Id.* at 2922 (Breyer, J., dissenting).

⁶⁶ . *Id.* at 2927 (Breyer, J., dissenting).

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definition of patentability [limited to processes, machines, manufactures, and compositions of matter] we would have a good start on the problem.⁶⁷

2. The Fair Use Exception

Some scholars argue that “specific market failures that current patent doctrine does not remedy” could be remedied by a fair use exception.⁶⁸ These scholars argue that fair use “could be used to excuse infringement by researchers attempting to invent around the patent even when the eventual end product is to be marketed commercially.”⁶⁹ While the courts could grant this exception, some academics argue that “[t]he expense and time involved in obtaining a patent for a non-pioneering, yet patentable invention may not be justified if a broad fair use defense is available.”⁷⁰ Thus, these academics contend that courts should reject an expanded version of the fair use doctrine. This argument should be challenged with regard to the impact of patents on private research institutions, particularly since the Supreme Court in 2005 partially recognized one fair use exception, noting that “The Patent Act’s safe harbor provision has often been compared to the ‘fair use’ defense in copyright law, since it immunizes from liability otherwise infringing acts . . . to advance compelling public policy interests.”⁷¹

The Patent Act’s safe harbor provision was addressed in *Integra Lifesciences I, Ltd v. Merck KGaA*. The Federal Circuit court held that the safe harbor provision (the Hatch-Waxman Act)⁷² for the use of patented inventions reasonably related

⁶⁷ . McClure, *supra* note 18.

⁶⁸ . Mireles, *supra* note 4, at 202.

⁶⁹ . Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1238 (2000).

⁷⁰ . Mireles, *supra* note 4, at 204.

⁷¹ . BRIAN T. YEH, CONG. RESEARCH SERV., SAFE HARBOR FOR PRECLINICAL USE OF PATENTED INVENTIONS IN DRUG RESEARCH AND DEVELOPMENT: *MERCK KGaA v. INTEGRA LIFESCIENCES I, LTD.* 3 (2005) [hereinafter YEH, SAFE HARBOR].

⁷² . 35 U.S.C. § 271(e)(1).

The statutory exception was created by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. This legislation modified the Patent Act by creating a new section 35 U.S.C. § 271(e), that provides “safe harbor” from infringement for pharmaceutical companies using patented invention in their drug research and development operations. The Hatch-Waxman act is widely credited with encouraging and expediting the creation and availability of generic versions of approved patented drugs.

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to the development and submission of information, applies only to the use of patented material in the FDA approval process of generic drugs, which should be allowed onto the market as soon as the patent on the name brand drug runs out.⁷³ To expedite the FDA approval process it is necessary, according to the court, to allow this narrow research exception.⁷⁴ The Supreme Court, however, unanimously held that

[I]t [is] apparent from the statutory text that §271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA. . . . This necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.⁷⁵

The Court then limited its decision and followed the Federal Circuit's holding that the exemption does not include all experimental activity. Basic research is unprotected unless the patented compound produces a "particular" physiological effect through a "particular" biological process.⁷⁶

Ultimately, the Supreme Court failed to answer one major question relevant to non-profit institutions. The Court refused to decide whether, or to what extent, the exemption applies to patented research tools,⁷⁷ since the matter was not at issue in the case.⁷⁸

YEH, *SAFE HARBOR*, *supra* note 71, at 2.

⁷³ . *Integra Lifesciences, Ltd. v. Merck KGaA*, 331 F.3d 860, 867-68 (Fed. Cir. 2003); Mireles, *supra* note 4, at 214-16.

⁷⁴ . *Integra Lifesciences*, 331 F.3d at 866-67.

⁷⁵ . *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (citations omitted).

⁷⁶ . YEH, *SAFE HARBOR*, *supra* note 71, at 8.

⁷⁷ . Research tools are defined as "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." *Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts*, 64 Fed. Reg. 72,090, 72,092 n. 1 (Dec. 23, 1999).

⁷⁸ . YEH, *SAFE HARBOR*, *supra* note 71, at 2.

3. The Experimental Use Exception

Historically, the courts developed a common law experimental use exception to patent law infringement.⁷⁹ The courts were initially unwilling to punish patent infringers for uses that were "for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement"⁸⁰ Congress reiterated this general philosophy by enacting the statutory experimental use exception, which exempted patented materials which were being used in clinical research trials. This statute could open the door for an expanded application of the experimental use exception. However, two recent Federal Circuit cases sharply narrow the exception.

First, the Federal Circuit court in *Madey v. Duke University* held that the exception could not be used in university research if there were any possible commercial uses, including simply furthering the universities' legitimate business interests.⁸¹ Thus, universities could be sued for patent infringement, despite a philanthropic motive behind the patent infringement. "The Federal Circuit's decision can contribute to the anticommons phenomena, as university researchers must either find and license patents to basic research tools or risk liability for patent infringement."⁸²

Further, while Duke, a private institution, may face liability, many public institutions will not. "A legal doctrine known as sovereign immunity protects states and state institutions from legal liability. Courts have held that participating in the federal patent system doesn't cost a state its immunity. The upshot—states can sue, but effectively can't be sued."⁸³ Although Congress passed laws limiting the states' ability to hide behind this shield, the Supreme Court overruled Congress in 1999 and continued to protect the states' immunity from lawsuits "giving states and state-sponsored institutions protection from patent-infringement lawsuits in federal court."⁸⁴ Private institutions,

⁷⁹ . Mireles, *supra* note 4, at 205.

⁸⁰ . Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.N.Y. 1861) (No. 11, 279).

⁸¹ . See *Madey v. Duke*, 413 F. Supp. 2d 601 (M.D.N.C. 2006).

⁸² . Mireles, *supra* note 4, at 209.

⁸³ . Peter Lattman, *Critics Take Aim at California's Patent Shield*, WALL ST. J., Nov. 13, 2007 at B1.

⁸⁴ . *Id.*

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including non-profits, enjoy no such protection. As the legal community and the federal government have attempted to balance, through patents, the uses and development of resources, the Heller and Eisenberg suggestion that in biomedical technology, "a proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development,"⁸⁵ continues to be debated. Some commentators appear to agree with the court rulings in these cases, stating "extension of the experimental use exception to include uses of research tools for some or any commercial purpose would effectively destroy the market for those tools, thus removing any incentives to create research tools."⁸⁶ Despite the courts' rulings, the intellectual debate regarding the actual impact of patents on downstream research continues.

E. STUDIES ASSESSING THE ACCURACY OF THE TRAGEDY OF THE ANTICOMMONS THEORY IN LIGHT OF CONGRESSIONAL AND JUDICIAL ACTION

A 2007 study found that the number of biotechnological patents per year peaked in 1998, when 5,977 patents were issued.⁸⁷ After 1998 there was a subsequent decline and leveling off.⁸⁸ As of 2004, only 4,324 biotechnological patents were issued.⁸⁹ Although one interpretation of this trend might suggest that research and technology is suffering, since the number of patents issued is declining, it could simply be that the patent office does not possess the resources to keep up with the number of patent applications.⁹⁰ Or, possibly, the boom in discovery fueled by technological breakthroughs just inherently slowed as the low lying fruit was picked during the "boom."⁹¹ The 2007 study noted that looking at the patent numbers alone does not confirm the prophesized harm to biotech research.⁹² In

⁸⁵ . Heller & Eisenberg, *supra* note 32, at 698.

⁸⁶ . Mireles, *supra* note 4, at 214.

⁸⁷ . David Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TX. L. REV. 1677, 1687 (2007).

⁸⁸ . *Id.*

⁸⁹ . *Id.*

⁹⁰ . *Id.*

⁹¹ . McClure, *supra* note 18.

⁹² . Adelman & DeAngeli, *supra* note 87, at 1687.

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addition, a 2002 study conducted by John P. Walsh, found no indication that drug discoveries have been impeded by the increased use of patents.⁹³ In fact, "the vast majority of respondents say that there are no cases in which valuable research projects were stopped because of intellectual property (IP) problems relating to research inputs."⁹⁴ The study eventually concluded that research is not inhibited because: (1) increased costs resulting from patent proliferation are not prohibitive for large firms; (2) universities are often allowed to continue research despite possible patent infringement for "educational purposes;" and (3) many up-start firms do not worry about patents because infringement is hard to detect, expensive to prosecute, and often small companies have few resources, making civil litigation for monetary recovery pointless.⁹⁵

On the other hand, a 1998 study conducted by the National Institutes of Health (NIH) suggested that researchers involved in biotechnology are concerned about difficulties and delays resulting from the increased privatization of "research tools."⁹⁶ The NIH study concluded that "virtually every firm . . . believed that restricted access to research tools is impeding the rapid advance of research and that the problem is getting worse."⁹⁷ Also, even the aforementioned Walsh study admitted that "small-start up firms and universities find the licensing fees for research tools prohibitively expensive . . . and that there are non-economic costs such as publication restrictions for university researchers."⁹⁸ Again, there is little consensus, but what all of the studies ignore is the impact on patients.

Overall, the most frequently discussed solutions,

⁹³ . See John P. Walsh et al., *Innovation in a Knowledge-Based Economy*, in PATENTING AND LICENSING OF RESEARCH TOOLS AND BIOMEDICAL INNOVATION 285 (Levin & Meyers eds. National Academies Press) (2003).

⁹⁴ . *Id.*

⁹⁵ . *Id.*

⁹⁶ . See Mireles, *supra* note 4, at 145 (explaining the study and defining "[a] research tool [as] a technology that is used by pharmaceutical and biotechnology companies to find, refine or otherwise design and identify a potential product or properties of a potential drug product," such as "fragment of a gene, a gene, 'cell lines, monoclonal antibodies.'"); NATIONAL INSTITUTES OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS 3 (1998), available at <http://www.nih.gov/news/researchtools/index.htm>.

⁹⁷ . NATIONAL INSTITUTES OF HEALTH, *supra* note 96, at 3.

⁹⁸ . See Walsh, *supra* note 93, at 285.

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Professor Peter Lee¹⁰⁶ suggests that "[a]rguments both for and against patents demonstrate the degree to which legal commentators have been preoccupied with relating patents to normal progress rather than to the evolution of scientific theory."¹⁰⁷ He suggests that "the argument that patents actually deter scientific exchange within prevailing paradigms is important in establishing the larger thesis that patents encourage the generation of alternate scientific theories that drive paradigm shifts."¹⁰⁸ Lee suggests that patents force inventors and researchers to look at scientific theories from a new perspective in an effort to invent around patented material, which furthers scientific invention by forcing researches to avoid using the already established ideas. This, in turn, promotes and generates downstream research.¹⁰⁹ Eventually these "paradigm shifts" will indeed occur through the natural course of research and development. Conversely, though, it seems likely that widely available information about successful research and unsuccessful research could lead scientists and doctors down that same "paradigm shifting" path, and possibly sooner than if scientists are forced to work in a vacuum regarding previous successes and failures. Regardless, Lee's work emphasizes the "unique status of research tools as gateways to basic scientific research and downstream development suggest[ing] that patent law should treat them differently than traditional end products."¹¹⁰ Arguably, the courts and Congress might consider addressing the patent problem from a new perspective to establish positive policies that are an agreeable compromise between patent supporters and detractors.¹¹¹

Unfortunately, a compromise is difficult because both sides of the debate are "correct" from certain perspectives. For example, as discussed above, small start-up firms need funding to perform the expensive work that biotechnology research requires. These start-ups focus on niche problems, add new ideas, and broaden overall scientific research and

¹⁰⁶ . Acting Prof. of Law, Univ. of Cal. at Davis, School of Law, <http://www.law.ucdavis.edu/faculty/lee.shtml> (last visited Feb. 10, 2008).

¹⁰⁷ . Lee, *supra* note 41, at 669.

¹⁰⁸ . *See id.*

¹⁰⁹ . *Id.*

¹¹⁰ . *Id.* at 679.

¹¹¹ . *See* Barfield & Calfee, *supra* note 25.

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diversity.¹¹² Since the Constitution protects innovation by guaranteeing the right to “their respective discoveries” for a certain amount of time,¹¹³ the Constitution arguably protects all types of discoveries in biotechnology, including basic research tools.¹¹⁴ This fundamental protection allows small inventors access to the market and encourages and increases diversity in research,¹¹⁵ thereby providing incentives for monetary gain and allowing start-up groups to develop funding—just as they are structured to do.¹¹⁶

Pharmaceutical companies, which also are fundamental to drug production and development, are similarly protected by patent law. For example, important research companies, like Pfizer,¹¹⁷ are able to fund unique projects as a result of sizeable revenues.¹¹⁸ Pfizer, though, while a cornerstone of research and development, is ultimately a corporation and, therefore, profit driven.¹¹⁹ Consequently, patent protection and licensing agreements are necessary; they enable Pfizer to insure that successful products will be monetarily rewarded. In reality, though, these companies pay little for their research while reaping significant financial rewards. For example:

A large pharmaceutical company wants to “partner” with us [Mayo]

¹¹² . See Mireles, *supra* note 4, at 163.

¹¹³ . U.S. CONST. art. I § 8, cl. 8; 35 U.S.C. § 154 (patents are generally protected for 20 years).

¹¹⁴ . See *generally* *Integra Lifesciences, Ltd. v. Merck KFaA*, 545 U.S. 193 (2005).

¹¹⁵ . See Mireles, *supra* note 4, at 163.

¹¹⁶ . *But see* McClure, *supra* note 18, who states, I don’t really buy the data that says the incentive of business collaboration drives scientific discovery, at least to the extent it is used as an argument for the current system. In my experience, most scientists will discover whether there is a business opportunity or not, if they are funded to do their work. I think it is a very small group that goes into basic research thinking they are going to make a big discovery and get rich. Most of the great discoveries are made by people passionate about investigation with no interest in the business end of their discoveries at all—just publication recognition.

¹¹⁷ . Pfizer represents “the world’s largest pharmaceutical research effort, which includes more than 13,000 scientists worldwide, supported by \$7.6 billion in funding during 2006.” Pfizer: Science Policy, http://www.pfizer.com/research/science_policy/science_policy.jsp (last visited Oct. 27, 2007).

¹¹⁸ . Pfizer conducts research in 19 different disease areas, “more than any other company,” and made \$48.4 billion in revenue in 2006. *Id.*

¹¹⁹ . *Id.*

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to develop a therapy and a clinical test to go along with it. Although they [the pharmaceutical company] would not disclose much at the early stages of negotiations, it sounds like they bought IP from a university regarding some genetic markers in a type of lymphoma. They are sure "it is a winner." They do not have the expertise to develop and validate a clinical test that will detect these markers and be able to be used for monitoring when therapy (their new drug) is used. They would like us to develop and validate the assay for them and get it approved by FDA (provided it gets that far). Our business people will negotiate some cut of the profits if it is successful. However, the cost of all of this up to now has been entirely funded by the taxpayer, either here or in a foreign country, depending on where they bought their IP. Any expenses the company incurs from here on out will get passed on in the cost of the product. The patent holders can make as much money as they want, as they can completely dictate how much everyone pays to use the test. But they won't have much cost, because Mayo is doing the work. Aside from any "cut" in the profits that Mayo might negotiate, the main incentive for Mayo to negotiate is to protect itself from the costs of running the test for its own patients, should the therapy be a big success. We will negotiate some "more reasonable" fee for ourselves to use the test when it is on the market (it is never free despite our involvement). So, while Mayo will get a break on the cost of running the test due to our "collaboration", the other big testing centers like us will not. Mayo, being non-profit, will pump any money from this back into our R&D costs and then we are back to the whole point of why we need so much more than others to cover our R&D costs. If the venture is not successful, they lose the money they spent on the IP and Mayo loses whatever money it spends associated with the effort. Despite our best negotiations, we still always feel like the loser, because if we don't negotiate to their liking, they will go to someone else who will. We then get a reputation for "not working well with industry" and, despite the reality, patients and management (even here) perceive that "working with industry" is a good thing and rank medical institutions, in part, by these types of collaborations.¹²⁰

Finally, under the Bayh-Dole Act, universities are allowed to patent discoveries researched with federal funding.¹²¹ Although university research is historically aimed at furthering knowledge and education and is spurred on by intellectual curiosity—the reason government funding is given to universities—the ability to protect that information through patents has led to joint ventures with private corporations.¹²² Today private corporations make money by leveraging government funds that support research

¹²⁰ . McClure, *supra* note 18.

¹²¹ . Gozner, *supra* note 20, at 0611.

¹²² . *Id.*

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tools is limited.¹²⁷ It also seems that patent expenses are a barrier to entry for small researchers who cannot find venture capitalist funding.¹²⁸ It is clear that increased protection of patents does, at the very least, drive up costs for researchers at all institutions and at all stages of research. In addition, pharmaceutical companies obtain patents at minimal cost.

The majority of patentable medical discoveries are made using government/tax dollar funding because this type of work is inherently costly and inefficient, with much money spent on dead ends with only an occasional useful discovery. The bulk of this work is done in university centers in the United States. More and more discoveries today, though, are made outside the United States and paid for by citizens of other countries. When the protections provided by a patent are granted to the discoverers to allow them to make money on their discovery, they don't actually pay for the costs associated with discovery—the people/patients have already paid them through taxes. Since the businesses are only going to buy patents for "inventions" they think will make them money, they are essentially avoiding almost all discovery costs, which the taxpayer is footing. The businesses avoid the real costs of medical discovery by trolling for good ideas in medical literature and meetings of academic institutions. They then purchase only promising technology and sell it at inflated prices back to the public, who both paid for it and put in the discovery effort. In addition, all of the legal fees involved in enforcing their patents get billed back to the people/health care system.¹²⁹

As a result, the non-profit institutions have to make more money to break even, which, inevitably, involves treating more patients, charging them more, and/or cutting costs in other areas of the hospital.

In sum, though patents do encourage potential monetary rewards and continued research and development, they also limit research and development by increasing costs for and

¹²⁷ . For example,

As evidence for a biomedical anticommons, analysts regularly cite the high profile case of 'probably the most hated diagnostics company,' Myriad Genetics. In the 1990s, Myriad Genetics patented and developed a test for variations in the BRCA1 and BRCA2 genes that greatly increase a woman's risk of breast and ovarian cancer. The company refused to license its patent or test to any other company. Thus, clinicians have to send all their samples from patients to Myriad Genetics at a cost of \$3000 per test. The refusal to license means, among other issues, that the test has not been validated by other researchers.

Bailey, *supra* note 31.

¹²⁸ . Mireles, *supra* note 4, at 163.

¹²⁹ . McClure, *supra* note 18.

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awarding patents to the inventor that files first, rather than the first inventor, and by allowing third party review of patent applications.¹³⁴

The House Bill and the Senate Bill diverge, though,¹³⁵ highlighting the lack of consensus regarding how to solve the current patent debate.¹³⁶ Although the House considered industry groups' perspectives,¹³⁷ the legislation remains contentious. For example, the Biotechnology Industry Organization (BIO)¹³⁸ approved some recent changes, but, believing the damages provision will deter innovation, refuses to support the bill.¹³⁹

While the proposed legislative changes seem necessary and, indeed, may improve the current patent system, the

¹³⁴ . *Id.*

¹³⁵ . See Kathi Lutton & Kelly Hunsaker, *Patent Reform Act of 2007: House Bill Passes!*, FISH AND RICHARDSON PATENT REFORM UPDATE (Sep. 7, 2007), available at <http://www.fr.com/news/2007/Sept/Patent%20Reform%20Pres%20Sept%202007.pdf> (describing the differences between the House and Senate versions of the patent reform act).

¹³⁶ . "It's not a perfect solution. This bill is the beginning of a process. I am open to suggestions for amending the language to improve its efficacy or rectify any unintended consequences." Statement of Rep. Berman, *supra* note 132.

¹³⁷ . See *id.* (listing industry groups involved as well as various proposals and suggestions presented to Congress).

¹³⁸ .

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the annual BIO International Convention, the global event for biotechnology.

Statement of Jim Greenwood, BIO president and CEO, *Bio Expresses Concern with Patent Reform Legislation As Reported out of House Judiciary Committee* (July 19, 2007) http://bio.org/news/newsitem.asp?id=2007_0719_01 (last visited Feb. 10, 2008).

¹³⁹ . We remain concerned, however, with provisions in the legislation that would change how damages against patent infringers are calculated, in a way that would often make infringement cheaper. We also believe changes are required to the provision that would require that courts peel away from the patented and infringed invention the value of all previously known elements and award damages based solely on the remaining elements. This provision severely devalues all underlying patent rights and could seriously undermine the incentive to develop novel new forms of medicines and other biotechnologies. Further, the bill continues to contain broad new rulemaking authority for the PTO, which is of great concern to BIO.

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impact on biotechnology is unclear.¹⁴⁰ Increased difficulty obtaining patents and third party review might increase the cost and length of the process itself, thereby failing to reduce the cost of obtaining and licensing patents for "downstream" research. The limited damages provision might forestall litigation, increasing the use of patented material downstream, but that might increase the ability to infringe upon legitimate patents. In light of the uncertain impact of legislation on patents in biotechnology, legislators must consider, and the courts must interpret, all current and future legislation in light of public policy considerations.¹⁴¹ It would be prudent to focus on the measure's over-all impact on medicine and patients, rather than narrow input to the views of IP lawyers and pharmaceutical CEOs, who have "vociferously argued that their ability to compete internationally depends on the full panoply of current intellectual property rights."¹⁴² One key to such focus is the plight of the private, non-profit, research institutions. These clinics—a crucial subset of the nation's medical research community, treating the general public, legislators, attorneys, and foreign dignitaries—are neither quintessential businesses nor purely charitable foundations. Rather, as discussed below in subsection D(1) their structure could be termed quasi-business.¹⁴³ If the patent problem is solved for the non-profit institutions, which develop innovative technology through their own research efforts, Congress and the courts will likely have found a balance among the business, the science, and the medical interests subject to biotech patent law.

C. ANALYSIS OF NON-PROFITS MIGHT IMPACT PUBLIC POLICY, LEGISLATION, AND LITIGATION.

To find a solution to the impasse, lawyers, researchers, courts and legislatures should, as Peter Lee did, think "outside the box." In terms of medical research, the overarching purpose of developing new gene therapies and new drugs is to serve patients' needs. In the discussion of

Id.

¹⁴⁰ . See Barfield & Calfee, *supra* note 25.

¹⁴¹ . *Id.*

¹⁴² . *Id.*

¹⁴³ . McClure, *supra* note 18.

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the "tragedy of the anticommons" in biotech patent law, the patient is forgotten.¹⁴⁴ The focus aims solely at increasing the research quantitatively.¹⁴⁵ Encouraging research, although an important public policy concern, does not outweigh the needs of the doctors and patients, although some legal experts do not believe patients are the major concern.¹⁴⁶ However, when a product affects a sick or dying person, rather than a retail consumer or a widget, additional factors should be considered in legislation and court review.¹⁴⁷ Congress and the courts should consider that:

In healthcare, physicians are required to treat patients based on "standard of care," which usually means providing the latest and best medicine. This may mean employing something that is already available or something that has just recently appeared in the literature as possibly useful. Neither the physician nor the patient really has any choice in this. This lack of choice is due to many factors, including our culture of (good quality) life at all cost, malpractice litigation fears, and no informed discussion as a country on how we really want our health care dollars spent. All of these contribute to this sense of "no practical choice" for physicians and patients. Without choice in the equation, and a huge supply of sick people, frequently desperate and not even thinking rationally, whoever controls the needed healthcare commodities essentially has no limits on their market - the market economy fails entirely.¹⁴⁸

1. Why Research Institutions are Ignored, but Still Important

The private, non-profit research hospitals and institutions located throughout the United States appear to be neglected because they are unique—providing both daily patient care and biotech research. Institutions such as the Mayo Clinic, the Cleveland Clinic, ARUP Laboratories, and Johns Hopkins Health and Medicine Center, among others, are hybrids—

¹⁴⁴ . E-mail from Rebecca Eisenberg, Robert and Barbara Luciano Professor of Law, Univ. of Mich., to Caroline Crenshaw, J.D. Candidate, Univ. of Minn. (Jan 11, 2008, 10:28:00 EST) (on file with author) ("I don't know of any research focusing on private nonprofit research institutions and it sounds like it would be interesting to pursue . . . I would not expect them to differ from other patent holders with respect to the impact of their patents on patients . . .").

¹⁴⁵ . "The current innovation system encourages researchers to patent and commercialize discoveries that in an earlier era were considered basic science insights. This has led to an active market in the building blocks of further research." Goozner, *supra* note 20, at 0612.

¹⁴⁶ . Eisenberg, *supra* note 144.

¹⁴⁷ . See *Lab. Corp. of Am.*, 126 S. Ct. at 2922 (Breyer, J., dissenting).

¹⁴⁸ . McClure, *supra* note 18.

part business, part pharmaceutical company, part university and part hospital—they are neither pharmaceutical companies, small start-up firms, nor universities (although some of them are attached to universities).¹⁴⁹ Since profit is fundamental to funding quality facilities, doctors' salaries, and research, these enterprises must act like businesses; patient fees and patenting discoveries become financial necessities. Any pecuniary gain, though, is funneled back into the hospital.¹⁵⁰ For example, "Mayo Clinic's diversified activities include health information publishing enterprises, clinical laboratory reference services, technology commercialization, and other services and products that use Mayo's medical and scientific knowledge base. These diversified activities generated \$35 million in 2006, which is reinvested in Mayo Clinic programs in medical research and education."¹⁵¹

Similarly, these clinics and labs act like pharmaceutical corporations in that they patent their discoveries and research tools in an effort to protect their research from exploitation. These institutions also are like universities. Their research is designed to further intellectual curiosity and develop new technologies for patient care. Their general mission is wide dissemination of all possible research.¹⁵² Still, under the current patent system, such freedom of information is clearly tempered by legal departments and a fear of litigation. For example, at the Cleveland Clinic:

Cleveland Clinic Foundation Innovations was founded in 2000 to promote innovation and expand treatment of the sick through the deployment of Cleveland Clinic technology. CCF Innovations commercializes new technologies developed at Cleveland Clinic, translating emerging therapies, devices and diagnostics into beneficial medical products through spin-off companies, licenses and equity partnerships. Under Cleveland Clinic conflict of interest policies, these transactions are subject to review in advance by independent physician and trustee conflict of interest committees

¹⁴⁹ . See generally The Mayo Clinic, <http://www.mayoclinic.com/> (last visited Nov. 4, 2007); The Cleveland Clinic, <http://www.clevelandclinic.org/> (last visited Nov. 4, 2007); ARUP Laboratories, <http://www.aruplab.com/> (last visited Nov. 4, 2007); Johns Hopkins Medicine, <http://www.hopkinsmedicine.org/> (last visited Nov. 4, 2007) (each describing the institutions, the patient care and the product and research developments).

¹⁵⁰ . MAYO CLINIC, *supra* note 2, at 52.

¹⁵¹ . *Id.*

¹⁵² . See McClure, *supra* note 18.

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to ensure that they are ethical and consistent with Cleveland Clinic policies and legal requirements. In addition, use of these products in clinical trials is subject to approval. Use of these medical products by Cleveland Clinic once they are commercialized is also subject to conflict of interest review.¹⁵³

Although arguably non-profit research institutions need not fear litigation from pharmaceutical corporations and/or start-up biotech firms because of the patient-oriented nature of their work, this argument is not persuasive. Large, well-known, and well-funded, non-profit research institutions have faced complex litigation over patent infringement.¹⁵⁴ Unlike start-up businesses, which are underfunded and use relatively small numbers of patented materials, the large institutions, because they are well-known, and because they use numerous research tools, are a prime target for patent infringement suits. Like large businesses, the likelihood of damage awards, even though the institutions are non-profit, is high.

Non-profits also suffer because "government funded discoveries that pharmaceutical companies and universities feed off of is actually really cheap in most cases because the labor costs are almost free. This is because grad students do much of the grunt work."¹⁵⁵ Finally the non-profits, because they are private, do not enjoy state university sovereign immunity protections. State universities, it seems, have a significant and unfair advantage in the patent litigation game.

In summary, the private, non-profit research institutions do not belong in the previously examined categories affected by the "tragedy of the anticommons" and patent law. Their hybrid business system—research guided by patient care—is both served and hurt by the current patent system. While patents bring in money from innovative techniques, the licensing agreements are expensive and time consuming for doctors. Nonetheless, the difficulties in obtaining patents are unlikely to halt research at these clinics, since research is the lifeblood of their exceptional patient care. The non-profit clinics will simply hire more

¹⁵³ . Cleveland Clinic, *About Us: Integrity in Innovation*, <http://www.clevelandclinic.org/aboutus/integrity.htm> (last visited Oct. 27, 2007).

¹⁵⁴ . See *generally* *Scripps Clinic & Research Found. v. Genetech*, 927 F.2d 1565 (Fed. Cir. 1991); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

¹⁵⁵ . McClure, *supra* note 18.

D. PROPOSED SOLUTIONS

The courts have recognized that the patent process is long and expensive.¹⁵⁸ To improve the process and to promote the timely entrance of generic drugs into the market upon expiration of the patented name-brand drug, the courts allow the use of some upstream patented materials in the research and development process in accordance with the safe harbor provision.¹⁵⁹ Yet, the experimental use exception for both universities and private research institutions is severely limited.¹⁶⁰ Consequently, while the Patent and Trademark Office is adjudicating patentable material and Congress is trying to find a balance between costs, timeliness, and innovation, the courts, at least in the realm of biotechnology, seem to be exacerbating the public policy problem and costing patients time and money.

By expanding the experimental use exception, which has been suggested but deemed dangerous to innovation,¹⁶¹ the courts would help protect patients at private, non-profit research institutions. Since the courts opted to allow state universities to continue patent infringement without liability, it would make sense for the courts to consider allowing non-profit institutions the advantage of an experimental use exception. Doctors could use materials without the fear of liability and cost of obtaining patented research tools. Further, it is unlikely that such exceptions would deter any research of these tools. While the tools would not provide financial incentives themselves, end products would still be patentable. Since the research tools are necessary for achieving the end product, it is unlikely that innovation of these tools would cease significantly.¹⁶² Also, if an end

¹⁵⁷ . *Id.*

¹⁵⁸ . United States Patent and Trademark Office, *Answers to the most frequently asked kids' questions about patents, trademarks and copyrights and the U.S. Patent and Trademark Office*, USPTO Kid's Page, <http://www.uspto.gov/web/offices/ac/ahrpa/opa/kids/kidprimer.html> (last visited Nov. 4, 2007).

¹⁵⁹ . See *Integra Lifesciences*, 545 U.S. at 202.

¹⁶⁰ . See *Madey*, 307 F.ed. 1351 at 1363.

¹⁶¹ . Mireles, *supra* note 4, at 214-16.

¹⁶² . Research liability for patent infringement: In light of the Federal Circuit's 2002 ruling that even noncommercial scientific

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product ultimately succeeded and proliferated, the companies could ask for royalties. Therefore, the courts should consider fostering a new relationship between patent use and biotechnology. This new balance must consider the large number of patients served and the purpose of the non-profit research institutions, which are seemingly ignored in the "tragedy of the anticommons" debate. Leading research institutions serving more than 500,000 patients annually should be able to treat all patients at the lowest possible costs.¹⁶³ Increased patient costs lead to increased insurance rates, which ultimately impact society at large, not just the patients visiting these institutions. It seems logical, then, to consider the needs of these institutions when establishing a new course for the patent system.

Another popular suggestion that seems possible for the courts to utilize on behalf of non-profit, medical research facilities is the oft-discussed patent pool. Multinational companies like IBM, Sony and Nokia are attempting to set up a patent pool "for companies to donate intellectual property that improves the environment."¹⁶⁴ In this patent pool each company will donate patents to the pool, which can be

research enjoys no protection from patent infringement liability, and in view of the academic research community's belief in the existence of such an exemption, and behavior accordingly, there should be some level of protection for noncommercial uses of patented inventions. Congress should consider appropriately narrow legislation, but if progress is slow or delayed the Office of Management and Budget and the federal government agencies sponsoring research should consider extending 'authorization and consent' to grantees as well as contractors, provided that such rights are strictly limited to research and do not extend to any resulting commercial products or services. Either legislation or administrative action could help ensure preservation of the 'commons' required for scientific and technological progress.

A PATENT SYSTEM FOR THE 21ST CENTURY 82 (Stephen A. Merrill et al. eds.) (2004).

¹⁶³ . Unlike software or even agricultural biotechnology—where the end products are relatively low cost, and the costs of development are relatively evenly distributed throughout the development process—biomedical research costs escalate once a therapeutically useful product reaches clinical trials. Applied research can take five to ten years from the start of human safety experiments. While the costs of pharmaceutical research are less than the drug industry claims, the investment required can run into the tens of even hundreds of millions of dollars. As a result this developmental research has almost always been funded by the private sector.

Gozner, *supra* note 20, at 0613.

¹⁶⁴ . William M. Bulkeley, *Companies to Share Eco-Friendly Patents*, WALL ST. J., Jan. 14, 2008 at B2.

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utilized without regard to patent liability. "We're pledging that we won't assert the patents that are put into the commons against anyone who is using them in an environmentally friendly way."¹⁶⁵ Major corporations are working together to advocate for the environment and solving problems through varying patent schemes. A similar device could help biotechnology research.

The federal government also might be able to intervene for non-profits if it recognizes the problems at these institutions. For example, as the government seeks to protect the public from the Avian Flu, it has forced pharmaceutical companies to sell some exclusive patents and allow other corporations to develop and market a flu vaccine.¹⁶⁶ The government issued "compulsory licenses to other drug companies to manufacture generic versions of the drug. Such option is available to countries under the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement, a component of the treaties that created the World Trade Organization (WTO) in 1995."¹⁶⁷ The government, then, has the power to ensure that there is enough vaccine and that it is affordable to citizens in the United States and abroad. If it addresses the non-profit problem, the government might find a similar solution for non-profit research institutions and ease some of their patent law and biotech research problems. Finally, the Court could re-evaluate its definition of patentable material and fashion a clear definition for patentable biological materials.

CONCLUSION

There is a significant amount of research and legislation regarding the balance between patent law and innovation. While most industries simply pass along the costs of protecting innovation to the consumers, who can choose to purchase the product or not, the biotechnology field differs. In terms of pharmaceutical corporations, doctors and hospitals can choose to buy new, innovative drugs or use old ones. Patients, however, who seek out new treatments and state-of-the-art care and procedures, particularly patients at the private, non-profit institutions, are often suffering from

¹⁶⁵ . *Id.*

¹⁶⁶ . YEH, INFLUENZA, *supra* note 9, at summary.

¹⁶⁷ . *Id.*

life-threatening illnesses. These patients have no alternative choices; they rely on the expensive techniques used at these clinics. Unfortunately, prices are rising at these clinics because of increased patent protection and decreased freedom of information. The courts are limiting exceptions that these institutions historically relied upon to avoid passing on costs to patients. Congress is changing the patent laws, but it appears to be ignoring the non-profit research institutions and their patients.

In a society where innovation and technological change continue unabated, but where medical costs continue to skyrocket, it is necessary to review the nation's patent laws and their impact on biotechnology from a perspective other than that of the pharmaceutical companies and patent attorneys. Doctors, who are busy caring for patients and developing treatments, have little time to propose new patent laws, but they need to be consulted. Costs and delays incurred by patients must be quantified. Private institutions must suggest policy changes, such as limiting the amount of time a diagnostic approach is protected under patent law, without being subject to criticism from pharmaceutical companies, start-up groups, universities, and academics.

Although NIH has performed a few studies that focus on the problem, the nation would benefit from a closer look at the number of patients harmed, how much costs have increased, and the number of doctors and researchers at these research institutions who have been frustrated as a result of the current patent system. The negative impact on patients may ultimately prove less severe than thought, but it is clear that patent law in biotechnology is different from patent law in other fields. Policies, laws, and court interpretations in biotechnological research and development need to evolve and take into consideration the public at large, rather than simply the impact on innovation. It is unlikely that the writers of the Constitution foresaw modern health care techniques. It seems equally unlikely that the Constitutional protection for innovation and commercialization in capitalist markets was meant to punish patients and limit health care quality and accessibility.