

LORELEI RITCHIE DE LARENA*

What Copyright Teaches Patent Law About “Fair Use” and Why Universities Are Ignoring the Lesson

Copyright law¹ has a clearly established doctrine of “fair use.”² While its parameters are frequently debated, the existence of the doctrine is statutory and undisputed. The laws governing patent³ and copyright are closely related and frequently intertwine, yet this important area of copyright has not been “taught” to patent law. Instead, patentees and infringers alike are typically left with more draconian, all-or-nothing options. This often acts as a disincentive to innovation. A clear and comprehensive doctrine of fair use in patent law, analogized from the sister jurisprudence of copyright, would serve the interests of the patent community, technology users, and public policy.

This Article considers the true purpose and accepted parameters of United States patent law (Part I); what copyright teaches patent law about fair use (Part II); the primary reasons why uni-

* Assistant Director, Prosecution and Copyright at UCLA and Adjunct Professor of Law at Loyola Law School. While my experience managing the patent and copyright portfolio at UCLA and teaching licensing at Loyola has been instrumental to my interest in and knowledge of this field, needless to say, this is an academic article and the views expressed herein are purely my own. That said, I gratefully acknowledge the help, support, and inspiration of the following legal scholars, including those who participated in the 2005 IP Colloquia at UCLA School of Law: Professor Neil Netanel, Professor David Nimmer, Professor John McDermott, Professor Mark Lemley, Professor Doug Lichtman, and the staff of the UCLA Law Library. Thanks also to the helpful staff of *Oregon Law Review*. Special thanks to Professor Victor Fleischer who donated valuable time and advice, and helped bring all of the pieces together.

¹ Copyright generally protects “original works of authorship fixed in any tangible medium of expression.” 17 U.S.C. § 102(a) (2000).

² *Id.* § 107. For a fuller discussion, see *infra* Part II.A.

³ Patents may be obtained for inventions and discoveries that are new, useful, and non-obvious. 35 U.S.C. §§ 101-103 (2000).

versities and other infringers who would benefit most from a statutory fair use doctrine in patent law do not advocate it — due to their conflicting positions in what this Article terms the “Paradox of the Patent Community” (Part III); and proposed solutions for a “fair” patent system, including a statutory, copyright-style balancing test for fair use where appropriate, a grant of royalty-bearing compulsory license in other cases, and in a smaller number of situations, no non-permissive rights at all (i.e., injunctive relief for the patentee) (Part IV). This logical scheme would satisfy the intent of our Founding Fathers to “promote the Progress of Science and useful Arts”⁴ by rewarding patentees while encouraging follow-on innovation.

I

PARAMETERS AND RIGHTS UNDER PATENT LAW

A. *The Purpose of Patent Law*

A patent is a federally granted, limited right to exclude others from making, using, or selling an invention, or from offering it for sale or importing it into the United States.⁵ A patent is not an absolute right,⁶ nor a monopoly,⁷ nor even a guarantee of the patentee’s ability to legally practice the patented invention.⁸ A patentee’s rights may be diminished by the existence of prior blocking patents on underlying technology,⁹ conflicting state regulations,¹⁰ geographical restrictions,¹¹ or the application of vari-

⁴ U.S. CONST. art. I, § 8 & cl. 8 (“The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

⁵ 35 U.S.C. § 271(a); *see also* 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.01 (2005).

⁶ *See* *Cantrell v. Wallick*, 117 U.S. 689, 694 (1886) (“Two patents may both be valid when the second is an improvement on the first, in which event, if the second includes the first, neither of the two patentees can lawfully use the invention of the other without the other’s consent.”).

⁷ *See id.* However, patents are sometimes viewed and have been characterized by the Supreme Court as monopolies. *See* *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 433 n.13 (1984) (referring to “the constitutionally sanctioned monopolies of the copyright and the patent”). This characterization is generally disfavored and considered an over-generalization. *See* 5 CHISUM, *supra* note 5, § 16.02[1][c].

⁸ 5 CHISUM, *supra* note 5, § 16.02[1].

⁹ *Id.* § 16.02[1][a].

¹⁰ *Id.* § 16.02[1][b]. One cannot practice a patent when doing so would violate state or federal law. *See, e.g.,* *Patterson v. Kentucky*, 97 U.S. 501, 505 (1878) (holding that a patent on oil could not be enforced if the sale of that oil was prohibited by law).

ous equitable doctrines.¹² Nevertheless, patents are powerful in our modern technological society and they can be wielded with enormous weight, whether an infringer is willful, knowledgeable of the patent at all, or simply using another's claimed technology for his own non-commercial research.¹³ This is so because United States patent law has no clear provision for a fair use doctrine, nor a clear exemption for infringement without intent.¹⁴

United States patent law as applied today is in some ways quite divergent from its proper historical purpose. The Supreme Court has mused upon the true objectives of our patent system:

First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.¹⁵

This sound philosophy, essentially setting forth a balance of interests, has been echoed by legal scholars over the years.¹⁶

¹¹ See 35 U.S.C. § 271 (2000).

¹² See 6 CHISUM, *supra* note 5, § 19.01. Four major substantive defenses can preclude enforcement of a patent against otherwise infringing conduct. These are, generally: (1) patent invalidity (which is a permanent remedy against the patentee); (2) fraudulent procurement or inequitable conduct (also invalidating the patent grant); (3) patent misuse or antitrust violation (expansive, but the patentee's rights will be restored once the misuse is "purged"); and (4) laches or estoppel (which is specific to the conduct at issue). *Id.*

¹³ See 5 CHISUM, *supra* note 5, § 16.02[4] ("One does not escape infringement by using a patented invention for a purpose not contemplated or disclosed by the patentee.").

¹⁴ See *id.* § 16.02[2] ("One making, using or selling matter covered by a patent without authority of the owner infringes regardless of knowledge or intent."); see also *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35-36 (1997) ("Application of the doctrine of equivalents . . . is akin to determining literal infringement, and neither requires proof of intent."); *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed. Cir. 1991) ("[T]here is no intent element to *direct* infringement.").

¹⁵ *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984) (quoting *United States v. Paramount Pictures*, 334 U.S. 131, 158 (1948)) ("The copyright law, like the patent statute, makes reward to the owner a secondary consideration."); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Chief Justice Burger delivered the opinion of the *Aronson* Court, allowing parties to freely contract for royalties to be paid if no patent is issued by the U.S. Patent and Trademark Office (USPTO), although it is considered misuse to contract for royalties beyond the expiration of the patent term. *Id.* at 264-66.

¹⁶ See Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1177 (2000) (explaining that the purpose of patent law, historically, is "to fashion an appropriate balance between the grant of exclusive rights to encourage innovation and the maintenance of a viable public domain from which

Our Founding Fathers also expressed views about patent law that seem to have been lost over years of aggressive lobbying and litigation.¹⁷ Commentator Ruth E. Freeburg notes that Thomas Jefferson did not see inventions as being something to privately retain like chattel or real property:

He who receives an idea from me, receives instruction himself without lessening mine; as he who lites his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the . . . improvement of his condition, seems to have been . . . designed by nature . . . incapable of confinement or exclusive appropriation. Inventions then cannot, in nature, be a subject of property.¹⁸

While analogies to real property may be appropriate under certain circumstances,¹⁹ it should be considered that the subject of a patent may in many cases be enjoyed—or even practiced—by others without damage to the patentee. In a recent article, Professor Mark A. Lemley criticized the trend toward applying the principles of real property law to intellectual property

further progress may result”); Katherine J. Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 91 (2004) (“[I]n principle, most inventions have the potential to benefit society in two ways: (1) through their direct utility to the users or consumers of embodiments of the invention; and (2) through the use of the inventive idea as a springboard to further innovation.”); see also Ruth E. Freeburg, *No Safe Harbor and No Experimental Use: Is it Time for Compulsory Licensing of Biotech Tools?*, 53 BUFF. L. REV. 351 (2005) (advocating a balanced approach to fair use and compulsory licensing); Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243 (1990) (discussing the common law “experimental use doctrine”); Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004) (examining recent federal circuit decisions on fair use and their rationale).

¹⁷ In her 2000 article, Maureen A. O’Rourke explained that the trend in Congress, the USPTO, and the courts is toward stronger patent protection because (1) the judiciary is expanding the subject matter of protection to include technologies previously not patentable or even anticipated; (2) the USPTO is issuing at a record rate, see *infra* notes 28-31; and (3) the Federal Circuit Court of Appeals is upholding patent validity more often. O’Rourke, *supra* note 16, at 1178-79.

¹⁸ Freeburg, *supra* note 16, at 391 (alteration in original) (quoting THOMAS JEFFERSON, WRITINGS 1291-92 (Merrill D. Peterson ed., Library of America 1984)). Freeburg also cites Lawrence Lessig: “With ordinary property, the law must both create an incentive to produce and protect the right of possession; with intellectual property, the law need only create the incentive to produce.” *Id.* (quoting LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE 133 (1999)).

¹⁹ See Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 642 (1999) (citing *Consol. Fruit-Jar Co. v. Wright*, 94 U.S. 92, 96 (1876)) (“A patent for an invention is as much property as a patent for land.”).

rights.²⁰ Lemley argues:

The assumption that intellectual property owners should be entitled to capture the full social surplus of their invention runs counter to our economic intuitions in every other segment of the economy. We do not permit producers to capture the full social value of their output. Nor do we permit the owners even of real property to internalize the full positive externalities associated with their property.²¹

Thus, sharing others' intellectual property is not at all like barging into their front parlor while they are sleeping, but rather resembles enjoying the fragrance of your neighbor's roses from your own backyard.²² Technology, like the fragrance of a rosebush, is not taken from its owner merely because it is enjoyed by another.²³

To push the analogy a step further, improving another's technology is like putting a hummingbird feeder on the border of your neighbor's garden. The benefit it provides to the neighbor's flowers—along with positive externalities to their nursery business—can certainly be as great as the benefit you enjoy in sitting on a bench under the feeder while smelling their roses. Clearly, this was the intent of Congress in allowing an inventor to patent an "improvement" on someone else's invention.²⁴ It allows both the patentee of the underlying technology and the patentee of the improvement to benefit from each other's technology without necessarily detracting economically or otherwise. Such improvements are akin to joining forces with your neighbor in a profitable aviary/nursery.

Today, the United States Patent and Trademark Office (USPTO) sets forth its understanding of the purpose of patent law in its Mission Statement: "The USPTO mission is to ensure that the intellectual property system contributes to a strong global economy, encourages investment in innovation, and fosters entrepreneurial spirit."²⁵ This seems slightly off-kilter from the idyllic balance of interests envisioned by Thomas Jefferson. Nevertheless, it is no wonder that the USPTO and the courts

²⁰ Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 (2005).

²¹ *Id.* at 1046.

²² *See id.* at 1048.

²³ *See id.*

²⁴ *See* 35 U.S.C. § 101 (2000).

²⁵ U.S. Patent & Trademark Office, Mission, <http://www.uspto.gov/web/menu/intro.html> (last visited Oct. 15, 2005).

have a hard time articulating a clear fair use doctrine in patent law. Congress has not yet created one.

B. Why a Fair Use Doctrine is Necessary in Patent Law

While there is ostensibly a strict procedure for proving the value and patentability of an invention through the USPTO examination process, there is no shortage of disputes over the validity of the many thousands of patents that make it through each year.²⁶ There have been over seven million patents issued by the United States government since the first was granted on July 31, 1790.²⁷ The number has increased dramatically over the years. In the year 1790, three utility patents were issued.²⁸ A century later, technology was taking off and 25,308 utility patents were issued in 1890.²⁹ In 1940, the number was 42,237.³⁰ In 2004, the last year for which data is currently available from the USPTO, 164,293 utility patents were issued, more than doubling in the past twenty years alone.³¹ Altogether, there were 1,633,355 United States utility patents actively in force in 2004.³² That is a lot of technology for a university (or any) researcher to sort through if he really wished to get permission from every patentee who may possibly allege any kind of infringement by his research. This is especially true of method claims, which can be difficult to locate in a prior-art search due to their potential breadth.

Since a patent currently grants a presumptive right to injunctive relief,³³ many scholars, researchers, businesspeople, and le-

²⁶ See O'Rourke, *supra* note 16, at 1239 n.245 (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-08 (1998)) (describing the results of their study, which demonstrated that forty-six percent of litigated patents were found invalid, generally for obviousness).

²⁷ PATENT TECH. MONITORING DIV., U.S. PATENT & TRADEMARK OFFICE, PTMD PRODUCTS AND SERVICES Brochure, available at <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/brochure.htm> (last visited Oct. 15, 2005).

²⁸ PATENT TECH. MONITORING DIV., U.S. PATENT & TRADEMARK OFFICE, U.S. PATENT ACTIVITY CALENDAR YEARS 1790 TO THE PRESENT 1 (2005), available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.pdf.

²⁹ *Id.* at 2.

³⁰ *Id.* at 3.

³¹ *Id.* at 4.

³² E-mail from Paul Harrison, U.S. Patent & Trademark Office, to author (Nov. 21, 2005) (on file with author). This was an increase of 3.75% over the prior year alone. See e-mail from Paul Harrison, U.S. Patent & Trademark Office, to author (July 15, 2005) (on file with author) (providing the number of active utility patents in 2003).

³³ See *Continental Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 430 (1908)

gal practitioners have expressed concern about the over-extension of patent ownership.³⁴ These concerns seem rightly placed. Even the federal government has begun to take note. In a highly acclaimed (and debated) report issued in October 2003, the Federal Trade Commission discussed ways of improving the patent system.³⁵ The report noted that researchers and companies currently engage in "willful ignorance" in order to avoid allegations of "willful infringement" that carry penalties of treble damages:

Some Hearings participants explained that they do not read their competitors' patents out of concern for such potential treble damage liability. Failure to read competitors' patents can jeopardize plans for a noninfringing business or research strategy, encourage wasteful duplication of effort, delay follow-on innovation that could derive from patent disclosures, and discourage the development of competition.³⁶

("Anything but prevention takes away the privilege which the law confers upon the patentee" even though the patentee was apparently not using or commercializing the claimed invention). This presumption is being questioned by Congress in the draft 2005 Patent Reform Legislation. While that particular aspect of the legislation appears to be dead in the water, the same issue is interestingly being questioned in parallel by the Supreme Court, which granted certiorari in *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 733 (2005) (mem.). In this case, which is expected to be heard and decided by June 2006, the Supreme Court will hear arguments on the issue of whether the Federal Circuit Court of Appeals was correct in presuming a patent holder's right to an injunction. In its grant of certiorari, the Court specifically asked that the parties brief and argue: "Whether this Court should reconsider its precedents, including *Continental Paper Bag Co., v. Eastern Paper Bag Co.*, on when it is appropriate to grant an injunction against a patent infringer." *Id.* (citation omitted). This would be a truly monumental change in patent law, and would be a great step forward to a scheme of "fair use" and compulsory licensing.

³⁴ See Lemley, *supra* note 20. However, this overbreadth of patent rights has been dealt with — at least ad hoc — in various forms, such as in the Supreme Court's decision in *Integra, infra*, Part I.E. See also Grossman, *supra* note 16, at 258 ("Case law has shown a tolerance for consideration of the knowledge and intentions of the infringer, whether or not there is identifiable or potential economic harm, and whether there is use for profit, that is commercial in context."); O'Rourke, *supra* note 16, at 1180; Jonathan Krim, *Evaluating a Patent System Gone Awry*, WASH. POST, May 5, 2005, at E1 (stating that Congress, which has "a track record of strengthening intellectual property" will likely pass "reforms" albeit they may not truly reform the problems of our current system).

³⁵ FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>. The report was met with a lot of interest in the patent community, but some resentment as well, including by USPTO officials who claimed that the report evidenced a lack of understanding of the necessity of monopoly power inherent in the patent grant.

³⁶ *Id.* at 16-17; see also 35 U.S.C. § 284 (2000) (allowing a court to increase damages up to three times the amount assessed); William F. Lee & Lawrence P. Cogs-

An example of a resulting negative externality under current law is the licensing practice of universities. In order not to give representations and warranties that would subject them to allegations of willful infringement, universities generally do not do prior-art searches.³⁷ Enactment of a clear fair use doctrine in patent law would eliminate this dilemma. A properly applied doctrine could, like its counterpart in copyright law, take into account a good faith belief that the infringement, while knowing, was fair.³⁸ With that protection in place, universities, research institutions, and companies alike would have more incentive to investigate existing technology so that they could truly innovate, including innovations aimed at creating patentable improvements and noninfringing “work-around” inventions.³⁹

Another argument for fair use is the right of society to obtain access to technology in exchange for granting exclusive rights to a patentee. We cannot assume that a patentee will act in the public interest by commercializing a patented invention if it is not in the patentee’s direct, short-term economic interest to do so. Consider, for example, a situation where a large, publicly traded drug company, Pharma A, develops, buys, or otherwise obtains a patent on an anthrax vaccine. This could be hugely

well, III, *Understanding and Addressing the Unfair Dilemma Created by the Doctrine of Willful Patent Infringement*, 41 HOUS. L. REV. 393, 424 (2004) (noting that under current law, “it is unclear whether a finding of willful infringement requires a determination that the defendant had intentionally infringed or whether a showing of recklessness or even negligence would suffice”). In either case, there appears to be no provision for a good faith belief of fair use as a defense to infringement under current patent law.

³⁷ Universities also lack sufficient economic resources to undertake extensive review of their patent portfolios.

³⁸ See 17 U.S.C. § 107 (2000) (regarding fair use in copyright law); Michael J. Madison, *A Pattern-Oriented Approach to Fair Use*, 45 WM. & MARY L. REV. 1525, 1555-56 (2004) (arguing that “the question ought not to be whether the defendant believed that he or she was acting legitimately, but whether the outcome of the defendant’s efforts was more socially valuable than the outcome produced by allowing the copyright holder to enjoy the use or obtain payment”).

³⁹ There is reason to hope that an exemption for good faith belief in valid use may already be on its way with the 2005 Patent Reform Legislation. In the proposed changes to 35 U.S.C. § 284, there would be no “willful infringement” if the infringer “had an informed good faith belief that the patent was invalid or unenforceable, or would not be infringed by the conduct later shown to constitute infringement of the patent.” Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 6 (2005) (emphasis added) (introduced by Rep. Lamar Smith). Broadly interpreted, this would include a belief of fair use, though of course it would be a lot easier to make that argument if Congress were to add an accompanying provision setting forth a fair use balancing test as advocated in this Article. See *infra* Part IV.A.

profitable since the United States has already been attacked with anthrax, and the fear of future anthrax attacks remains. However, vaccines, while socially valuable, are a risky business for companies.⁴⁰ Now suppose that Pharma A also obtains a patent on a higher-revenue-generating therapy for treating anthrax. While the public would clearly benefit from a vaccine, Pharma A would rather avoid the low profit margins and high liability of vaccines in favor of its therapeutic treatment. Accordingly, Pharma A may simply sit on its vaccine rights, neither commercializing nor allowing others to commercialize—or even research—the patented technology. Pharma A can instead stand by and watch the U.S. population become infected with anthrax, thereby driving up the market for Pharma A's therapeutic anthrax treatment, for which Pharma A can then surely charge huge monopoly rents. Under current United States patent law, Pharma A is generally entitled to do this.⁴¹ This situation, where public health is at issue, presents a prime candidate for a fair use analysis and perhaps a compulsory license of the vaccine technology.⁴²

We also cannot assume that a license will always be available or affordable for follow-on innovation. In some cases, more licenses would be needed to practice an invention than could be justified by projected revenue. Consider a scenario in the crowded field of biotechnology. Researcher 1 holds a patent to a composition of matter. Researcher 2 finds that the composition of matter can be used to treat schizophrenia, and he obtains a patent on that method of use. Researcher 3 then finds that the

⁴⁰ See Bernard Wysocki, Jr., *Agency Chief Spurs Bioterror Research — And Controversy*, WALL ST. J., Dec. 6, 2005, at A1 (“Publicly traded drug companies have tended to stay away from vaccines, antibiotics and related drugs. These products have low profit margins and are especially prone to liability suits.”).

⁴¹ 35 U.S.C. § 271(d) reads in relevant part:

No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following . . . refused to license or use any rights to the patent . . .

⁴² Commentator David C. Hoffman notes: “Proponents of the patent system assume that most patent holders will act rationally to maximize the economic utility of their inventions by freely granting licenses.” David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1010-11 (2004). This is not always true, particularly in the biotechnology area where inventions “stand on the shoulders” of prior innovations. *Id.* See *infra* Part IV.B. for a fuller discussion about this author's proposed compulsory license scheme.

composition of matter can also be used to treat epilepsy, and she obtains a patent on that method of use. In order to market (or even research) the compound developed by Researcher 1 for the purposes discovered by Researchers 2 and 3 to be effective, any of Researchers 1, 2, or 3 would need a license from the other. Certainly for follow-on Researchers 4, 5, 6 . . . 100, trying to work through the thicket would be daunting, if even possible. Furthermore, one patentee may, under current law, legally refuse to license under any terms whatsoever, rendering the rest of the developments unusable.⁴³ This type of licensing thicket is very common, particularly in the biotechnology arena.⁴⁴ Here again, a fair use doctrine (or in some cases a compulsory license scheme)⁴⁵ would resolve many of the administrative problems of ad hoc licensing or infringement, thereby resulting in an efficient system that benefits society through further innovation.

Furthermore, the scenarios are not limited to healthcare concerns. An oil company may purchase exclusive patent rights to an alternative-fuel technology. Although the alternative-fuel technology may be very valuable or even necessary to the United States economy in the aggregate, the oil company is entitled to quietly hold onto the patent rights without practicing the invention or allowing others to practice it. Indeed, the oil company may not have even developed the alternative-fuel technology itself, but may have purchased the patent rights essentially for the purpose of secreting the technology. As long as there are no antitrust or other legal violations, there is currently no overriding requirement in United States patent law that would require the oil company to practice the technology or grant a license to others to do so. This seems unfair to the public, which justifiably expects a return for the grant of exclusionary patent rights.

In reality, it is in a patentee's best interest to have a clear fair use doctrine, since (1) it would clarify expectations about which infringing behaviors may be actionable, thereby avoiding ad hoc application of a common law doctrine; and (2) it is a relatively less draconian doctrine compared to the invalidity charges faced by most patentees when they bring infringement lawsuits. Since invalidity is a binding determination across the board, the results

⁴³ See 35 U.S.C. § 271(d)(4).

⁴⁴ See Freeburg, *supra* note 16, at 404-09; Hoffman, *supra* note 42, at 1009-11.

⁴⁵ Hoffman, *supra* note 42, at 1039-41. See *infra* Part IV.B. for a fuller discussion about this author's proposed compulsory license scheme.

can be economically devastating for a business that suddenly finds many millions of dollars of research and development down the drain, compared with a specific, case-by-case finding of non-actionable fair use that does not affect third parties.⁴⁶

It is also in the interest of constitutional goals,⁴⁷ society, and every taxpayer to have a fair use doctrine in United States patent law. Every year the federal government spends billions of dollars on research contracts and grants. While universities are some of the main recipients of this money,⁴⁸ the federal government funds studies by research institutions, nonprofit organizations, and private companies as well. These expenditures are less likely to lead to meaningful developments if university and other researchers self-censure or if taxpayer money is wasted on unreasonable license fees or damage awards to patentees.

Meanwhile, without a clear fair use doctrine, many are taking matters into their own hands. The National Institutes of Health, for example, in a frustrated effort to disseminate research results, has created databases and issued guidelines intended to cut down the proprietary nature of research results.⁴⁹ Although this may indeed be a noble effort given the current climate against application of fair use in patent law, it should awaken those with a keen interest in preserving protections to act in turn, by enforce-

⁴⁶ See generally, Allison & Lemley, *supra* note 26, regarding frequent judicial findings of invalidity.

⁴⁷ See U.S. CONST. art. I, § 8, cl. 8.

⁴⁸ According to a self-reporting survey, universities noted that they received \$41.2 billion in research funds in 2004 (an increase of 7.1% over 2003), sixty-seven percent of which was from the federal government. ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2004 14 (2005), available at <http://www.autm.net/events/File/FY04%20Licensing%20Survey/04AUTM-USLicSrvy-public.pdf>. See *infra* Part IV for a fuller description of the role of universities in the patent fair use debate.

⁴⁹ See Eric Wills, *American Chemical Society Lobbies Against a Free NIH Database That it Sees as a Competitor*, CHRON. HIGHER EDUC., June 16, 2005; see also OFFICE OF EXTRAMURAL RESEARCH, NAT'L INSTS. OF HEALTH, NIH GRANTS POLICY STATEMENT (2003), available at http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm ("It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public."). These guidelines generally discourage indiscriminate patent filings.

Scientists and legal scholars are also starting to gather together in a group modeled after—and owned by—copyright's "Creative Commons." The "Science Commons," a project of Creative Commons, states as its mission: "Our goal is to encourage stakeholders to create areas of free access and inquiry using standardized licenses and other means: a 'Science Commons' built out of voluntary private agreements." Science Commons, Welcome to Science Commons, <http://sciencecommons.org> (last visited Oct. 16, 2005).

ing respect for ownership and allowing infringement only in a controlled and balanced fashion. Among this crowd are the major research universities that turn a blind eye to infringement when it is their own, but are keen to stop fair use by others when the university is the owner.⁵⁰ A clear fair use doctrine would eliminate this paradoxical position by providing explicit guidelines for both owners and infringers.

Professor Maureen A. O'Rourke made an innovative argument for a clear fair use doctrine in 2000, before the Federal Circuit Court of Appeals severely narrowed what little common law doctrine existed.⁵¹ Certainly, that argument is even more necessary today, although I would note that it is not as radical as Professor O'Rourke suggested. Rather, I propose it is merely a logical step, ultimately as beneficial to patentees as to those who would infringe.

C. *The History of Various Fair Use Exemptions in Patent Law*

There is some historical basis for a fair use doctrine in United States patent law. Such application is made more complicated, however, by the challenge of what to even call such a doctrine. The existing common law exemption has variably been called the "common-law research exemption",⁵² "experimental use defense",⁵³ "experimental use exemption",⁵⁴ and the "experimental purpose doctrine,"⁵⁵ among others. Each of these characterizations has slightly different implications. The existing common law doctrine is rarely, though, if ever, referred to as what it really is—a fair use doctrine in patent law. This doctrine needs to be clarified and expanded by Congress.⁵⁶

The existing common law doctrine of fair use in patent law stems from a decision by Justice Story in the 1813 case of *Whitte-*

⁵⁰ See *infra* Part III for a fuller discussion about the complex paradox of patent users and owners, particularly universities.

⁵¹ See O'Rourke, *supra* note 16 (arguing for copyright-style fair use in patent law, but in a moderated manner).

⁵² See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 863 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated*, 125 S. Ct. 2372 (2005).

⁵³ See *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

⁵⁴ See Mueller, *supra* note 16, at 917.

⁵⁵ See 5 CHISUM, *supra* note 5, § 16.03[1].

⁵⁶ As further explored herein, there is a specific statutory fair use doctrine in Title 35, at 35 U.S.C. § 271(e) (2000). This was the subject of the recent Supreme Court decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

more v. Cutter.⁵⁷ In a discussion about the purpose of patent law, Justice Story opined that there must be legal protection for one who acts “merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the [patented invention] to produce its described effects.”⁵⁸ Several scholars have noted that the word “philosophical” was used in Justice Story’s time to refer to what we now call “scientific.”⁵⁹ In other words, Justice Story’s opinion suggests that infringement for the purpose of scientific inquiry should not be actionable.⁶⁰

Although he may not have known just how important it would still be two hundred years later, neither did Justice Story abandon the common law fair use doctrine he had created.⁶¹ Just a few months after the *Whittemore* decision, he cited it with approval.⁶² In a prescient discussion that sets forth a true balance of interest as relevant today as it was then, Justice Story noted that infringement must include “an intent” not only to “infringe the patent-right” but also to “deprive the owner of the lawful rewards of his discovery.”⁶³ In short, patent protection should extend only where there is specific intent to harm the interest of the patentee.

Since Justice Story’s time, the common law fair use doctrine has been of great interest to scholars,⁶⁴ but apparently not as much so to courts⁶⁵ or Congress. The doctrine has only identifiably been applied positively in six cases (to deny infringement)⁶⁶

⁵⁷ *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). Numerous scholars have taken note of this origin. See *Integra*, 331 F.3d at 874-75 (Newman, J., dissenting); Mueller, *supra* note 16, at 927.

⁵⁸ *Whittemore*, 29 F. Cas. at 1121.

⁵⁹ *Integra*, 331 F.3d at 875 n.8 (Newman, J., dissenting); Mueller, *supra* note 16, at 929 (“Multiple authorities confirm that in Story’s day philosophical meant scientific.”).

⁶⁰ Even assuming that we leave the word “philosophical” as is, the result should be the same.

⁶¹ See Mueller, *supra* note 16, at 928.

⁶² *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

⁶³ *Id.*

⁶⁴ See *supra* note 16 for a partial list of scholars who have considered the importance of expanding the common law experimental use doctrine.

⁶⁵ There are exceptions, however, such as Judge Newman’s dissent in *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 874-75 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated*, 125 S. Ct. 2372 (2005).

⁶⁶ See 5 *CHISUM*, *supra* note 5, § 16.03[1][b]; see also *Kaz Mfg. Co. v. Chesebrough-Ponds, Inc.*, 317 F.2d 679 (2d Cir. 1963) (upholding dismissal of infringement action where defendant only used patentee’s product for illustrative purposes in advertising); *Finney v. United States*, 209 Ct. Cl. 742 (1976) (unpublished) (allowing

and recognized but held inapplicable in roughly a dozen others.⁶⁷

Except for the specific drug-development exemption codified in 35 U.S.C. § 271(e),⁶⁸ Congress has not acted to include any further iterations of fair use in patent law. Indeed, as this Article goes to press, Congress is weighing the 2005 Patent Reform Legislation, which, if passed as written in its committee print of June 1, 2005, or a similar version,⁶⁹ will bring sweeping changes to the United States patent system. However, fair use is not mentioned in the bill.⁷⁰ Indeed, at a conference about the pending legislation in the summer of 2005, Congressman Adam Schiff⁷¹ confirmed in response to a question from the audience⁷² that no provision on fair use was considered, nor would one be likely to pass the strict, business-oriented Judiciary Committee.⁷³

experimental use defense to be invoked at trial); *Chesterfield v. United States*, 159 F. Supp. 371 (Ct. Cl. 1958) (infringement denied because the United States only used patented technology experimentally); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223 (S.D.N.Y. 1944) (infringing device excluded from consideration because it was used experimentally only); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305 (N.D. W. Va. 1937) (patented machine used only for experimental purpose of testing efficacy, etc.); *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697 (D. Colo. 1935) (infringing parts sold to Colorado School of Mines excluded from damage calculation because they were used for experimental purposes in the lab), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936), *abrogated by* *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).

In *Kaz Manufacturing*, the court clearly relied on lack of intent to infringe as a defense. In a footnote, the court further cited the defendant's clever wording as an example: "[O]ne who constructs a patented wall safe but uses it only as an anchor for his boat would not be a patent infringer since such use would not be for the purpose of utilizing the teachings of the patent." *Kaz Mfg.*, 317 F.2d at 680 n.3.

⁶⁷ See 5 CHISUM, *supra* note 5, § 16.03[1][b]; Mueller, *supra* note 16, at 918-19 ("In the Federal Circuit's four precedential decisions [since 1982] in which an accused infringer asserted a common law-based experimental use defense, not once has the Federal Circuit applied the doctrine to absolve liability."); see also *Integra*, 331 F.3d 860; *Madey*, 307 F.3d 1351; *Embrex Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000); *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), *superseded by statute*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e) (2000)).

⁶⁸ See *infra* Parts I.D.-E., discussing the case of *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

⁶⁹ Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005) (introduced by Rep. Lamar Smith).

⁷⁰ Derivative terms of fair use, such as "research exemption" or "experimental use doctrine," are also missing.

⁷¹ Congressman Adam Schiff (D-California) is a member of the House Judiciary Committee, as well as the Subcommittee on Courts, the Internet, and Intellectual Property.

⁷² Admittedly, the question came from this author.

⁷³ Congressman Adam Schiff, Remarks at a luncheon program sponsored by the

D. *The Apparent Death of "Fair Use": The Federal Circuit Court of Appeals, 2002-2003*

In its 2002-2003 session, the Federal Circuit Court of Appeals⁷⁴ decided two key cases regarding fair use in patent law. In both cases, the majority opinions took an extremely narrow view of any application of "fair use." The first case, *Madey v. Duke University*, concerned the common law fair use doctrine.⁷⁵ The second case, *Integra Lifesciences I, Ltd. v. Merck KGaA*, related to a specific statutory exemption for drug-development.⁷⁶ By declining to apply either the common law or the statutory fair use doctrines in these two cases, the court virtually sounded the death knell on fair use in patent law.⁷⁷

I. *Madey v. Duke*

The *Madey v. Duke* decision brought to the forefront the issue of infringement via scientific research. In particular, the university community experienced a chill when the court clearly noted that there is no blanket halo for educational or research institutions to infringe.⁷⁸ Dr. John M.J. Madey was a former Stanford University professor who gained sole ownership of two patents that he later brought with him to Duke University to be practiced in a research lab that he set up there.⁷⁹ Duke eventually dis-

law firm of Christie, Parker & Hale at the California Institute of Technology (July 7, 2005). Interestingly, however, the House Committee on the Judiciary did recommend a research exemption in a 1990 bill known as the "Patent Competitiveness and Technological Innovation Act of 1990." H.R. 5598, 101st Cong. (1990). Perhaps even more interesting, the Committee apparently believed that a statutory research exemption would merely "codify and clarify current case law in the United States which currently excludes experimental use or research as an act of infringement." H.R. REP. NO. 101-960, pt. 1, at 41 (1990). The Committee added: "It is a central tenet of American patent law that there is a right to use scientific information to create new and better inventions in competition with the patented invention." *Id.*

⁷⁴ The Federal Circuit Court of Appeals, created in 1982, has sole jurisdiction on most patent appeals and thus, absent Supreme Court intervention, has exclusive authority on most issues in patent law.

⁷⁵ 307 F.3d 1351 (Fed. Cir. 2002).

⁷⁶ 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 125 S. Ct. 2372 (2005).

⁷⁷ In an article written before the Supreme Court delivered its opinion in *Merck*, Janice M. Mueller characterized the Federal Circuit's recent decisions as unnecessarily rigid and formalistic interpretations of the law. See Mueller, *supra* note 16, at 962 ("Through its four experimental use decisions culminating in *Integra*, the Federal Circuit has effectively shrunk the availability of the experimental use defense to a practical nullity.").

⁷⁸ *Madey*, 307 F.3d at 1360-61.

⁷⁹ *Id.* at 1352.

missed Madey from his position but continued to operate some of the equipment in the research lab, thereby practicing Madey's patented technology without permission.⁸⁰ Madey brought suit and Duke responded with several defenses, including the common law fair use doctrine, referred to in this case as the "experimental use defense."⁸¹ The district court agreed with Duke's defense and found no actionable infringement.⁸²

On appeal, the Federal Circuit Court of Appeals held in no uncertain terms that the "experimental use defense" did not apply to Duke's use of the patented technology.⁸³ In doing so, the court did recognize the existence of the doctrine, stating: "Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form."⁸⁴ The opinion further commented that not only is the "slightest commercial implication"⁸⁵ sufficient to defeat the defense but so is "any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."⁸⁶ Rather, the court held that the common law doctrine is "very narrow and limited to actions performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'"⁸⁷ So, in the case of a major research university like Duke that specifically claims it does "not undertake research or development work principally for the purpose of developing patents and commercial applications," infringement for the lofty purposes of "teaching, research and the expansion of knowledge" was sufficient to defeat the defense.⁸⁸

If indeed a university actionably infringes patented technology whether using it for purposes of direct commercialization, research, or education, then it would be difficult to imagine a scenario in which a major research university could ever use another's unlicensed, patented technology without incurring lia-

⁸⁰ *Id.* at 1352-53.

⁸¹ *Id.*

⁸² *Id.* at 1355.

⁸³ *Id.* at 1362-63.

⁸⁴ *Id.* at 1360.

⁸⁵ *Id.* at 1362 (quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1353 (Fed. Cir. 2000) (Rader, J., concurring)).

⁸⁶ *Id.*

⁸⁷ *Id.* (quoting *Embrex*, 216 F.3d at 1349).

⁸⁸ *Id.* at 1356 (quoting DUKE UNIV., POLICY ON INVENTIONS, PATENTS, AND TECHNOLOGY TRANSFER, Preamble and Objectives, available at <http://www2.mc.duke.edu/admin/aa/policy/invent1.htm> (last visited Oct. 16, 2005)).

bility. The *Duke* court put the nail in that coffin by adding, correctly, that Duke, "like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream."⁸⁹ This is factually accurate but inapposite. Duke was presumably not suggesting it could market Madey's technology commercially without a license. The question should more clearly have been directed toward Duke's research purposes.

The *Duke* case may actually not have been the best test case for universities to plead a research exemption, since Duke was in fact using the patented technology for the very purpose it was intended, rather than experimenting on it to create something new, as is so often done by university (and other) researchers. Therefore, at least one commentator has suggested that while Duke perhaps should not have prevailed after all, the case could simply have been decided on more narrow grounds.⁹⁰ Meanwhile, with the language employed by the *Duke* court, there has been an inevitable chilling effect on universities and their researchers, many of whom are just now realizing that maybe they do not get to create their own set of rules after all.⁹¹

2. *Integra v. Merck*

As noted previously, there is a very specific statutory fair use doctrine in United States patent law for certain actions related to drug development. The statute reads in relevant part: "It shall not be an act of infringement to make, use, offer to sell, or sell

⁸⁹ *Id.* at 1363 n.7.

⁹⁰ See Mueller, *supra* note 16, at 940.

⁹¹ See, e.g., Memorandum from William Hopper & Michelle D. Christy, Office of Research & Project Admin., Princeton Univ., to Faculty, Research and Technical Staff, Princeton Univ. (Dec. 29, 2003), available at <http://www.princeton.edu/orpa/memos/DukevMadeymemo012904.htm> (warning researchers "to be mindful of their use of patented technologies in their respective research activities and to continue to acquire the appropriate rights before using such technologies"). Also, this author, while writing this Article, received a letter from a purported patentee, threatening possible infringement action for research allegedly going on in a laboratory at UCLA (letter on file with author). Public universities such as the University of California are probably subject to Eleventh Amendment immunity from patent infringement liability (at least for now) pursuant to the Supreme Court ruling in *Florida Prepaid Postsecondary Educational Expense Board v. College Savings Bank*, 527 U.S. 627, 646-47 (1999), even though Congress had tried to abrogate that immunity when it enacted 35 U.S.C. § 271(h) in 1992. Congress may try again more successfully in the future. For a fuller discussion about universities and their place in the debate over fair use in patent law, see *infra* Part III, describing the Paradox of the Patent Community.

. . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs”⁹²

The issue in *Integra v. Merck* involved the parameters and application of this statutory provision to pre-clinical research.⁹³ Specifically, there was a question as to how far back in time the exemption reaches and whether it protected sponsored research done at the nonprofit Scripps Research Institute, if that research was pre-clinical only and if some or all of the results of the research might never actually be submitted to the Food and Drug Administration for approval.⁹⁴

In an opinion by Judge Rader, the majority held that the exemption should only be enforced under extremely narrow conditions.⁹⁵ The court further opined that the common law fair use doctrine, referred to in the case as the “common-law research exemption,” was not only *not* at issue, but should not be considered at all material to the court’s decision.⁹⁶ In a powerful dissent, Judge Newman disagreed with both statements, declaring instead that the pre-clinical research fell squarely under both common law and statutory definitions of fair use.⁹⁷

An interesting and somewhat radical opinion, Judge Newman’s dissent argued that it is totally fair for someone to use patented technology for the purpose of reviewing an experiment, creating work-around technology, or creating an improvement.⁹⁸ As she sagely noted, refusing to accept and apply the common law research exemption would undermine the rationale for allowing improvements to be independently patentable⁹⁹:

Were such research subject to prohibition by the patentee the advancement of technology would stop, for the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology.¹⁰⁰

⁹² 35 U.S.C. § 271(e) (2000).

⁹³ *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 125 S. Ct. 2372 (2005). This was an entirely different panel of judges from the one that ruled in *Madey v. Duke*.

⁹⁴ *See id.* at 865-68.

⁹⁵ *See id.* at 866.

⁹⁶ *Id.* at 863 n.2.

⁹⁷ *See id.* at 876-77 (Newman, J., dissenting).

⁹⁸ *See id.* at 875-76.

⁹⁹ *See id.*

¹⁰⁰ *Id.* at 875.

Noting that the common law fair use doctrine in patent law has the same origins as the fair use doctrine in copyright,¹⁰¹ Judge Newman suggested that 35 U.S.C. § 271(e) was Congress’ answer to parallel fair use doctrines in patent and copyright law.¹⁰² If this were true, one might note that Congress could have been a great deal clearer and broader in its language, opening it up beyond drug development. Recognizing this, perhaps, Judge Newman went on to boldly argue that the statutory exemption comes in where the common law exemption ends.¹⁰³ Still, one has the sense that this is not what Congress intended, although perhaps it should have been.

Meanwhile, Judge Newman’s view would not give blanket permission to infringe, nor would it necessarily obviate the ability to patent research tools. As she cleanly noted, we must be able to distinguish between “investigation *into* patented things, as has always been permitted, and investigation *using* patented things, as has never been permitted.”¹⁰⁴ She opined that this was simply misunderstood by the *Duke* majority.¹⁰⁵

E. A Surprising Savior: The Supreme Court’s *Integra* Decision

In a well-written and potentially very significant holding, the Supreme Court issued its reversal of *Integra v. Merck* on June 13, 2005.¹⁰⁶ Putting aside discussions about the Supreme Court’s presumed rationale,¹⁰⁷ the opinion is simply a good one for promoting fair use in patent law.

Writing for a unanimous court,¹⁰⁸ Justice Scalia largely vetted the comments of Judge Newman’s federal circuit dissent. In what will probably become a famous quote, the Court held that there must be a “wide berth” of exemption for activities, regard-

¹⁰¹ *Id.* at 876 n.9. For a fuller discussion of the parallels between copyright and patent law and their common origins, see *infra* Part II.

¹⁰² *Integra*, 331 F.3d at 876 n.9 (Newman, J., dissenting).

¹⁰³ *Id.* at 876. Presumably, the converse applies as well.

¹⁰⁴ *Id.* at 878 n.10 (emphasis added).

¹⁰⁵ See *id.*; see also Mueller, *supra* note 16, at 943.

¹⁰⁶ See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

¹⁰⁷ Cynics note that big pharmaceutical companies supported the position taken by the Supreme Court and that, therefore, the Court did not stray far from its recent presumed favoritism of big business interests. See Andrew Pollack, *Justices Expand Rights to Experiment with Patented Drugs*, N.Y. TIMES, June 14, 2005, at C1 (noting big pharmaceutical and biotechnology companies supported a broad interpretation of the research exemption).

¹⁰⁸ It is encouraging that the Supreme Court felt so strongly about the need for a broad fair use doctrine that there was no dissent.

less of clinical stage, “reasonably related to the development and submission of *any* information under the FDCA.”¹⁰⁹ As an example, the Court noted that the FDA is required to balance the respective values of safety and efficacy for any given application.¹¹⁰ Applicants must submit data to support the results of such tests.¹¹¹ The Court reasoned, therefore, that an applicant’s use of infringing technology to test for safety and efficacy is reasonably related and generally protectable.¹¹² Since no one has a crystal ball on the results of such tests *ex ante*, applicants, and even their upstream researchers, must test more compounds more broadly than will likely be submitted to the FDA for approval.¹¹³ The Court concluded that applicants and their predecessor researchers must be allowed leeway to infringe for these purposes.¹¹⁴

Interestingly, by exempting certain activities based on the purpose of the infringement, the Court added an intent element to the statute that might not actually be there. This result of (dare I say it?) rare judicial activism is actually important in this case because an exemption based on intent is the first step toward a broader fair use doctrine. Furthermore, although the Court did not specifically address the application of the common law fair use doctrine, it did mention the doctrine in passing as having been properly applied by the district court to exempt certain early, infringing activities.¹¹⁵ Thus the Court not only significantly expanded the statutory fair use doctrine, it also tacitly endorsed the common law doctrine.

While the reasoning of the Supreme Court’s decision (and Judge Newman’s dissent) is tempting, it does not quite square with the actual language of 35 U.S.C. § 271(e). Indeed, a broad interpretation of the Supreme Court’s opinion would open up the statutory exemption to any research that *might potentially* support an FDA drug application one day, regardless of the underlying technology. For example, a scientist working in University X’s physics department may test out another’s patent on cold

¹⁰⁹ *Merck*, 125 S. Ct. at 2380. For more information about the FDCA, see 21 U.S.C. §§ 301-399 (2000).

¹¹⁰ *See Merck*, 125 S. Ct. at 2381.

¹¹¹ *See id.*

¹¹² *See id.* at 2383-84.

¹¹³ *See id.* at 2383.

¹¹⁴ *See id.*

¹¹⁵ *See id.* at 2382 & n.7.

fusion. At first blush, the research appears to be entirely non-biological in nature, not likely to ever be mentioned in an FDA application, and therefore not subject to exemption under 35 U.S.C. § 271(e). However, with interdisciplinary projects so common now, the physicist's research might one day be utilized by his medical-school colleagues to create methods of treating trauma patients. By the logic of the *Integra* Court, the physicist's research should thereby be non-actionable as long as he claims to have the intent to use the technology one day for a protected purpose. This could obviously be argued whether or not the physicist's work is ever actually included in an FDA application. Indeed, to hold otherwise would seem imbalanced, since cold fusion is just as important to our society as some experimental drug uses. Yet it seems clear that the current wording of 35 U.S.C. § 271(e) is simply not that broad.

Many issues arise from the Supreme Court's *Integra* decision, therefore, and it is not entirely clear how they will be resolved. On the other hand, this is exactly how copyright fair use became an entirely accepted common law doctrine, so much so that when it was finally codified by Congress there was little debate about the value of its existence or the factors relevant to its application.¹¹⁶ The fair use doctrine in patent law has a long way to go in that direction, but this is an auspicious beginning.

II

WHAT COPYRIGHT TEACHES PATENT LAW ABOUT "FAIR USE"

A. *Development and Application of a Fair Use Doctrine in Copyright Law*

Copyright has a well-developed statutory doctrine of fair use. The legislation states in relevant part that use of another's work "for purposes such as . . . teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright."¹¹⁷ While the application of the doctrine is not always so simple,¹¹⁸ it is still a good model for a statutory fair use doctrine in patent law.

Interestingly, while the copyright doctrine of fair use was not codified by Congress until 1976, the doctrine existed previously

¹¹⁶ See *infra* Parts II.A.-B.

¹¹⁷ 17 U.S.C. § 107 (2000).

¹¹⁸ See Madison, *supra* note 38, at 1551.

in common law, not unlike the current state of the patent research exemption/experimental use defense. Furthermore, it is well-recognized that the doctrine of fair use in copyright law stems from the very same Justice Story who initiated a fair use doctrine in patent law.¹¹⁹ These comparisons weigh heavily in favor of logically extending to patent law the same statutory scheme that has been afforded to copyright.

In particular, the factors considered by Justice Story to be important to a determination of fair use under copyright law formed the basis of the balancing test later codified by Congress.¹²⁰ In the case of *Folsom v. Marsh*, Justice Story set forth the factors to consider in evaluating whether an author could use President Washington's letters without permission from the copyright owner:

In short, we must often, in deciding questions of this sort, look to the nature and objects of the selections made, the quantity and value of the materials used, and the degree in which the use may prejudice the sale, or diminish the profits, or supersede the objects, of the original work.¹²¹

This looks strikingly like the statutory balancing test adopted by Congress 135 years later.¹²²

As with his justification of fair use in patent law,¹²³ Justice Story captured the essence of activity that, for public policy reasons, should be exempt from infringement liability. The four-part balancing test set forth in 17 U.S.C. § 107, as further examined in Part IV.A., *infra*, is an adept, if imperfect, attempt to continue providing economic incentives to the creators of intellectual property,¹²⁴ while providing incentives and means for others to innovate. While some scholars have bemoaned the fact that with the codification of the fair use doctrine in copyright law nothing really changed,¹²⁵ the statutory enactment of fair use is

¹¹⁹ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 876 n.9 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated*, 125 S. Ct. 2372 (2005); *Basic Books, Inc. v. Kinko's Graphics Corp.*, 758 F. Supp. 1522, 1529 (S.D.N.Y. 1991); Mueller, *supra* note 16, at 926-27.

¹²⁰ 17 U.S.C. § 107.

¹²¹ 9 F. Cas. 342, 348 (C.C.D. Mass. 1841) (No. 4,901).

¹²² See 17 U.S.C. § 107.

¹²³ See *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

¹²⁴ In this case copyright, but just as properly applied to patent law, as done by Justice Story in *Whittemore*, 29 F. Cas. 1120, and *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

¹²⁵ See Madison, *supra* note 38, at 1551.

still quite valuable. It serves the general public policy goals in American law of setting reasonable expectations for the parties and of balancing interests, while allowing room for judicial interpretation of fairness on a case-by-case basis.

The statutory doctrine of fair use in copyright law has also served as a torch in the night during an era where other aspects of the law have shifted heavily in favor of copyright owners. As Professor Mark A. Lemley notes:

By virtually any measure, intellectual property rights have expanded dramatically in the last three decades. Terms of protection are longer, the number of things that are copyrightable has increased, it is easier to qualify for copyright protection, copyright owners have broader rights to control uses of their works, and penalties are harsher. In addition, Congress has created entirely new rights.¹²⁶

Recent Supreme Court interpretations upholding strong copyright protections make the doctrine of fair use that much more essential.¹²⁷

The doctrine of fair use should be no less important in Title 35 than it is in Title 17. Although a grant is much easier to obtain in copyright, and the terms are much longer, patents present an even greater monopoly, with a significant concentration in the hands of a few.¹²⁸ Furthermore, it would seem difficult to argue

¹²⁶ Lemley, *supra* note 20, at 1042. Furthermore, term extensions were upheld by the Supreme Court after Professor Lemley's article was written. See *Eldred v. Ashcroft*, 537 U.S. 186, 208 (2003).

¹²⁷ In addition to *Eldred*, which upheld term extensions well beyond a lifetime, 537 U.S. at 206-07, the Supreme Court found liability in *MGM, Inc. v. Grokster, Ltd.*, 125 S. Ct. 2764, 2782 (2005) (upholding strong exclusive rights of copyright owners). See also *Rip. Mix. Burn*, *ECONOMIST*, July 2, 2005, at 13, expressing discontent with the overprotective copyright regime created by Congress. The article notes the "balance" necessary between media firms (which are primarily copyright owners) and technology firms (which are in recent times frequently accused of infringing copyrights based on theories of contributory infringement). *Id.* In an argument that could as easily be spoken about the current state of patent law, if not more so because of the lack of any clear fair use doctrine outside of drug discovery, the article sadly notes: "Yet tech and electronics firms are also correct that holding back new technology, merely because it interferes with media firms' established business models, stifles innovation and is an unjustified restraint of commerce." *Id.* In arguing for a greater application by Congress of shorter copyright terms and more fair use, the article notes that "[t]echnology has tipped the balance in favour of the public domain." *Id.* at 14.

¹²⁸ Of the 164,293 U.S. utility patents issued in 2004, twenty-five percent were held by the top fifty patentees, with more than 10,000 held by the top five alone. See OFFICE OF ELEC. INFO. PRODS., U.S. PATENT & TRADEMARK OFFICE, PATENTING BY ORGANIZATIONS: 2004 (2005), available at www.uspto.gov/web/offices/ac/ido/

that a copyrighted song from the popular rapper Eminem is of greater value to the public interest than a patented anthrax vaccine.¹²⁹

B. Other Shared Doctrines Between Copyright and Patent Law that Justify the Comparison

Copyright and patent law are sister bodies of jurisprudence, and they have often shared legal applications with one another. The two were placed hand-in-hand in the Constitution by the Founding Fathers, and they were enacted together by Congress in 1790.¹³⁰ Accordingly, several doctrines developed in patent law — such as misuse, contributory infringement, licensee estoppel, and first sale — have been applied to copyright law simply for the fact that the two are so closely related. Just as copyright has benefited from the development of patent law, copyright can teach patent law about “fair use.”

In applying the doctrine of patent misuse to copyright, the Fourth Circuit Court of Appeals in *Lasercomb America, Inc. v. Reynolds* discussed the reasons why it is entirely reasonable for the two to share legal applications:

The origins of patent and copyright law in England, the treatment of these two aspects of intellectual property by the framers of our Constitution, and the later statutory and judicial development of patent and copyright law in this country persuade us that parallel public policies underlie the protection of both types of intellectual property rights.¹³¹

The court further noted that “the similarity of the policies underlying patent and copyright is great and historically has been consistently recognized.”¹³²

oeip/taf/topo_04.pdf [hereinafter USPTO, PATENTING BY ORGANIZATIONS]. Also, patent rights protect even against innocent, unknowing infringers, while copyright does not provide protection against those who independently create. See O’Rourke, *supra* note 16, at 1192.

¹²⁹ While rappers like Eminem are socially interesting and provide a point of “philosophical” debate, patented technology is more likely to present significant public health and other scientific benefits. As noted, *supra* Part I.B., locking up the practice of such knowledge could actually be very damaging for society. Presumably, no one dies without access to Eminem.

¹³⁰ See U.S. CONST. art. I, § 8, cl. 8; O’Rourke, *supra* note 16, at 1181 n.6.

¹³¹ 911 F.2d 970, 974 (4th Cir. 1990) (applying the doctrine of patent fair use to copyright law in a software case); see also PORT ET AL., LICENSING INTELLECTUAL PROPERTY IN THE INFORMATION AGE ch. 9 (2d ed. 2005) (discussing the doctrine of misuse).

¹³² *Lasercomb*, 911 F.2d at 976.

Other courts have applied the patent doctrines of “licensee estoppel” and “contributory infringement” to copyright law with similar rationale. In *Twin Books Corp. v. Walt Disney Co.*, a federal district court followed both Supreme Court and Ninth Circuit Court of Appeals precedent in stating, “[w]here precedent in copyright cases is lacking, it is appropriate to look for guidance to patent law, ‘because of the historic kinship between patent law and copyright law.’”¹³³

Another area of patent law that has been applied to copyright by analogy is the doctrine of “first sale” and resulting “exhaustion of rights.” The Eleventh Circuit Court of Appeals in *Allison v. Vintage Sports Plaques* noted that the doctrine applies equally, by analogy, to patent, copyright, and trademark law.¹³⁴

Finally, the very doctrine of fair use has been discussed as being as applicable to patent as it is to copyright law.¹³⁵ This is entirely sensible given the similarity of development of patent and copyright law, the multitude of doctrines that they already share, and the fact that not only do copyright and patent law share common origins, but so do their doctrines of “fair use.”

C. International Application of Fair Use in Patent Law

There is also precedent for a patent fair use doctrine in the statutes of other industrialized countries.¹³⁶ While the United States does not commonly adopt laws from even its closest allies,¹³⁷ it is not always averse to doing so.¹³⁸ In fact, Title 35 has

¹³³ 877 F. Supp. 496, 500 (N.D. Cal. 1995) (quoting *Harris v. Emus Records Corp.*, 734 F.2d 1329, 1333 (9th Cir. 1984)) (extending Supreme Court’s abolition of “licensee estoppel” to copyright law), *rev’d on other grounds*, 83 F.3d 1162 (9th Cir. 1996).

¹³⁴ 136 F.3d 1443, 1448 (11th Cir. 1998); *see also* 5 CHISUM, *supra* note 5, § 16.03[2][a] (Supp. 2005).

¹³⁵ *See supra* note 119.

¹³⁶ Many nations have an experimental use exemption in their patent laws, including Germany, Japan, the United Kingdom, Korea, and India. John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 718 (2002); Mueller, *supra* note 16, at 969-70; *see infra* notes 143-44 (Germany and Japan).

¹³⁷ *See, e.g., The Insidious Wiles of Foreign Influence*, ECONOMIST, June 11, 2005, at 25. Regarding the United States Government’s fear of influence of foreign law, particularly in the current political climate, this article states: “Republicans have now introduced a resolution in Congress banning inappropriate reliance on foreign laws or judgments in interpreting the constitution. Although almost certainly a violation of the separation of powers, it has already attracted a lot of support.” *Id.* at 26.

¹³⁸ 5 CHISUM, *supra* note 5, § 16.02[5][g]. *But see* PATENT PUB. ADVISORY COMM., U.S. PATENT & TRADEMARK OFFICE, ANNUAL REPORT 17 (2004), *available at* http://www.uspto.gov/web/offices/com/advisory/acrobat/ppac_annual_04.pdf

been significantly overhauled over the past decade to comply with international treaty obligations.¹³⁹ Such updates have included expansion of rights covered by patent law,¹⁴⁰ implementation of provisional patent filings,¹⁴¹ and, most recently, in the pending 2005 Patent Reform Legislation, a move toward a “first to file” system.¹⁴²

The laws of Germany and Japan, for example, provide good models for statutory research exemptions. Section 11 of the German Patent Code reads: “The effects of a patent shall not extend to [1] acts done privately and for non-commercial purposes; [or] [2] acts done for experimental purposes relating to the subject matter of the patented invention.”¹⁴³ Japan’s law similarly states: “The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.”¹⁴⁴ Commentators have even gone so far as to argue that with the prevalence of these types of research exemptions in other countries, where one does not exist in the United States, companies have an economic incentive to outsource their research, thereby negatively impacting the United States economy.¹⁴⁵

Despite some concerns to the contrary,¹⁴⁶ an appropriately applied fair use doctrine in United States patent law should fit squarely within the limitations imposed by the World Trade Organization in its treaty regarding Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹⁴⁷ Intended to curb intellectual

(describing the World Intellectual Property Organization, which administers patent treaties as “an international bureaucracy, the priorities of which are not always aligned with those of the United States”).

¹³⁹ 5 CHISUM, *supra* note 5, § 16.02[5][g].

¹⁴⁰ *Id.*

¹⁴¹ 35 U.S.C.S. § 111(b) (2005).

¹⁴² Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 6 (2005) (introduced by Rep. Lamar Smith).

¹⁴³ Patentgesetz (PatG) [Patent Law] Dec. 18, 1980, § 11, *trans. available at* http://www.wipo.int/clea/docs_new/en/de/de081en.html [hereinafter German Patent Law] (amended by Laws of July 16 and Aug. 16, 1998).

¹⁴⁴ Tokkyoho [Patent Law], Law No. 121 of 1959, § 69(1), *trans. available at* http://www.wipo.int/clea/docs_new/en/jp/jp036en.html [hereinafter Japanese Patent Law] (amended by Law No. 220 of 1999).

¹⁴⁵ Mueller, *supra* note 16, at 920. This is an interesting argument, although considering the length of time that such laws have already been in force in other countries (in Germany since 1980, in Japan since 1959), the scenario does not appear very likely.

¹⁴⁶ O’Rourke, *supra* note 16, at 1202 & n.109 (discussing possible overbreadth of United States copyright law outside compliance with TRIPS).

¹⁴⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15,

property piracy by developing countries, TRIPS Article 30 gives sufficient leeway to allow a doctrine of fair use in United States patent law, just as it has been applied in other countries: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."¹⁴⁸

Therefore, a properly worded statutory doctrine of fair use in United States patent law would comply with TRIPS Article 30, provide harmonization with other nations, and put United States researchers on a level playing field to conduct innovative research without constant fear of liability.

III

THE PARADOX OF THE PATENT COMMUNITY: THE MAJOR RESEARCH UNIVERSITY AS INFRINGER (BUT ALSO AS OWNER . . .)

It is an interesting conundrum that it is difficult to know who is on which side of the patent fair use debate. The answer seems to vary widely on a case-by-case basis. This is due to the internally conflicting interests of the largest players in the inventive community, who perform both research (i.e., use) and development (i.e., ownership) of technology. In copyright law there is a fairly clear line between the primary owners (entertainment and publishing companies) and the primary infringers (high-tech companies, universities, and consumers).¹⁴⁹ Not so in the patent community, where the primary patent owners (large private companies and universities) are also the primary infringers, and are therefore loath to petition for a fair use doctrine that will benefit their research programs but also might lower revenue for their licensing (and litigation) units. This Article terms that socio-economic disincentive the "Paradox of the Patent Community."

It is a dirty little secret of major research universities that they

1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm [hereinafter TRIPS]; see also Duffy, *supra* note 136, at 718; Mueller, *supra* note 16, at 971.

¹⁴⁸ TRIPS, *supra* note 147, at art. 30.

¹⁴⁹ See *supra* note 127 regarding copyright tussles between owners and users.

are prime culprits in the Paradox of the Patent Community to the effect that they fight fair use in patent law as much as they fight for it. Universities are probably some of the biggest patent infringers because faculty and graduate students are unlikely to seek patent licenses to conduct their research, and universities do not have the resources or authority to supervise internal infringement the way private companies might (although they often do not). Therefore, universities have intermittently argued for a research exemption in patent law. This is the exact (unsuccessful) argument put forth by Duke University in defense of the allegations that it infringed a patent via its research programs in *Madey v. Duke University*.¹⁵⁰

At the same time, universities have become fairly major patent owners since the passage of the Bayh-Dole Act in 1980.¹⁵¹ The Bayh-Dole Act enables small businesses, nonprofit corporations, and university recipients of federal government research funds to take title to resulting inventions.¹⁵² Since 1980, university technology transfer has become a multi-billion dollar industry. Although any given patent is not likely to generate significant (or any) income, the University of California alone earned over \$93 million in licensing fees in fiscal year 2004.¹⁵³ Overall, \$1.385 billion was collected by universities in licensing revenue in 2004.¹⁵⁴ This provides a strong economic incentive for universities to pursue patent rights, including, where large amounts are at stake,

¹⁵⁰ See 307 F.3d 1351, 1355-56 (Fed. Cir. 2002). For a fuller discussion of this case see *supra* Part I.D.1.

¹⁵¹ 35 U.S.C. §§ 200-212 (2000). It may actually be argued that universities are irresponsibly and overly aggressive in their patenting practices, since anyone seeing a published or issued patent on the easily accessed USPTO website may be deterred from practicing a socially valuable invention even though the university-owner is not commercializing it. Furthermore, it is probably a waste of funds for universities to spend millions of dollars a year to sustain large portfolios of patents, many of which are never licensed.

¹⁵² This is a generalized statement for purposes of this Article. The Bayh-Dole Act and its associated regulations are not simple, and proper compliance requires some expertise. The Act is not without controversy, either, but that is the subject of another article.

¹⁵³ Matt Krupnick, *Possible Change in Patent System Could Hurt Universities*, CONTRA COSTA TIMES, July 13, 2005. The University of California, representing ten campuses, is the largest patent holder of any university, with 422 patents issued in 2004, the latest year for which data was currently available from the USPTO. USPTO, PATENTING BY ORGANIZATIONS, *supra* note 128, at B1-2. The California Institute of Technology has the highest number of patents issued to a single campus, with 135 in 2004. *Id.* at B1-6.

¹⁵⁴ ASS'N OF UNIV. TECH. MANAGERS, *supra* note 48, at 23.

infringement suits.¹⁵⁵

As a result of this paradox, the university community is torn. As researchers, they want full and free access to patented technology owned by others. As owners, however, universities are concerned that a research exemption could be construed to protect those who would infringe university patents as much as the reverse. In that conflicted position, universities actually argued against a broad interpretation of the current statutory fair use exemption of 35 U.S.C. § 271(e) at issue in *Merck v. Integra*.¹⁵⁶ A number of large research universities, including the patent giant University of California, signed onto an amicus brief, which unsuccessfully encouraged the Supreme Court to take a narrow view of the existing statutory exemption for drug development.¹⁵⁷

The universities explained their interest in the case by claiming that "the university sector's ability to patent technology arising from its research efforts is the basis for transferring such technology to the public for its use and benefit."¹⁵⁸ This is a circular argument. The issue is not whether universities are getting sufficient income from their technology transfer programs. The true public policy issue is whether allowing a broader fair use exemption provides an incentive to innovation in general such that the public receives its just reward for the exchange of exclusivity to an inventor (or, more commonly, the inventor's assignee). The universities could not properly argue to the contrary, since university research, by the universities' own admission, is rarely undertaken specifically for the purpose of commercialization.¹⁵⁹ Therefore, it seems disingenuous for universities to state that an expansion of the definition of permissible fair use under § 271(e), as indeed ordered by the Supreme Court despite this plea, "would have an adverse effect on the research community as a

¹⁵⁵ A non-exhaustive search on Westlaw for "patent infringement" cases to which a "university" is party produced 219 results (as of July 22, 2005).

¹⁵⁶ The existence of the fair use exemption in § 271(e), and the fact that it is very specifically limited to drug development, is probably a testament to the sharp divisions in the patent community over the highly lucrative pharmaceutical business.

¹⁵⁷ Brief of Amici Curiae Wisconsin Alumni Research Foundation, et al. in Support of Respondents, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237) [hereinafter Brief of Amici Curiae]. This author had no involvement with the University of California's decision to participate in the amicus brief, nor with its drafting.

¹⁵⁸ *Id.* at 1.

¹⁵⁹ *See, e.g.,* *Madey v. Duke Univ.*, 307 F.3d 1351, 1356 (Fed. Cir. 2002).

whole, and the university research community in particular.”¹⁶⁰ In fact, university research funds are generally separate from, and much greater than, technology transfer income.¹⁶¹ Furthermore, there is no indication that the research money will decrease due to the Supreme Court’s broad interpretation of § 271(e).¹⁶²

One of the more ironic points about the Paradox of the Patent Community evidenced in the *Merck* case is the fact that infringer Scripps, which argued for a broad fair use interpretation of § 271(e) in its defense, made the exact opposite argument about the same statutory provision in another case where Scripps was the owner rather than the infringer.¹⁶³ Meanwhile, Scripps may yet be on the other side again, since it became the proud owner of more patents in this area during the period of infringement.¹⁶⁴

Thus, the cycle continues, thereby providing a strong economic disincentive via the Paradox of the Patent Community for anyone to actually fight for a clear fair use doctrine in patent law. Instead, universities (and other major patent owners/users) would rather continue to sue infringers of their patents as necessary¹⁶⁵ and hope that they do not get sued in turn.¹⁶⁶ This is un-

¹⁶⁰ Brief of Amici Curiae, *supra* note 157, at 2.

¹⁶¹ In 2004, the same year that universities reported \$1.385 billion of income in licensing revenue, they reported having received \$41.2 billion in research funds, sixty-seven percent of which was from the federal government. ASS’N OF UNIV. TECH. MANAGERS, *supra* note 48, at 14, 25.

¹⁶² There is not yet a clear indication of whether technology transfer revenue will decrease, either. Fallout from the decision has not yet been determined, but there have been no major alerts in the university community as of yet.

¹⁶³ See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987), *aff’d in part, rev’d in part, vacated in part*, 927 F.2d 1565 (9th Cir. 1991); see also *Scripps Clinic & Research Found. v. Baxter Travenol Labs., Inc.*, Civ. A. No. 87-140-CMW, 1988 WL 22602 (D. Del. Mar. 9, 1988).

¹⁶⁴ Inhibition of Angiogenesis in Disease States with an Anti-alpha3 Monoclonal Antibody, U.S. Patent No. 6,887,473 (filed May 19, 1998) (issued May 3, 2005); Inhibition of Angiogenesis and Tumor Growth, U.S. Patent No. 6,803,383 (filed Sept. 27, 2002) (issued Oct. 12, 2004); Methods and Compositions Useful for Modulation of Angiogenesis and Vascular Permeability Using SRC or Yes Tyrosine Kinases, U.S. Patent No. 6,685,938 (filed Dec. 22, 1999) (issued Feb. 3, 2004); Methods and Compositions Useful for Inhibition of Angiogenesis, U.S. Patent No. 6,500,924 (filed Mar. 23, 1999) (issued Dec. 31, 2002); Cyclic Adhesion Inhibitors, U.S. Patent No. 5,866,540 (filed Jan. 4, 1995) (issued Feb. 2, 1999); Methods and Compositions Useful for Inhibition of Angiogenesis, U.S. Patent No. 5,766,591 (filed Dec. 30, 1994) (issued June 16, 1998); Methods and Compositions Useful for Inhibition of Angiogenesis, U.S. Patent No. 5,753,230 (filed Mar. 18, 1994) (issued May 19, 1998).

¹⁶⁵ Infringement suits are not common practice for universities which have neither

fortunate, since public policy would be served by legal clarity.¹⁶⁷

IV

PROPOSED SOLUTIONS FOR A "FAIR" PATENT SYSTEM

Once it has been established that a clear and consistent doctrine of fair use would be a beneficial addition to United States patent law, there is the obvious practical question of how the doctrine should be implemented. A somewhat vague and infrequently applied doctrine currently exists in the common law,¹⁶⁸ and a perhaps broader but topic-specific doctrine exists in Title 35.¹⁶⁹ Judges can continue to use the common law doctrine to justify further applications, but with the strictures imposed by the Federal Circuit Court of Appeals during its 2002-2003 session,¹⁷⁰ it seems unlikely that such broadening would be upheld. Instead, it would be more prudent to seek a legislative solution, along the lines of, but separate from, the existing doctrine in 35 U.S.C. § 271(e). This Part discusses first the factors that should be weighed in consideration of such a fair use doctrine, followed by an analysis of compulsory licensing options in patent law.

A. Adopting a Statutory "Fair Use" Balancing Test in Title 35

A statutory scheme for fair use in patent law must be balanced, consistent, and, indeed, "fair." This is perhaps most easily analogized to the existing statutory doctrine of fair use in copyright law, whereby Congress set forth a non-exhaustive list of four factors to be considered in the determination of whether an in-

the economic resources nor in most cases the desire for possibly negative public relations, unless a significant amount of damages is at stake.

¹⁶⁶ Infringement suits against universities and nonprofits are also not common, although this is of course belied by the *Integra* case. There have been rumblings that the landscape might change since *Duke* unleashed the hounds.

¹⁶⁷ While it is not surprising that universities would act in their own self interest, it is surprising that they believe their best interest is to avoid fair use. As patent owners, universities often state that their mission is more focused on bringing technology to the public than on making money through technology transfer programs. See *Madey v. Duke Univ.*, 307 F.2d 1351, 1356 (Fed. Cir. 2002). Yet the arguments they made in the *Merck* amicus brief are to the contrary. Brief of Amici Curiae, *supra* note 157.

¹⁶⁸ See *supra* Parts I.C.-E.

¹⁶⁹ 35 U.S.C. § 271(e) (2000); see *supra* Parts I.D.-E.

¹⁷⁰ See *Madey*, 307 F.3d 1351; *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 125 S. Ct. 2372 (2005). Both cases are described more fully in Part I.D., *supra*.

fringement of copyright constitutes non-actionable fair use.¹⁷¹ Using the same four factors as a base point, this Part analyzes how the four factors could be applied to a test for fair use in patent law.

1. *The Purpose and Character of the Use, Including Whether Such Use is of a Commercial Nature or is for Nonprofit Educational Purposes*¹⁷²

Certainly in copyright law, this first prong of the balancing test has been interpreted with sufficient breadth to excuse some commercial infringements, while not exempting some “educational” uses.¹⁷³ For universities, the two are often intertwined, since, after all, education is a “legitimate business” of educational institutions.¹⁷⁴ In patent law, this inquiry should also include questions regarding the intent of the infringer. At one extreme, a competitor may infringe in a commercial setting to sell its own product. At the other extreme a university researcher may test the pat-

¹⁷¹ 17 U.S.C. § 107 (2000). “Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, *teaching* (including multiple copies for classroom use), *scholarship*, or *research*, is *not an infringement* of copyright.” *Id.* (emphasis added). This introduction is followed by a list of factors to be considered in determining whether the use of a work is noninfringing. *Id.*

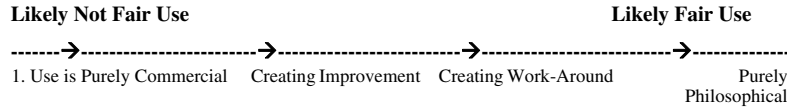
¹⁷² *Id.* § 107(1).

¹⁷³ See *Basic Books, Inc. v. Kinko’s Graphics Corp.*, 758 F. Supp. 1522, 1530-31 (S.D.N.Y. 1991) (finding that a duplication business reproducing unauthorized copies for university coursepacks was not exempt from infringement simply because of an educational purpose); *Princeton Univ. Press v. Mich. Document Servs., Inc.*, 99 F.3d 1381, 1383 (6th Cir. 1996) (holding that a copyshop’s unauthorized reproduction of copyrighted works for university coursepacks was commercial in nature). The notes of the House Judiciary Committee include the guidelines fashioned by authors, publishers, and educational institutions on fair use for educational purposes. H.R. REP. NO. 94-1476, at 67-70 (1976). As stated, the guidelines provide the minimum and not the maximum standards of educational fair use under Section 107, *id.*, but in reality they often act as limits for conservative institutions that do not wish to be sued, see, e.g., UNIV. OF CALIFORNIA, 1986 POLICY AND GUIDELINES ON THE REPRODUCTION OF COPYRIGHTED MATERIALS FOR TEACHING AND RESEARCH (1986), available at <http://www.universityofcalifornia.edu/copyright/systemwide/pgrcmtrp.html> (stating in its preamble: “‘Fair use’ is a limited exception to the exclusive use of the copyright owner, which if exceeded, can subject the one making unauthorized copies and the University to severe penalties.”).

¹⁷⁴ See *Madey*, 307 F.3d at 1356, discussed more fully in Part I.D.1., *supra*. Furthermore, universities frequently collaborate with industry partners to develop technologies. See ASS’N OF UNIV. TECH. MANAGERS, *supra* note 48, at 14 (stating that \$2.938 billion of the 2004 research funds were from industry). Therefore, while the nonprofit status of an infringer may be a consideration in determining fair use, it cannot be the only, or even necessarily the most important, factor.

ented technology simply to see if it works as claimed.¹⁷⁵ In between are situations where a researcher infringes for the purpose of creating an improvement, or even a non-infringing work-around.¹⁷⁶ This spectrum is shown visually in Diagram A.

DIAGRAM A (FACTOR 1)



2. The Nature of the (Underlying) Work¹⁷⁷

In patent law, this factor would consider the amount of time, money, and effort¹⁷⁸ that went into the patented technology. Several questions could inform this inquiry. Is the patented technology revolutionary or one improvement in a crowded field? Did the patentee invest many millions to create it? Other equitable factors that might be considered include: (1) the nature of the patentee’s business; (2) the value of the patented technology to that business (this may weigh in favor of a compulsory license or in some cases an injunction); and even (3) whether the technology is owned by an individual inventor, a small or large company, a university, or a troll.¹⁷⁹ This spectrum is shown visually in Diagram B.

¹⁷⁵ This should already be covered by the existing common law experimental use defense even as severely narrowed by recent federal circuit decisions. See, e.g., *Madey*, 307 F.3d at 1361.

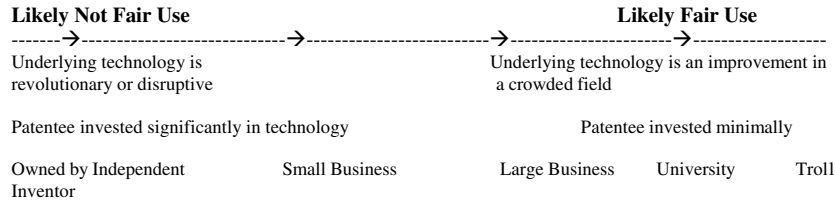
¹⁷⁶ Although some scholars have suggested that infringement for the purpose of creating improvements or work-arounds weighs against fair use, such conduct is actually socially beneficial and the results are independently patentable. See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 876 (Fed. Cir. 2003) (Newman, J., dissenting), *vacated*, 125 S. Ct. 2372 (2005).

¹⁷⁷ 17 U.S.C. § 107(2).

¹⁷⁸ Not necessarily in that order, however.

¹⁷⁹ Any consideration based on ownership would surely be controversial, yet it fits as one factor to consider in the balance, depending on the value of the invention to its owner. In fact, universities do not rely on invention income to the same extent as private companies, particularly small ones that may be based entirely around a single patent. “Trolls,” meanwhile, may rightfully claim that they rely heavily or entirely on licensing income, but many see them as less sympathetic for the reason that they did not contribute intellectually to the patents they purchase.

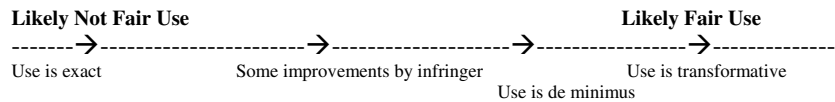
DIAGRAM B (FACTOR 2)



3. *The Amount and Substantiality of the Portion Used in Relation to the (Underlying) Work as a Whole*¹⁸⁰

ince a patented technology is typically either infringed or not infringed, but not frequently partially infringed, in patent law this factor would properly focus on the type and manner, rather than pure volume, of use. Important issues in this prong are whether the use is transformative, whether it is *de minimus*, and whether use of the patented technology is only one of a series of steps undertaken by the infringer. This factor would consider the “on” or “with” inquiry discussed by Judge Newman’s *Integra* dissent, distinguishing “between investigation *into* patented things, as has always been permitted, and investigation *using* patented things, as has never been permitted.”¹⁸¹ This spectrum is shown visually in Diagram C.

DIAGRAM C (FACTOR 3)



4. *The Effect of the Use upon the Potential Market for or Value of the (Protected) Work*¹⁸²

In copyright law, this factor is held to be the most important in many cases.¹⁸³ After all, it is inherent in intellectual property law that there must be some incentive to inventors,¹⁸⁴ and in our modern capitalist society the incentive is typically monetary. This is even truer in patent law than in copyright, since scientific

¹⁸⁰ *Id.* § 107(3).

¹⁸¹ *Integra*, 331 F.3d at 878 n.10 (Newman, J., dissenting) (emphasis added).

¹⁸² 17 U.S.C. § 107(4).

¹⁸³ See 1 STEVEN Z. SZCZEPANSKI, *ECKSTROM’S LICENSING IN FOREIGN AND DOMESTIC OPERATIONS* § 5:4 (updated by David M. Epstein 2005) (citing *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539 (1985)).

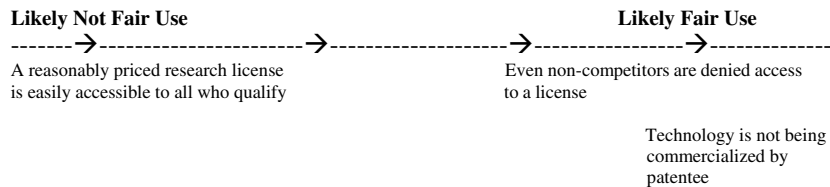
¹⁸⁴ See *supra* Part I.A. for a fuller discussion about the purposes of United States patent law.

experiments can be significantly more costly.¹⁸⁵ On the other hand, in the patent fair use scheme suggested by this Article, that consideration is already taken into account by the first three balancing factors.

In patent law, then, this factor might actually be the least important in making a determination of fair use, and would act instead as a transition to the question of compulsory licensing where fair use is not otherwise found to be appropriate. In that transitional role, this factor would consider the availability of a reasonably priced research license and whether a paid or unpaid license is more appropriate to the facts of the case, as well as considering whether the technology is being practiced by the patentee.

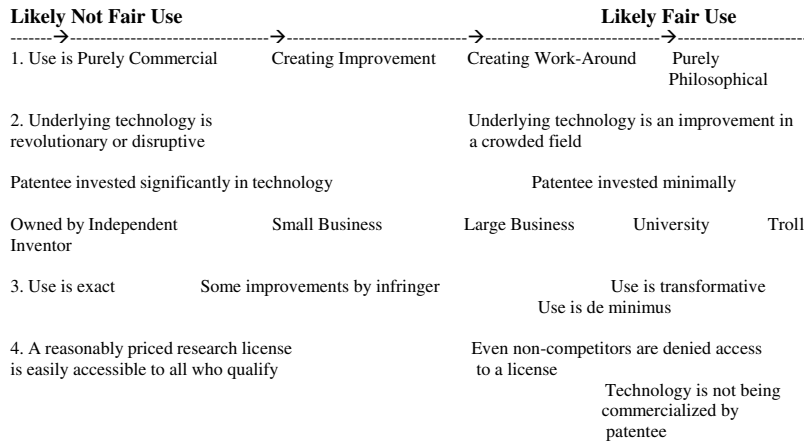
This spectrum is shown visually in Diagram D.

DIAGRAM D (FACTOR 4)



Together, the most important fair use balancing factors might look something like the spectrum shown in Diagram E.

DIAGRAM E (COMPILATION OF FACTORS)



¹⁸⁵ Although this author might like to think that a law review article can be as beneficial to society as some patented technology, generally such copyrightable projects command a lot of time and effort, but not a great deal of money.

There are many other factors that could be helpful in determining whether a particular, non-permissive use of patented technology is fair.¹⁸⁶ Most importantly, the test needs to provide sufficient clarity for a reasonable determination *ex ante*, to avoid the transaction costs of an unduly results-oriented (as compared with a more appropriate intent-oriented) approach.¹⁸⁷ If it were to move forward with a statutory doctrine, Congress should consider the varied input of technology owners and users (noting their disincentives to change due to the Paradox of the Patent Community), academics, and public interest groups, always mindful of its mission to “promote the Progress of Science and useful Arts”¹⁸⁸ as that can best be accomplished today.

B. The Value of a Compulsory License Scheme

In many cases, instead of the royalty-free license that impliedly is granted by a determination of fair use, it may be very appropriate to grant a paying, royalty-bearing compulsory license. This could be socially beneficial where a technology is not being brought to the market by the patentee or where transaction costs are very high for licensees or consumers, but where the patentee invested significantly in the patented technology. A compulsory license may also be appropriate in other situations where the fair use assessment is highly polarized in different prongs of the test (e.g., infringer is using technology purely for commercial reasons, but patentee is not otherwise commercializing it and has no plans to do so). As explored in Part IV.A., *supra*, the final factor of a statutory fair use test should transition to an inquiry into the appropriateness of a compulsory license.

Like fair use, a compulsory license scheme has precedent in

¹⁸⁶ For example, Professor O’Rourke listed a number of possible considerations, including:

- (i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the impact of the use on the patentee’s incentives and overall social welfare; and (v) the nature of the patented work.

O’Rourke, *supra* note 16, at 1205.

¹⁸⁷ It is appropriate to consider results in a damages assessment, of course, but intent must be given greater value in a fair use determination. *See, e.g.*, Grossman, *supra* note 16, at 246.

¹⁸⁸ U.S. CONST. art. I, § 8 & cl. 8.

patent law.¹⁸⁹ As one commentator notes, compulsory licensing is already accepted in various provisions of United States patent law, copyright law, Federal Trade Commission regulations, and in foreign patent schemes.¹⁹⁰ Several scholars have made persuasive arguments for compulsory licensing of biotechnology tools.¹⁹¹ This could be applied more fairly to all areas of patented technology, just as it is equally available to all copyrightable works. This is particularly important since, as discussed in Part I.E., *supra*, it is not always clear how a patented technology will be used, and much of today's most promising research is interdisciplinary.

Many patented technologies, and especially most university-owned patents, are already subject to compulsory licensing. The Bayh-Dole Act, which governs the disposition of technology resulting from federally funded research, permits government-mandated compulsory licenses in two scenarios. First, each time a university elects to pursue patent rights in a federally funded invention, it is obligated to grant a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."¹⁹² Second, the federal government maintains "march-in" rights to license or require licensing of the technology in certain scenarios.¹⁹³ At least two companies have unsuccessfully petitioned the National Institutes of Health to exercise march-in rights.¹⁹⁴ Although the government has not yet fully exercised this authority under the Bayh-Dole Act, recipients of federal research funds and their licensees are ever mindful of the possibility.¹⁹⁵

¹⁸⁹ See, e.g., Strandburg, *supra* note 16, at 140 ("Compulsory licensing has long been proposed as a solution to perceived excesses of patentee exclusivity.").

¹⁹⁰ See Freeburg, *supra* note 16, at 408-10; see also 17 U.S.C. §§ 114-115 (2000) (relating to licensing schemes in copyright law).

¹⁹¹ See Freeburg, *supra* note 16, at 408; Hoffman, *supra* note 42, at 1036-41.

¹⁹² 35 U.S.C. § 202(c)(4) (2000).

¹⁹³ *Id.* § 203.

¹⁹⁴ For further information about these petitions, see March-In Petition from Cell-Pro, Inc. to Donna E. Shalala, Secretary, Dep't Health & Human Servs. (Mar. 3, 1997), available at http://www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro1.pdf; Statement of James Love, President, Essential Inventions, Inc. on NIH Meeting on Norvir/Ritonavir March-In Request (May 25, 2004), available at <http://ott.od.nih.gov/Meeting/James-Love-Pres-Essential-Inventions-Inc.pdf>.

¹⁹⁵ In fact, several in the university community have noted that they may use this to their advantage, following the decision in *Madey v. Duke*, which left open the possibility of the federal government granting, hand-in-hand with research awards, a

Compulsory licensing schemes for patented inventions are common in other countries, particularly where there is concern that the invention is not being “worked” by the patentee.¹⁹⁶ This makes sense from a public policy perspective because innovating solely for the purpose of excluding is hardly the true purpose of patent law.¹⁹⁷ The incentive in that situation, if any, is purely to stop competition in a manner unfair to the public, which does not benefit from the invention at all, at any price or under any circumstances. Instead, a compulsory license would give a reasonable royalty to the patentee and give access to the fruits of the innovation to the public.

Consider, for example, the patent laws of Japan and Germany, two highly industrialized nations. Their laws take into account many of the issues that one would expect patentees to raise. Both countries have successfully implemented their systems for many years,¹⁹⁸ and neither country is considered anathema to creation or enforcement of patented technology.

Some of the factors that the United States may consider borrowing from these successful models include:

1. The amount of time lapsed since the filing date of the patented technology.¹⁹⁹
2. The amount of time during which the “patented invention has not been sufficiently and continuously worked.”²⁰⁰
3. A procedure for “consultations” between the patentee and the person who seeks the compulsory license.²⁰¹
4. A procedure for seeking arbitration if consultations are not successful.²⁰²

license to infringe someone else’s patented technology that was also federally funded. See *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002). This would, though, be at best a partial and imbalanced solution, for the university community and others.

¹⁹⁶ See German Patent Law, *supra* note 143, § 11; Japanese Patent Law, *supra* note 144, § 69(1).

¹⁹⁷ See *supra* Part I.A. for a fuller discussion about the purpose of United States patent law.

¹⁹⁸ See *supra* notes 143-44.

¹⁹⁹ German Patent Law, *supra* note 143, § 24(5) (after grant of the patent); Japanese Patent Law, *supra* note 144, § 83(1) (four years).

²⁰⁰ Japanese Patent Law, *supra* note 144, § 83(1) (three years).

²⁰¹ German Patent Law, *supra* note 143, § 24 (requiring that (1) “the applicant for a license has unsuccessfully endeavored during a reasonable period of time to obtain from the patentee consent to exploit the invention under reasonable conditions usual in trade;” and (2) “public interest commands the grant of a compulsory license”); Japanese Patent Law, *supra* note 144, § 83.

²⁰² Japanese Patent Law, *supra* note 144, § 83(2); see also German Patent Law, *supra* note 143, § 81(1) (allowing remedy by “legal action”).

5. Formal requirements and hearings, including, importantly, an opportunity for a patentee to submit a "legitimate reason" for not working the patented invention.²⁰³
6. Explanation of the terms of the compulsory license, including "scope," "consideration," and "method and time of payment."²⁰⁴
7. Application to conflicts and improvements.²⁰⁵

Interestingly, the proposed Patent Reform Act of 2005 shows movement toward a broader acceptance of compulsory licensing in the United States. A proposed amendment would limit a patentee's automatic right to an injunction by taking into account the patentee's use of the technology.²⁰⁶ This is akin to other countries' grant of compulsory licenses for not working the invention.²⁰⁷ Predictably acting as much against as for their interest under the paradigm of the Paradox of the Patent Community, university representatives have fought against relaxation of injunctions, even though universities probably infringe as often as they own patents, and could easily be enjoined themselves.²⁰⁸

A compulsory license scheme in United States patent law could be effectively administered by a Collective Rights Organization (CRO), as has successfully been done in copyright.²⁰⁹ In a CRO scheme, industry participants, rather than ex ante statutes

²⁰³ Japanese Patent Law, *supra* note 144, §§ 84-85.

²⁰⁴ German Patent Law, *supra* note 143, § 24(5); Japanese Patent Law, *supra* note 144, § 86(2). In Germany, "[t]he patentee shall be entitled to remuneration from the holder of a compulsory license that shall be commensurate with the circumstances and shall take into consideration the commercial value of the compulsory license." German Patent Law, *supra* note 143, § 24(5). There is also a provision for this to be adjusted as necessary over time. *Id.*

²⁰⁵ German Patent Law, *supra* note 143, § 24(2); Japanese Patent Law, *supra* note 144, §§ 72, 92(2).

²⁰⁶ Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 7 (2005) (introduced by Rep. Lamar Smith).

²⁰⁷ See, e.g., Japanese Patent Law, *supra* note 144, § 83(1).

²⁰⁸ See Goldie Blumenstyk, *University Researchers Worry as Pressure Builds in Congress to Reform the Patent System*, CHRON. HIGHER EDUC., June 16, 2005 (on file with author), available at <http://chronicle.com> ("At least one official whose institution is a leader in patenting, Carl E. Gulbrandsen, says some of the proposed changes would be 'a step backward for university patenting and commercialization efforts.'"). Mr. Gulbrandsen is absolutely right that sometimes injunctions are appropriate, but the new proposals merely would require patentees to make an adequate showing to obtain one, as with most other areas of law. Due to aggressive lobbying by universities and other large patent owners, the proposed relaxation of injunctions already seems to be a non-starter in the 2005-2006 Congress. It is, however, being considered in parallel by the Supreme Court. See discussion *supra* note 33.

²⁰⁹ See Hoffman, *supra* note 42, at 1039.

or ex post court decisions, set the licensing rates.²¹⁰ This makes the rates more likely to fit market conditions and more easily adjustable with them.²¹¹ In the case of patent law, as noted in Part III, *supra*, the Paradox of the Patent Community means that the users are the owners, but this can be a real benefit in the CRO scheme because it will act as an economic incentive to all participants. A CRO scheme could standardize the rules, rates, and situations where litigation (or preferably for most, arbitration), and even injunctions, become appropriate.

Where compulsory licensing has been applied in patent law it has met with success. As discussed by Professor Janice M. Mueller: "Some recent scholarship rejects the historically-accepted categorical assumption that compulsory licensing harms the incentives for innovation that patents represent."²¹² Indeed, the idea has already been successfully implemented in sister-copyright law, the patent laws of international economic partners, and some areas within the current United States patent law. As with fair use, there is a strong case for implementing a clear and comprehensive system for compulsory licensing in United States patent law.

V

CONCLUSION

As explored in this Article, a finding of fair use would not be appropriate in every case of patent infringement. To argue otherwise would be to decimate all incentives of the somewhat befuddled, but still highly functional, United States patent system. Sometimes a compulsory license would be more appropriate, and in some cases only an injunction will suffice to serve the needs of the patentee and public policy. A truly informed analysis of the options would require a very clear, comprehensive, and consistently applied fair use doctrine that does not exist in United States patent law today.

Copyright, which shares many other applications with patent law, provides a framework for considerations of fair use in patent law. International economic partners provide models in their

²¹⁰ See *id.* at 1039-40.

²¹¹ *Id.* at 1040.

²¹² Mueller, *supra* note 16, at 968 (citing Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 880-91 (2003)).

patent laws as well. Congress is currently considering significant amendments to the United States patent laws. In doing so, it should consider one of the most important historical principles of patent law — fair access to the patented technology. Public policy dictates that it would be highly logical for patentees and infringers alike (perhaps even more so when, like universities, they are one and the same) to have reasonable expectations of access without undue litigation and cross-allegations.

Simply put, United States patent law needs a doctrine of fair use, and Congress need only follow its own lead in copyright to make it happen.

