THE INFORMAL EXPERIMENTAL USE EXCEPTION: UNIVERSITY RESEARCH AFTER *MADEY V. DUKE UNIVERSITY*

CRISTINA WESCHLER*

A recent decision of the Federal Circuit, Madey v. Duke University, *highlights the extremely limited protection granted to universities conducting noncommercial research from claims of patent infringement. The proper scope of the experimental use exception has been hotly debated among legal scholars, with many asserting that a broad defense is necessary to allow universities to freely conduct valuable experimental science and basic research. This Note examines the structure of university research in an effort to explain why, despite any significant legal protection, it is often in the interest of patent holders to allow infringing noncommercial research to continue unchallenged. Specifically, the commercial ties that exist between universities and for-profit entities serve to protect academic noncommercial research. While providing universities with less protection than a strengthened common law or statutory defense, this nonlegal "informal" research exception performs much the same function as a recognized experimental use exception.*

INTRODUCTION

From a strictly legal standpoint, university researchers must obtain prior authorization from patent holders before using patented technology to study the accuracy of claims published in a scientific journal, to make a breakthrough discovery in cancer research, or even presumably to demonstrate to a biochemistry class the workings of a novel laboratory technique.[1] Historically, some of these uses of pat-

* B.S., 1999, Duke University; J.D., 2004, New York University School of Law. Much appreciation is owed to Kristi Hutchinson, Lindsay Traylor, Erin McCormack, and the entire staff of the *New York University Law Review* for their impeccable editing and insightful suggestions. Additional thanks go to Lawrence Lederman and Milbank Tweed for sponsoring the fellowship for which this piece was written.

[1] A United States patent grants the owner the right to exclude others from using the patented invention without regard to the nature or purpose of the use. *See* 35 U.S.C. § 154(a)(1) (2000) ("Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States . . . ."); 35 U.S.C. § 271(a) (2000) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent."). The question of what constitutes "use" of an invention rarely has arisen. However, it is widely recognized that use liability exists even when a researcher does not incorporate the patented material into a product that ultimately is sold. *E.g.*, JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 275–76 (2003) ("Nonconsensual uses of patented inventions that lead to the

ented material would have been exempted from infringement liability under the common law doctrine of experimental use: Recognizing that the law should not prevent all "uses" of a patented item, the courts, for almost two hundred years, have allowed scientists to use patented materials to satisfy philosophical inquiries, to amuse themselves, and to accomplish other noncommercial objectives.[2] However, the Federal Circuit, in *Madey v. Duke University*,[3] recently narrowed the already limited experimental use exception and made it difficult, if not impossible, for university researchers to rely on it as a defense in patent infringement suits.[4]

The decision in *Madey* has angered researchers nationwide. Some have predicted devastating consequences for university science, claiming that the decision will have a "chilling effect" on academic scientific research, "most severe[ly] . . . in biotechnology and biomedicine."[5] Others have asserted that the decision will hasten the move to conduct research and development overseas in order to take advantage of less strenuous patent laws.[6] If critics are right, and the narrow definition of the experimental use defense makes it more difficult for university researchers to continue to research and develop new technologies, the consequences for future advancement in science and medicine, as well as for the economy in general, could be immense. In 2000, American "[u]niversities spent more than $30 billion on scientific research and development,"[7] a large portion of which

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development of other products may result in patent infringement liability, even though sales of these products do not involve a making or selling of the patented invention itself.").

[2] *See infra* notes 12–16 and accompanying text.

[3] 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (2003).

[4] *Id.* at 1362.

[5] Brief for Association of American Medical Colleges, et al., as *Amici Curiae* in Support of Petitioner at 14, Duke Univ. v. Madey, 123 S. Ct. 2639 (2003) (No. 02-1007); *see also id.* (expressing "grave[ ] concern[ ]" that *Madey* will "encourage patent holders to assert claims in a manner that will impede or altogether frustrate university scientists' ability to make further basic advances in critical areas of biotechnology and biomedicine"); David Malakoff, *Universities Ask Supreme Court to Reverse Patent Ruling*, 299 SCI. 26, 27 (2003) (reporting concern of academics that *Madey* will have "disastrous" implications for university science).

[6] *See* Malakoff, *supra* note 5, at 26 (noting opinion that "cutting-edge research" will move to Asia if *Madey* stands); Stephen B. Maebius & Harold C. Wegner, *Ruling on Research Exemption Roils Universities*, NAT'L L.J., Dec. 16, 2002, at C3; *see also infra* note 11 and accompanying text.

[7] Brief for Association of American Medical Colleges, et al., as *Amici Curiae* in Support of Petitioner at 2, *Madey* (No. 02-1007).

was devoted to basic research[8] that is more valuable to society than more commercially oriented "applied" research.[9]

Despite the dire predictions regarding *Madey*'s implications, it appears that university research thus far has survived largely unscathed. Many university researchers continue to use patented materials without permission and are not being sued, or even questioned, by the relevant patent holders. Since universities are virtually precluded from asserting the experimental use defense by this most recent decision, why are companies not more aggressive in asserting their intellectual property rights?

The answer, this Note posits, is at least partially structural: Due to the unique working relationship that exists between universities and industry, one characterized as much by cooperation and interdependence as by competition, it is often in companies' interests to come to a working arrangement where, for example, patented materials either are licensed at extremely low rates or a blind eye is turned towards infringing behavior. The commercial relationships that exist between universities and industry thus serve to protect the noncommercial research undertaken by universities in much the same way as a formal experimental use exception would. Many other factors also contribute to making it beneficial for companies to refrain from suing universities for patent infringement, including the desire to maintain a positive public image, the difficulties of detecting infringing behavior, and the small amount of expected damages.

Thus far, legal scholarship in this area has focused on the proper scope of the experimental use exception. This Note instead focuses on how a nonlegal solution can address the failure of the legal system to provide adequate protection for university research. While imperfect, the existence of this informal experimental use exception allows universities to use patented technologies more liberally than what the legal exemption, narrowly interpreted by courts, would suggest.

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[8] "'[B]asic research' . . . refer[s] to 'pure' research directed solely toward expanding human knowledge, as opposed to 'applied' research directed toward solving practical problems," often with more immediate commercial implications. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 178 n.1 (1987). However, this dichotomy may be hard to apply in some contexts, particularly in the field of biotechnology, where the boundaries between basic research and applied research are becoming blurred. *Id.* The products of biotechnology research often can be commercialized immediately, even when they have enormous implications for future research. *Id.* at 195; *see also infra* notes 42–55 and accompanying text.

[9] One study conducted in the 1970s estimated that the social rate of return on university research was twenty-eight percent. *See* Wesley M. Cohen et al., *Industry and the Academy: Uneasy Partners in the Cause of Technological Advance*, *in* CHALLENGES TO RESEARCH UNIVERSITIES 171, 174 (Roger G. Noll ed., 1998).

Part I of this Note provides an overview of the common law experimental use doctrine and assesses the implications that *Madey* has for university research. Part II describes the rationales that have been put forth in support of an experimental use defense and assesses the merits of proposed statutory amendments. Part III examines the structure of university research and posits why, despite the absence of any significant legal protection, companies tend not to assert their patent rights aggressively against university researchers. Finally, Part IV discusses the continued viability of the informal experimental use exception, as well as the problems inherent in this nonlegal solution.

I
THE "VERY NARROW AND STRICTLY LIMITED"[10] EXPERIMENTAL USE EXCEPTION

In contrast to most other industrialized countries, the United States does not recognize a statutory defense to patent infringement for nonconsensual uses of patented materials for experimental or research purposes.[11] Federal courts, however, do recognize a limited defense under a common law tradition dating back nearly two hundred years. The experimental use exception first appeared in dictum in the often-cited opinion of *Whittemore v. Cutter*,[12] in which Justice Story observed: "[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the suffi-

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[10] Madey v. Duke Univ., 307 F.3d 1351, 1361 (Fed. Cir. 2002).

[11] According to one commentator, international norms, as expressed in the Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994), strongly favor allowing infringement in circumstances where it is socially beneficial. Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1201–02 (2000) (stating that construction of TRIPS Agreement "suggests that some type of patent fair use is not only permissible but also expected"). The lack of a codified experimental use provision in the United States stands in sharp contrast to the rest of the world. Great Britain, for example, exempts from infringement liability those acts "done privately and for purposes which are not commercial" and those acts "done for experimental purposes relating to the subject-matter of the invention." Patents Act, 1977, § 60(5)(a), (b) (Eng.). Germany's patent laws state that the "effects of the patent shall not extend to . . . acts done for experimental purposes relating to the subject matter of the patented invention." Patentgesetz [Patent Act] § 11.2, v. 16.12.1980 (BGBl. I S.4) (F.R.G.), *translated in* BUSINESS TRANSACTIONS IN GERMANY app. 11-8, 11-9 (Bernd Rüster et al. eds., 2004). Japan's laws similarly affirm that "[t]he effects of the patent right shall not extend to the working of the patented invention for the purpose of experiment or research." Tokkyoho [Patent Law], Law No. 121 of 1959, art. 69 (Japan), *translated in* 6 LAW BULLETIN SERIES: JAPAN SA-A 60 (1994).

[12] 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

ciency of the machine to produce its described effects."[13] Later, in *Sawin v. Guild*,[14] Justice Story clarified his view that patent infringement necessarily must involve the making of an invention with an intent to profit, thereby turning the accused infringer's commercial intent into the "hallmark of liability."[15] Future courts adopted this doctrine, such that, by 1861, the law was "well settled" that "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, [was] not an infringement of the rights of the patentee."[16]

Modern courts continue to recognize the existence of an experimental use defense, following Justice Story's line of reasoning and often refusing to apply the exemption after finding that the defendant was engaged in what was deemed to be "commercial activity."[17] The Federal Circuit reiterated this limited interpretation in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[18] Holding the exception to be "truly narrow," the court rejected a contention that the experimental use defense covered the use of a patented drug to perform tests necessary to gain regulatory approval for a generic competitor from the Food and Drug Administration.[19] Noting the profit motive

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[13] *Id.* at 1121.

[14] 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

[15] Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 20 (2001).

[16] Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

[17] *See, e.g.*, Deuterium Corp. v. United States, 19 Cl. Ct. 624, 633 (1990) (holding experimental use defense inapplicable because Department of Energy's demonstration of "economically feasible commercial application" of patented technology was not "strictly intellectual experimentation"); Pitcairn v. United States, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976) (rejecting government's contention that testing and evaluation of helicopters were experimental because they were "intended uses" and were "in keeping with the legitimate business of the using agency").

[18] 733 F.2d 858 (Fed. Cir. 1984).

[19] *Id.* at 861–63. Congress expressly overruled this portion of *Roche* with a provision of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified as amended at 35 U.S.C. § 271(e) (2000)). The Act authorizes the manufacture, use, or sale of a patented device "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." 35 U.S.C. § 271(e) (2000). This narrow exception from liability allows for nonconsensual uses of patented drugs to prepare test data necessary to gain regulatory approval from government agencies like the Food and Drug Administration. Finding such an exception to be necessary to prevent branded drugs from receiving a de facto extension to their patent terms, the Supreme Court since has interpreted § 271(e) broadly. *See* Nicholas Groombridge & Sheryl Calabro, Integra Lifesciences v. Merck—*Good for Research or Just Good for Research Tool Patent Owners?*, 22 BIOTECHNOLOGY L. REP. 462, 465 (2003) ("The express purpose of the § 271(e)(1) exception was to facilitate generic drug entry into the market by allowing companies to engage in bioequivalency and other testing prior to patent expiration."). In *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990), the Court held that § 271(e) applies to medical

behind the unauthorized use, the court stated that it could not "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry ha[d] definite, cognizable, and not insubstantial commercial purposes."[20] An experimental use had to be, in the words of the court, a "dilettante affair."[21]

Later courts, though acknowledging that "[b]inding precedent" required them to recognize a "narrow defense" when patented materials were used "'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry,'"[22] often rejected the application of the experimental use defense to the facts of a case after finding that an accused infringer used patented materials for a commercial purpose.[23] Although in formulation not considerably different than Justice Story's original construction, the "commercial purpose" test had the effect of virtually precluding any successful reliance on the defense. The few cases in which a defendant effectively has relied upon the experimental use defense involved the use of patented materials to test their applicability to a commercial process, suggesting that this is one area that might not be deemed "commercial" by the courts.[24]

Despite the difficulties involved in asserting the experimental use exemption, many researchers have believed that educational institutions should be covered by the defense.[25] It seemed as if Justice Story

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devices as well as pharmaceuticals. Most commentators agree that the common law exception for experimental use survived the enactment of § 271(e). *See, e.g.*, Mueller, *supra* note 15, at 26 (noting that legislative history of § 271(e) addresses "use" of patented inventions only for purposes of regulatory data gathering).

[20] *Roche*, 733 F.2d at 863.

[21] *Id.* The court also clarified that a "use" that does not result in a sale is still actionable. *Id.* at 861 ("[T]he patentee does not need to have *any* evidence of damage or lost sales to bring an infringement action.").

[22] Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000) (quoting *Roche*, 733 F.2d at 863).

[23] *See, e.g., id.* at 1346, 1349 (finding that defendant engaged in commercial use by using patented material in attempt to "design around" technology). Judge Rader, in her concurring opinion, stated that the experimental use defense no longer was viable. *Embrex*, 216 F.3d at 1353 (Rader, J., concurring). She described the Supreme Court as having held in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 34 (1997), that "infringement does not depend on the intent underlying the allegedly infringing conduct." *Id.*

[24] *See, e.g.*, Akro Agate Co. v. Master Marble Co., 18 F. Supp. 305, 333 (N.D. W. Va. 1937) (stating that defendant's brief use of plaintiff's patented machinery prior to embarking on commercial production was not infringement because no sale resulted); Chesterfield v. United States, 159 F. Supp. 371, 376 (Ct. Cl. 1958) (noting that defendant built device only experimentally, and neither manufacture nor sale resulted).

[25] *See, e.g.*, Ed Ergenzinger & Murray Spruill, *Basic Science in US Universities Can Infringe Patents*, SCIENTIST, Mar. 10, 2003, at 43, 43 ("Many US university officials and researchers have operated under the mistaken belief that basic science is protected by an experimental use exception to patent law."); *see also* Ronald D. Hantman, *Experimental*

had universities—generally regarded as houses of "disinterested" philosophical inquiry—in mind when he crafted his opinion in *Whittemore*. And, for a while, it appeared as if the judiciary agreed. In *Ruth v. Stearns-Roger Manufacturing Co.*,[26] the sole case to address experimental use by nonprofit educational institutions before *Madey*, a district court held that manufacturers accused of contributory infringement were entitled to rely on the experimental use defense when the end-user, the Colorado School of Mines, used the patented equipment in furtherance of its educational purpose.[27]

The Federal Circuit, however, altered this conception of the university in *Madey* when it declined to uphold a district court decision allowing Duke University to rely on the experimental use defense in a patent infringement suit.[28] In that case, Madey, a professor in Duke's physics department, held patents on some of the equipment used in the research laboratory where he served as director. After a dispute over the management of the lab caused Madey to be removed as director and subsequently resign, Duke continued to operate some of the equipment in the lab; Madey subsequently brought suit, alleging patent infringement.[29] The district court granted summary judgment for Duke, finding that Madey failed to show that Duke's use of the patent had "'definite, cognizable, and not insubstantial commercial purposes.'"[30] In holding the experimental use defense applicable, the district court stated that precedent recognized an exemption from infringement liability "where the uses were solely for research, academic, or experimental purposes."[31]

On appeal, the Federal Circuit reversed on this issue and remanded the case,[32] stating that the district court relied on an "overly

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Use as an Exception to Patent Infringement, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 633 (1985) ("Few would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function.").

26 13 F. Supp. 697 (D. Colo. 1935).

27 *Id.* at 703, 713.

28 Madey v. Duke Univ., 266 F. Supp. 2d 420 (M.D.N.C. 2001).

29 *Id.* at 421–23.

30 *Id.* at 425 (quoting Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984)). The court cited Duke's Policy on Inventions, Patents, and Technology Transfer, which states:

> Duke University is dedicated to teaching, research, and the expansion of knowledge. Although the University does not undertake research or developmental work principally for the purpose of developing patents and commercial applications, patentable inventions sometimes result from the research activities carried out wholly or in part with University funds and facilities.

Id. at 426 (emphasis omitted).

31 *Id.* at 425.

32 Madey v. Duke Univ., 307 F.3d 1351, 1361–63 (Fed. Cir. 2002).

broad conception" of the experimental use defense.[33] Experimental use, according to the Federal Circuit, is "very narrow and strictly limited."[34] The court explained:

> [R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or nonprofit status of the user is not determinative.[35]

Duke, according to the court, would not be entitled to rely on the experimental use defense if its use of the patented materials was in furtherance of its "legitimate business objectives," which it defined to include "educating and enlightening students and faculty," "increas[ing] the status of the institution and lur[ing] lucrative research grants."[36]

The decision in *Madey* has implications that far exceed the governance of patent disputes between an employer and its employee. In making the experimental use defense unavailable to an alleged infringer when the use is in furtherance of it's "legitimate business objectives" and then adopting such an expansive definition thereof, the Federal Circuit made it difficult, if not impossible, for the district court to apply the defense in favor of Duke on remand. For the same reason, the decision makes it infeasible for *any* university researcher to successfully assert experimental use as a defense to a claim of patent infringement.[37] A research project conducted at a university

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[33] *Id.* at 1361. The Federal Circuit also stated that the district court improperly placed the burden of proving the experimental use defense on the plaintiff. According to the circuit court, "The defense, if available at all, must be established by [the defendant]." *Id.*

[34] *Id.*

[35] *Id.* at 1362.

[36] *Id.* (relying on *Pitcairn v. United States*, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976), for proposition that "use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense"). The Federal Circuit remanded the case back to the district court to determine the proper application of the experimental use defense. According to the Federal Circuit, "The correct focus should not be on the nonprofit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 1363.

[37] The United States Solicitor General, however, argues that this reading, though possible, is not plausible, and that the Federal Circuit instructed the district court to consider not only Duke's "'legitimate business'" but also "'whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'" Brief for the United States as Amicus Curiae at 10, Duke Univ. v. Madey, 123 S. Ct. 2639 (2003) (No. 02-1007) (quoting Madey v. Duke Univ., 307 F.3d at 1363). According to the Solicitor General, "If engaging in the 'legitimate business' of research itself were enough to divest an institution of any experimental use defense, then there would have been no reason for

invariably will have the effect, if not the explicit purpose, of educating students or attracting research grants. Under the framework established in *Madey*, such a project cannot be protected under the experimental use exception even if it would be considered noncommercial under any other definition of the term.[38] On its face, the decision thus creates an illogical distinction between individual researchers and those working at a university, disadvantaging university employees merely because they are in the "business" of educating students.[39] Predictably, the Federal Circuit's narrow interpretation of the experimental use defense has generated enormous debate among universities and scientists, with many decrying the "chilling impact" that *Madey* will have on university research.[40]

II
THE NECESSITY OF AN EXCEPTION FOR EXPERIMENTAL USE

The experimental use defense is an exception to the otherwise absolute property rights granted to the recipient of a patent for the term of protection granted under United States law.[41] Because the defense runs counter to a fundamental premise of patent protection—that the grant of temporary monopoly power to those who discover new, useful inventions best encourages long-term innovation—its justification must be compelling. Consistent with other scholars' conclusions, this Note argues that traditional patent exclusivity should be abrogated in the face of certain noncommercial research uses. This Part begins with a discussion of justifications traditionally put forth in support of unrestricted access to materials used in particular research settings, such as the promotion of scientific progress, the effective scrutiny of research claims, and adherence to the traditional scientific ideals of cooperation and communism. It then analyzes some of the

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the court of appeals to have instructed the district court to undertake the second half of the inquiry set forth above." *Id.* at 10–11.

[38] For example, using a patented DNA sequence to replicate the work of a scientist who recently claimed to have discovered a novel use for the corresponding protein presumably would not be considered experimental use under *Madey*, though most commentators agree that this sort of research should be protected. *See infra* notes 56–57 and accompanying text.

[39] *See* Tom Saunders, Case Comment, *Renting Space on the Shoulders of Giants:* Madey *and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 265 (2003).

[40] *See supra* notes 5–6 and accompanying text.

[41] A patent holder has no obligation to use its patented technology in a socially beneficial manner or to license its invention to interested users. *See supra* note 1 and accompanying text.

proposals made by commentators for a broadened experimental use exception.

A. The Justifications for an Experimental Use Exception

There are many compelling justifications for making patented materials freely accessible to researchers in certain circumstances. Unauthorized use of patented materials can serve several socially beneficial purposes, such as facilitating new research, allowing for scrutiny of research claims, and maintaining the scientific community's historical dedication to communal ownership of research materials.

Perhaps most importantly, access to patented materials may be essential to promoting rapid scientific progress. Science is cumulative in nature, and the creation of new technologies often depends on building upon the old.[42] As intellectual property rights become increasingly fragmented, however, it becomes more difficult for researchers working on complex projects to amass the necessary authorizations from upstream patent holders. In this situation, a "tragedy of the anticommons" can arise: Multiple parties each own small pieces of property, thus allowing increased transaction costs and strategic behavior to prevent the efficient exploitation of resources.[43] This tragedy results from the proliferation of intellectual property rights upstream and ultimately can "stifl[e] life-saving innovations further downstream in the course of research and product development."[44] As the United States is currently in an era of unprecedented patent growth,[45] the risk of an anticommons suppressing scientific progress may be particularly acute. In order to counteract the problems associated with increased propertization, commentators have suggested that an expanded view of experimental use may be appropriate.[46]

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[42] *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1055–59 (1989).

[43] *See* Michael A. Heller, *The Boundaries of Private Property*, 108 YALE L.J. 1163, 1197–98 (1999) (discussing boundary between viable private property regime and tragedy of anticommons); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698–701 (1998) (describing potential problems associated with anticommons arising from concurrent licenses and stacking licenses).

[44] Heller & Eisenberg, *supra* note 43, at 698.

[45] The number of patents granted in the United States has grown from 56,860 in 1983 to over 166,000 in 2001. U.S. PATENT & TRADEMARK OFFICE, U.S. PATENT STATISTICS, CALENDAR YEARS 1963–2001 (March 2002), *available at* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf. Some of this growth can be attributed to the explosion in biotechnology patents. *See infra* note 50.

[46] *See, e.g.*, Mueller, *supra* note 15, at 42 (stating that "[a]n expanded experimental use doctrine is in keeping with the need for 'safety valves' in all areas of intellectual property

However, the inability to license patented technologies efficiently is not limited to situations where property rights are fragmented. Commentators have shown that the self-interested use of just one patent, "although lacking the encumbrances of multiple claimants . . . may also impede innovation where a technology is cumulative."[47] Often, patent holders have strategic incentives to refuse to license their inventions freely. This problem is of particular concern when it is impossible to invent around a patent to find an alternative, noninfringing approach to developing a technology. Some patent holders, in an effort to preserve the market value of their patents, might decide not to license their technologies to others who could use the patented materials to develop competing products.[48] In other instances, cognitive biases may cause patent holders to overvalue their own inventions at the same time that they undervalue those of others, thus preventing potentially efficient transactions from occurring.[49]

Nowhere are the problems described above more acute than in biotechnology and biomedical research. The past two decades have witnessed an explosion of patents in these areas, with the number of patents growing by more than 600% from 1985 to 2000.[50] Patent applications routinely are granted for "inventions" that have little immediate commercial application and tremendous implications for future downstream research. Since the early 1990s, scientists have obtained patents on anonymous gene fragments without demonstrating any knowledge of their utility or possible commercial application.[51] Without an exception for experimental use, the holder of such

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law"); *id.* at 7 (noting that "proliferation of patents on 'upstream' basic tools of biotechnological and biomedical research will stymie the development of sufficient numbers of downstream application products").

47 John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 288 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (citations omitted).

48 *See* O'Rourke, *supra* note 11, at 1237.

49 *See* Heller & Eisenberg, *supra* note 43, at 701; O'Rourke, *supra* note 11, at 1237. *See generally* Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCI. 1124 (1974) (discussing how cognitive biases affect decisionmaking).

50 The number of biotechnology patents awarded annually in the United States has grown from 2000 in 1985 to 13,000 in 2000. Walsh et al., *supra* note 47, at 293.

51 Heller & Eisenberg, *supra* note 43, at 699. In 1991, the National Institutes of Health (NIH) began patenting anonymous gene fragments with its patent applications on expressed sequence tags (ESTs). Though the NIH since has adopted "a more hostile position toward patenting ESTs," private firms continue to file applications on "newly identified DNA sequences . . . before identifying a corresponding gene, protein, biological function, or potential commercial product." *Id.*; *see also* Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1670 (2001) (explaining that European and American researchers agree that "'[t]hose who would patent DNA sequences without real knowledge of their utility are

a patent effectively controls all future innovation, both commercial (e.g., the development of a pharmaceutical) and noncommercial (e.g., researching the genes and proteins associated with the sequence) with regard to the sequence for the term of the patent.[52] Such control is diametrically opposed to traditional patent law principles,[53] and it may be particularly harmful to society when patent holders are not equipped to exploit the value of a patent fully,[54] or when it is impossible to invent around a patent.[55]

Unrestricted access to patented materials also allows the scientific community to scrutinize effectively the claims of prior researchers.[56] A "peer review" system is widely utilized in the research community so that new discoveries are tested and replicated

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staking claims not only to what little they know at present, but also to everything that might later be discovered about the genes and proteins associated with the sequence'" (quoting Bruce Alberts & Sir Aaron Klug, *The Human Genome Itself Must Be Freely Available to All Mankind*, 404 NATURE 325, 325 (2000)).

[52] Many commentators, in fact, argue that the distinction between basic and applied research in biotechnology is practically nonexistent. *See, e.g.*, Francis Narin & Dominic Olivastro, *Status Report: Linkage Between Technology and Science*, 21 RES. POL'Y 237, 248 (1992) (suggesting that link between science and technology is becoming closer over time, particularly in fields of pharmaceuticals, chemicals, computing, and communications); Walter W. Powell, *Inter-Organizational Collaboration in the Biotechnology Industry*, 152 J. INSTITUTIONAL & THEORETICAL ECON. 197, 199 (noting that "biotechnology has largely collapsed the distinction between basic and applied science").

[53] In *Brenner v. Manson*, 383 U.S. 519 (1966), the Supreme Court refused to grant a patent for a new process for making a known steroid because it did not satisfy the Patent Act's utility requirement, which mandates that patentable inventions be "new and useful," among other things, 35 U.S.C. § 101 (2000). The Court emphasized that the patent system is not designed to grant researchers control over future innovation, explaining that a patent "is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner*, 383 U.S. at 536.

[54] From a social welfare perspective, limiting access to patented material for the purpose of subsequent discovery is harmless as long as the patent holder is able to explore the material's potential contribution equally as well as other potential researchers. Walsh et al., *supra* note 47, at 290–91. There are many reasons to assume that this is not true, however. First, entities are often limited in the amount of resources they are able to devote to any one area of research, as well as in the capabilities and expertise they possess. *Id.* at 291. Second, "there is often a good deal of uncertainty about how best to build on a prior discovery," and it is often the case that subsequent innovation will be maximized when many different approaches are taken to address a given problem. *Id.*

[55] Many diseases, such as cancer and AIDS, can be attacked using "multiple approaches to the metabolic pathways." *Id.* at 323. Others, however, including cystic fibrosis, involve a single target and a single protein, such that one patent could confer exclusive rights to researching a disease. *Id.* at 323–24. "[T]he lack of substitutes for certain biomedical discoveries (such as patented genes or receptors) may increase the leverage of some patent holders, thereby aggravating holdout problems." Heller & Eisenberg, *supra* note 43, at 700.

[56] *See* Eisenberg, *supra* note 42, at 1048–55.

before they gain acceptance.[57] Requiring a scientist to obtain authorization from the researcher whose work he intends to critique poses obvious conflict-of-interest problems and can discourage the proliferation of different viewpoints. After publishing the results of a scientific study, a researcher has a clear incentive to withhold patented materials from others trying to replicate his work, particularly if the results were tampered with or inaccurate. Alternatively, a scientist could disseminate the materials selectively in an effort to ensure a favorable outcome. Thus, the ability to withhold patented materials from other researchers serves as a barrier to unrestricted evaluation of scientific theories and can result in tainted and biased scientific studies.

Finally, it has been suggested that "enforcing . . . exclusive rights in new discoveries against researchers fundamentally conflicts with traditional scientific norms calling for free dedication of new knowledge to the scientific community."[58] This view, premised on the notion that all scientific advances are cumulative, is particularly prominent among university researchers, who historically have shared information freely with their colleagues.

B. Proposals for a Broadened Experimental Use Exception

Almost all existing literature addressing the experimental use exception attempts to delineate the exception's appropriate scope. While this Note attempts to do something very different—examine the *extralegal* structures that function to protect noncommercial university research—it is nonetheless useful to address the academic commentary briefly. Besides imparting necessary background information, this examination will provide an appropriate framework for comparing the legal and extralegal approaches to the problem discussed in Part III.

The academic community is fairly unified in its support of some type of experimental use defense to patent infringement, though the appropriate scope of the defense remains a subject of intense

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[57] *See* Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q.J. 457, 470 (1989) (noting that "virtually all major scientific accomplishments are fully accepted . . . only after independent review and verification"). *But see* Eisenberg, *supra* note 42, at 1053–54 (arguing that "[c]ritical scrutiny of research claims may be far less common than the popular image of science would suggest").

[58] Eisenberg, *supra* note 42, at 1046; *see also* Robert K. Merton, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267, 273–75 (Norman W. Storer ed., 1973) (discussing "communal character of science").

debate.[59] In her pioneering article, Rebecca Eisenberg attempted to address this issue by examining whether increased innovation could be obtained in any situation by breaching the absolute rights granted to patent holders in the United States.[60] In order to do so, it was necessary for Eisenberg to examine the sometimes conflicting interests of patent holders and subsequent researchers.[61] While protecting absolute patent rights allows for more innovation ex ante, allowing subsequent researchers to use patented materials without authorization may result in more innovation over time. In analyzing these competing concerns, Eisenberg made a series of recommendations regarding the proper scope of an experimental use exception:[62] (1) use of a patent to check the "validity of the patent holder's claims . . . should be exempt from infringement liability;"[63] (2) "[r]esearch use of a patented invention with a primary or significant market among research users should not be exempt from infringement liability when the research user is an ordinary consumer of the patented invention;"[64] and (3) "[a] patent holder should not be entitled to enjoin the use of a patented invention in subsequent research in the field of the invention, which could potentially lead to improvements in the patented technology or to the development of alternative means of achieving the same purpose," though it may be appropriate "to award a reasonable royalty" to assure that "the patent holder receives an adequate return on the initial investment."[65]

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[59] *See, e.g.*, ROCHELLE COOPER DREYFUSS, VARYING THE COURSE IN PATENTING GENETIC MATERIAL: A COUNTER-PROPOSAL TO RICHARD EPSTEIN'S *STEADY COURSE* 8–11 (New York Univ. Sch. of Law Pub. Law & Legal Theory Research Paper Series No. 59, 2003) (suggesting that scientists who self-select as basic researchers should be exempt from remedy provisions of patent laws in return for agreeing to publish findings and not patent discoveries), *available at* http://ssrn.com/abstract_id=394000; *see also infra* notes 60–76 and accompanying text (describing proposals of Eisenberg, Gitter, Mueller, and O'Rourke).

[60] Eisenberg, *supra* note 42.

[61] *See id.* at 1075–78.

[62] *Id.* at 1074–78.

[63] *Id.* at 1078; *see also id.* at 1075 (noting that patent holders "should not be able to use their exclusive rights to block such scrutiny").

[64] *Id.* at 1078. According to Eisenberg, when a researcher is an "ordinary consumer" of an invention, the experimental use exception seems most likely to undermine "critical patent incentives." *Id.* at 1074. In the situation where university researchers constitute a significant market for a research tool, for example, applying the experimental use exception would leave future researchers with little incentive to develop new tools. In addition, patent holders presumably will see university researchers as potential consumers of the technology, rather than as "hostile rivals," and accordingly will want to extend licenses to all interested parties in an attempt to maximize profits. *Id.*

[65] *Id.* at 1078; *see also id.* at 1075 (noting that "conflict between the interests of the patent holder and the interests of subsequent researchers seems most intractable" in this situation).

Other scholars since have modified Eisenberg's framework, suggesting that it no longer can be assumed that research tools and other patented technologies will be available to "ordinary users" at reasonable costs.[66] Thus, Janice Mueller has suggested a broadened rule of "development use" that would permit researchers to use patented research tools without prior authorization as long as they pay an ex-post royalty based on the ultimate commercial success of the product developed through use of the material.[67] Mueller argues that this "reach-through" royalty approach would preserve incentives to develop research tools while ameliorating the restrictions and up-front costs associated with their use.[68]

Other researchers have attempted to ascertain the proper scope of an experimental use exception through comparisons to copyright law. Through its doctrine of fair use, copyright exempts from infringement uses that are socially beneficial in character. Statutorily enacted as part of the 1976 Copyright Act, the long-standing equitable doctrine of fair use[69] "was traditionally defined as 'a privilege in others than the owner of the copyright to use the copyrighted material in a reasonable manner without his consent.'"[70] Fair use ensures that socially valuable activities are not deemed to be infringing if they do not harm the copyright owner's incentives substantially and market failures would prevent the parties from bargaining for a license. Private bargaining could be frustrated, for example, when transaction costs are high (e.g., in the case of an anticommons), when positive externalities prevent the infringer from paying for a license (e.g., in the case of criticism and commentary), and when the copyright owner has incentives to refuse to grant a license at any cost (e.g., in the case of parody).[71] Maureen O'Rourke argues that many of the concerns addressed by fair use are equally applicable to patent law, and so an

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66 Mueller, *supra* note 15, at 57 (suggesting that "[t]he royalty stacking problem in biotechnology, occasioned by increasing need for patented tools that are not freely available for purchase by ordinary consumers in the marketplace, has escalated in severity since the 1989 publication of Professor Eisenberg's article").

67 *Id.* at 66. Similarly, Donna Gitter has proposed a compulsory licensing scheme where patent holders must license DNA sequences to commercial researchers in return for a royalty that would depend on the "commercial value of the product developed as a result of the research." Gitter, *supra* note 51, at 1679. As part of the reform, an experimental use exception would allow government and nonprofit researchers to "pursue research on patented DNA sequences for noncommercial purposes, free of any licensing fee and without facing liability in an infringement action." *Id.* at 1684–85 (citations omitted).

68 Mueller, *supra* note 15, at 66.

69 Pub. L. No. 94-553, § 107, 90 Stat. 2541, 2546 (codified as amended at 17 U.S.C. § 107 (2000)).

70 Harper & Row, Publishers, Inc. v. Nation Enters., 471 U.S. 539, 549 (1985) (quoting H. BALL, LAW OF COPYRIGHT AND LITERARY PROPERTY 260 (1944)).

71 *See* O'Rourke, *supra* note 11, at 1188–89.

experimental use provision could be crafted to resemble the copyright statute.[72] Furthermore, scholars urge that a scope-limiting doctrine, such as experimental use, is a necessary addendum to the broad patent rights granted under the current system—a means of assuring that patent law achieves its constitutional mandate of promoting progress in the useful arts.[73]

Even those scholars who remain opposed to codification of an experimental use defense nonetheless recognize that there is some noncommercial research that should be exempt from infringement liability.[74] Stephen Grossman, for example, notes that there may be an increasing number of instances in which conduct that is literally infringing, such as teaching or research, results in no harm to the patentee.[75] Rather than adopt a formal experimental use exception, however, he suggests that when deciding infringement cases, courts should continue to consider such equitable concerns as the infringer's intent, the economic harm to the patentee, and whether the infringement is de minimis.[76]

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[72] *See id.* at 1180–81. The model espoused by O'Rourke "emphasizes factors relevant to patent law and departs from the copyright model by authorizing courts to impose a fee on the fair user." *Id.* at 1203. The five-factor test examines:

> (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.

Id. at 1205; *see also* Mueller, *supra* note 15, at 42 ("The policies underlying the fair use doctrine of copyright law can readily support an expanded experimental use doctrine in patent law.").

[73] *See* U.S. CONST. art. I, § 8, cl. 8 (providing Congress with 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"); Mueller, *supra* note 15, at 43 ("As a means of lessening or alleviating the restrictions on research and development that have been occasioned by the patenting of research tools, an expanded experimental use doctrine would likewise promote the constitutional goal of progress in the useful (technological) arts.").

[74] *See infra* notes 70–71. *But see, e.g.*, R.E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957) (arguing that experimental use is contrary to clear and express language of patent statutes and is not good law).

[75] Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243, 263–64 (1990). According to Grossman:

> As relief flows to the patentee, and the more liberal attitude in the Patent and Trademark Office for qualifying subject matter [continues] . . . courts may soon be faced with a request for relief in what appears to be a form of infringement that has practically no effect on the incentive purpose of the patent laws to promote investment based risk, and in fact, contributed to the progress of science and the useful arts or some form of technological innovation.

Id. at 263.

[76] *See id.*

III
OPERATING IN THE SHADOW OF THE LAW: THE "INFORMAL" RESEARCH EXCEPTION

Since universities, like their for-profit counterparts, must obtain licenses to use patented material even for ostensibly "noncommercial" purposes, one would expect that universities that routinely use patented materials without permission would be sued for patent infringement. In fact, however, they are not. Instituting a patent infringement suit against a university is extremely rare.[77] This lack of litigation is particularly surprising when one considers that universities spend more than $30 billion annually on research and development, or eleven percent of the nation's total expenditures in this area.[78] How and why universities are not sued, particularly within the notoriously litigious and "balkanized" biotechnology industry,[79] is a question that has not been explored fully by legal scholars.[80] This Part attempts to explain the existence of an "informal" research exception. It first analyzes how companies effectively allow universities to use patented materials for noncommercial uses without express authorization. It then suggests why this informal arrangement exists, positing that companies rationally strive to maintain their reputation both within the biotechnology field and with the general public, in addition to struggling with practical impediments to bringing suit.

A. How the Informal Exception Functions

1. Rational Ignorance

University researchers frequently ignore intellectual property rights in conducting their research.[81] Although nearly every major research university has established a technology transfer office that develops stringent procedures for obtaining authorization to use pat-

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[77] A Westlaw search reveals only one case, excluding *Madey*, in which a university was sued directly for patent infringement: *John J. McMullen Associates v. State Board of Higher Education*, 268 F. Supp. 735 (D. Or. 1967).

[78] In 2000, the federal government paid for approximately 58% of university research and development, while industry (7%), internal funds (20%), state and local governments (7%), and nonprofit organizations (8%) financed the remaining portion. DIV. OF SCI. RES. STATISTICS, NAT'L SCI. FOUND., NATIONAL PATTERNS OF R&D RESOURCES (tbl. 1A 2002), *available at* http://www.nsf.gov/sbe/srs/nsf03313/pdf/tab1a.pdf.

[79] Gitter, *supra* note 51, at 1680–81.

[80] Note, however, that a group of sociologists briefly acknowledged the existence of such an arrangement in a recent article. *See* Walsh et al., *supra* note 47, at 317–19 (describing generally nonconfrontational relationship between universities and industry); *see also id.* at 317–18 (noting that one "major exception to this norm of leaving university researchers alone . . . is . . . clinical research based on diagnostic tests using patented technologies").

[81] *See id.* at 324.

ented materials,[82] individual researchers often ignore the established practices. According to one study, every university surveyed admitted to using patented materials without a license occasionally, and respondents thought that such infringement was "widespread."[83] Using patented materials without a license is particularly common when the technology can be replicated easily in a laboratory,[84] or when it is available through an unauthorized supplier on terms more favorable than those offered by the patent holder.[85] Companies are often disinclined to stop these practices, as confirmed by an industry insider who acknowledged that "university researchers, to the extent they are doing noncommercial work, are largely left alone."[86] In some circumstances, companies eager to discover new uses for their patents even may encourage unlicensed use of their technology.[87]

2. *Below-Market Licensing*

As an alternative to litigation, many companies allow universities to license their patented materials at radically reduced rates. For instance, some genomics firms allow university and government researchers access to their databases at a discounted cost. After completing a draft of the entire genome, for example, Celera promised to charge academic institutions very low rates for access to its full collection of genomic data, software tools, annotations, and supercomputing powers.[88] While Celera charges companies up to $15 million for these

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[82] Eyal Press & Jennifer Washburn, *The Kept University*, ATLANTIC MONTHLY, Mar. 2000, at 39, 46.

[83] Walsh et al., *supra* note 47, at 327. According to Walsh and his colleagues:

> The firms felt that much of their research would not yield commercially valuable discoveries, and thus they saw little need to spend money to secure the rights to use the input technology, particularly because it is very difficult to police such infractions. If the research looked promising, then they would get a license, if necessary.

Id.

[84] *Id.* at 324 (noting that researchers "do not feel they should be required to pay royalties" for "'do-it-yourself' technologies").

[85] *Id.* at 325 n.56 (citing university respondent who admitted to buying limited quantities of licensed peptide to benchmark experiments and remainder from unlicensed supplier for fraction of retail cost).

[86] *Id.* at 317. Walsh and his colleagues also note that "[m]any firms claim to be reluctant to enforce their patents against universities to the extent that the university is engaging in noncommercial research." *Id.* at 325.

[87] *Id.* at 317.

[88] Gitter, *supra* note 51, at 1630 n.37. Upon publishing its findings in *Science*, Celera, in compliance with the publication's policies, made the data available free of charge to both commercial and academic researchers seeking to verify, replicate, or challenge the findings. *Celera and* Science *Spell out Data Access Provisions*, 291 SCI. 1191 (2001), *available at* http://www.sciencemag.org/feature/data/announcement/gsp.shl.

services, university labs must pay only $7500 to $15,000.[89] Similarly, Incyte Genomics allows academic researchers to obtain a subscription to its Proteome Database for rates starting at $5000,[90] a price presumably much lower than for-profit institutions must pay.[91] In addition, Myriad Genetics offers academic researchers conducting projects funded by the National Institutes of Health (NIH) access to its patented breast cancer gene (BRCA1) for less than half the regular market price, netting the company no profit.[92] Other companies have begun to offer lower-priced products to entities with fewer resources, providing them with the opportunity to take advantage of patented materials, albeit on a somewhat limited basis.[93]

By offering universities and other nonprofit organizations the opportunity to participate in below-market licensing arrangements on specified terms, genomic firms are able to achieve a subtle form of price discrimination: Academic institutions and other nonprofit entities obtain the same product for significantly less than those entities engaged in commercial research or profit-oriented joint ventures.[94] This balance is achieved by requiring academic researchers to sign carefully designed license agreements that prevent them from using the patented materials at the request, or for the benefit of, a commercial entity.[95] Thus, universities, at least to the extent that they are

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89 Walsh et al., *supra* note 47, at 302.

90 Incyte Genomics, *BioKnowledge Library Subscriptions*, *at* http://proteome.incyte.com/control/researchproducts/insilico/proteome/subscriptions (last visited Sept. 8, 2004).

91 STEPHEN M. MAURER, PROMOTING AND DISSEMINATING KNOWLEDGE: THE PUBLIC/PRIVATE INTERFACE 50 (paper prepared for the U.S. National Research Council's Symposium on the Role of Scientific and Technical Data and Information in the Public Domain, Sept. 5–6, 2002) (noting price discrimination created by Incyte's licensing scheme), *available at* http://www7.nationalacademies.org/biso/PD_Maurer_pdf.pdf.

92 Tom Reynolds, *NCI-Myriad Agreement Offers BRCA Testing at Reduced Cost*, 92 J. NAT'L CANCER INST. 596, 596 (2000), *available at* http://jncicancerspectrum.oupjournals.org/cgi/content/full/jnci;92/8/596; Walsh et al., *supra* note 47, at 302.

93 For example, Incyte decided to allow users to conduct single-gene searches of its database for free, charging a nominal fee for ordering sequences or physical clones. *See* Walsh et al., *supra* note 47, at 302 (noting that this policy makes information more accessible to small users).

94 Besides reducing deadweight loss, this price discrimination helps universities access patented materials at low costs and also benefits firms that would not have been able to attract university business at prevailing market prices. *See* MAURER, *supra* note 91, at 49–51.

95 Incyte's license, for example, "prevent[s] academic researchers from using the database 'at the request or for the benefit of a commercial or for-profit entity'" and prohibits the use of the database "while participating in any collaboration that includes unlicensed members." *Id.* at 50 (quoting Incyte license). Celera's Academic License similarly "requires researchers to use the database "'solely to conduct research in the interest of and for the sole benefit of the [i]nstitution.'" *Id.* (quoting Celera Academic License).

engaged in "noncommercial" research, often are able to obtain access to patented materials at significantly reduced rates.

B. Why the Informal Exception Functions: A Structural Explanation

This Note posits that much of the explanation for the unique working arrangement described above is structural. Because of the nature of the connections between universities and industry, it is extremely costly to bring a patent infringement suit against a university. This Part explores a patent holder's incentives to bring suit, concluding that when a university is engaged in noncommercial research, it is often worthwhile for the patent holder to choose a mutually beneficial solution by, for example, allowing unauthorized use to go unchallenged or offering a license on generous terms. First, this Part will examine the collective power of universities to impose sanctions on companies that are overly aggressive in asserting their intellectual property rights. Second, it will discuss the importance of maintaining a good reputation with the consuming public. Finally, this Part will look at the practical impediments to bringing an infringement suit where the user is engaged in basic research, namely the prohibitive cost of litigation and the difficulty of detecting infringing behavior.

1. Threat of Sanction: Reputation Within the Industry

The necessity of maintaining a close working relationship with universities tempers the willingness of firms to pursue their intellectual property rights aggressively against their academic counterparts. Companies in high-technology industries are intensely dependent on university research; they rely on universities to expand their internal research capabilities, stay abreast of new developments, provide access to the highest quality scientists, and gain access to cutting-edge technologies. The existence of these commercial relationships, this Note contends, serves to protect *noncommercial* research conducted by universities from litigation. In tightly knit research communities, universities have enormous power to sanction companies that are overly aggressive in asserting their intellectual property rights. In addition, close personal ties between the two spheres may lead to less vigorous enforcement.

More than ever before, the scientific research community is closely networked. The academic literature is replete with examples of the increasing ties between academia and industry.[96] As one group

[96] *See, e.g.*, Annetine C. Gelijns & Samuel O. Their, *Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections*, 287 JAMA 72,

of commentators noted, there has been "unprecedented growth in corporate partnering and reliance on various forms of external collaboration" over the past few decades.[97] The passage of the Bayh-Dole Act in 1980[98] had an enormous influence on university-industry relations.[99] Intended by Congress to promote the widespread utilization of technologies developed with government money, the Act allows universities and other nonprofit organizations to retain the property rights to inventions developed with federal funds.[100] As the sponsors of the Act believed, granting universities ownership of patent rights has motivated them to commercialize their inventions in partnerships with financially motivated corporate actors.[101] Since passage of the Act, there has been a marked increase in licensing, as well as rapid growth in the number of cooperative research endeavors between universities and corporations.[102] According to one study conducted in 1994, more than ninety percent of life-science firms reported having some relationship with academia,[103] and that percentage presumably is even higher today.

Corporations increasingly are relying on universities to supply key innovations.[104] Employing strategies of "external innovation," firms utilize university resources to develop commercial technologies rather than rely solely on research and development conducted in their in-house laboratories.[105] As one insider notes, corporate

72 (2002) ("[M]edical innovation depends on extensive interactions between universities and industry, with knowledge and technology transfer flowing in both directions."); Press & Washburn, *supra* note 82, at 39–41 (asserting that "academic-industrial complex" puts at risk disinterested inquiry and makes universities behave like for-profit corporations).

97 Walter W. Powell et al., *Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology*, 41 ADMIN. SCI. Q. 116, 116 (1996).

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

99 *See* Walter W. Powell & Jason Owen-Smith, *Universities and the Market for Intellectual Property in the Life Sciences*, 17 J. POL'Y ANALYSIS & MGMT. 253, 255 (1998) (noting that "legislation allowed universities, nonprofit institutions, and small businesses to retain the property rights to inventions deriving from federally funded research").

100 The Act states that its purpose is "to use the patent system to promote the utilization of inventions arising from federally supported research or development." 35 U.S.C. § 200 (2000).

101 Powell & Owen-Smith, *supra* note 99, at 255–56; Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290 (2003).

102 Powell & Owen-Smith, *supra* note 99, at 256.

103 David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Study*, 334 NEW ENG. J. MED. 368, 369 (1996) (also reporting that almost sixty percent of such firms supported research conducted by academic institutions).

104 *See* Mueller, *supra* note 15, at 33–34.

105 *Id.*; Jeff Gerth & Sheryl Gay Stolberg, *Drug Makers Reap Profits on Tax-Backed Research*, N.Y. TIMES, Apr. 23, 2000, at A1 (noting that Bayh-Dole Act has allowed phar-

research has evolved from performing "significant basic research" in-house to the current model where corporations "build[ ] on the results of long-term university research" to solve "specific short-term problems."[106]

In order to secure access to cutting-edge developments, corporations must channel significant resources through university laboratories. Hundreds of universities, for example, have sponsored industry "affiliates programs," where corporate members fund a particular department or school and correspondingly receive benefits such as the ability to attend research group meetings and receive early announcements of research progress.[107] Various other arrangements are also common. Some, such as the operation of research centers or the sponsorship of undirected research through grants or fellowships, involve minimal restrictions on universities and usually do not grant companies any formal intellectual property rights.[108] Alternatively, companies can purchase individualized research projects, such as the development of specific commercial products, through directed grants and sponsored research.[109]

Cross-ties between universities and firms also can be of a personal nature. Many technology companies are populated with graduates from nearby universities. In fact, a good number of prominent biotechnology firms have emerged as university spin-offs, with former faculty members at the helm.[110] University professors also spend much time conferring with industries' top management and scientists: Faculty members are increasingly accepting positions as consul-

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maceutical companies to "shift resources away from in-house research and development and toward outside collaborations").

106 Richard C. Atkinson, *Universities: At the Center of U.S. Research*, 276 SCI. 1479, 1479 (1997).

107 MAURER, *supra* note 91, at 13, 31–32.

108 *Id.* at 13, 32–36. Industry participants provide approximately one-third of the total support costs for university campus research centers. *Id.* at 32.

109 *Id.* at 13, 34–36. Sponsored research contracts have several important drawbacks for universities. They often involve granting the sponsoring company intellectual property rights, and they may make faculty less willing to share information with their colleagues. In addition, about half of sponsored research contracts provide for some sort of publication delay, which can last up to a year. *Id.* at 13–14.

110 *See generally* UNIVERSITY SPIN-OFF COMPANIES: ECONOMIC DEVELOPMENT, FACULTY ENTREPRENEURS, AND TECHNOLOGY TRANSFER (Alistair M. Brett et al. eds., 1991) (discussing role of spin-off corporations in commercializing university technology); Susan L-J Dickinson, *Biotech Firms' Research Chiefs Balance Demands of Science and Competition*, SCIENTIST, Aug. 20, 1991, at 1, 12 (discussing experiences of academics who took management positions at biotechnology firms). University of California Professor Herbert Boyer co-founded Genentech, the nation's first successful biotechnology company, after he and a Stanford professor developed recombinant DNA technology. Karen I. Boyd, *Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 BERKELEY TECH. L.J. 311, 313–14 (1997).

tants,[111] and occasionally are even awarded equity stakes in the firms with which they work.[112]

Research- and development-intensive sectors such as biotechnology are widely considered to be the most dependent on external collaborations.[113] As the source of many of the breakthrough discoveries and techniques, universities played a critical role in the development of the industry. Many biotechnology firms were created by academic scientists who "contracted out" financial and managerial aspects of the business.[114] Consequently, these firms developed an organizational model characterized by an "open architecture," in that many of the firms' key functions are provided externally or through joint collaboration with other organizations.[115] While the commercialization of discoveries is still undertaken predominantly by biotechnology firms, universities play an important role by contributing valuable research.[116] The connections between the two spheres are so strong that one commentator notes that "[t]he cross-traffic between universities and biotech companies is so extensive and reciprocal that it is appropriate to consider them part of a *common technological community*."[117]

Nowhere are the connections between academia and industry more apparent than in locations of concentrated high-tech development. Almost without exception, these "technopoleis" have sprung up around major research universities capable of supplying a constant stream of new innovations, attracting federal funding, spinning off new companies, providing an educated workforce, and housing

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111 MAURER, *supra* note 91, at 19–20. It is estimated that approximately half of all engineering and biotechnology faculty consulted for industry in the latter half of the 1990s. *Id.* at 36.

112 *Id.* at 21. During the early 1990s, eight percent of all biotechnology faculty reportedly received an equity share from private corporations. *Id.* In addition, roughly two-thirds of universities hold equity in start-ups that sponsor research at their institutions. Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 454 (2003).

113 *See, e.g.*, Powell, *supra* note 52, at 198.

114 *Id.* at 200.

115 *Id.* Reliance on external collaboration is particularly useful in a field such as biotechnology, where the diversity and cost of relevant assets prohibit their assembly in a single organization. *See id.* (noting that in biotechnology field, "[t]he incompleteness of financing . . . encourages firms to look for external partners").

116 *Id.* at 199. Because the distinction between basic and applied science essentially has "collapsed" with biotechnology, much of the fundamental research in the biosciences immediately becomes "commercially relevant." *Id.*; *see also supra* notes 42–55 and accompanying text.

117 Powell, *supra* note 52, at 200 (emphasis added).

professors with whom firms can consult.[118] The firms' close ties to area universities have been shown to facilitate research and development and accelerate innovation. Silicon Valley, for example, owes much of its growth to its proximity to Stanford University, which provided the area with many of its companies, much of its workforce, and cutting-edge technology.[119] Termed a "network of networks" by many commentators, Silicon Valley's extensive personal contacts facilitate information exchange "so that news about people changing jobs, about new products, or about manufacturing successes and failures all are instantly common knowledge."[120] Other areas, such as Research Triangle Park in North Carolina and Route 128 in Massachusetts, share a similar pattern of industry-university maturation and codependence.[121]

Maintaining a network of connections with universities can be of the utmost importance to firms. Industry experts consider the ability to sustain connections with universities a competitive advantage, as these connections have been shown to help firms produce more patents while reducing research and development costs.[122] Evidence even suggests that firms with better collaborative opportunities may have stronger subsequent growth.[123]

The undeniable benefits that firms receive from their affiliations with academic institutions allow universities to pose a credible threat to firms that attempt to bring claims of patent infringement or enforce

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[118] *See* David V. Gibson & Raymond W. Smilor, *The Role of the Research University in Creating and Sustaining the U.S. Technopolis*, *in* UNIVERSITY SPIN-OFF COMPANIES: ECONOMIC DEVELOPMENT, FACULTY ENTREPRENEURS, AND TECHNOLOGY TRANSFER 31, 32 & fig.2.1 (Alistair M. Brett et al. eds., 1991).

[119] *See* Gibson & Smilor, *supra* note 118, at 37–38 (noting that "the rise of Stanford's prominence as an internationally recognized research university facilitated the takeoff of Silicon Valley's microelectronics industry and the other high-tech industries—such as biotechnology and telecommunications—that were to follow"); Press & Washburn, *supra* note 82, at 47.

[120] Gibson & Smilor, *supra* note 118, at 60.

[121] *See* Press & Washburn, *supra* note 82, at 47 ("The clustering of computer-engineering and biotech firms around academic-research centers in Silicon Valley; Austin, Texas; Route 128 in Massachusetts; and the Research Triangle, in North Carolina, derives in large measure from the synergy between universities and industry that Bayh-Dole has fostered."). In Austin, Texas, for example, fifty-two percent of small- to medium-sized technology-based companies reported having a direct or indirect tie to the University of Texas. Gibson & Smilor, *supra* note 118, at 55.

[122] Jason Owen-Smith & Walter W. Powell, *Knowledge Networks as Channels and Conduits: The Effects of Spillovers in the Boston Biotechnology Community*, 15 ORG. SCI. 5, 6 (2004) (citing 2002 study by George et al., but noting that 1994 study by Shan et al. found no significant effect of maintaining research and development agreements with universities).

[123] *See* Powell et al., *supra* note 97, at 133–43 (modeling effects of network connections on variables such as financing and clinical trials).

arduous licensing requirements. An overly aggressive company quickly could lose opportunities for collaboration and harm personal relationships, not only at the targeted university, but at others as well. As one technology transfer officer explained, it does not make sense for companies to sue universities as the two "scratch each others' backs."[124] A company accordingly would "become an instant pariah" if it initiated a suit against a university.[125]

This mutually dependent relationship, termed "the paradox of competition and cooperation" by two commentators,[126] leads to a degree of cooperation between universities and companies far in excess of what would exist absent this interconnection. Because firms must rely on universities to provide research and human capital in the future, their behavior today is constrained. In effect, the interdependence of the two spheres requires companies to factor into their decisions the harm done to universities, as they take a long-term view of decisions rather than looking at them as single-round games. Under traditional game theory analysis, by threatening to punish defections in later rounds, players can produce cooperative outcomes.[127] As one commentator explains:

> Partners learn to rely on one another out of mutual need and an anticipation of the benefits of continued interaction. By taking a long-term view and practicing mutual forbearance, partners overcome suspicion and the tendency to defect from a relationship when the going gets tough or the rewards look too promising to share.[128]

Some go as far as to suggest that "members of a close-knit group develop and maintain norms whose content serves to maximize the aggregate welfare that members obtain in their workaday affairs with one another."[129]

The ability of universities to sanction offensive behavior effectively is strengthened by their ability to join together. Reputation

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124 Walsh et al., *supra* note 47, at 325.

125 *Id.*

126 Gibson & Smilor, *supra* note 118, at 33.

127 *See* ROBERT C. ELLICKSON, ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES 164–66 (1991) (explaining that repeated play leads to outcomes more beneficial than in one-period games).

128 Powell, *supra* note 52, at 210. Powell and his colleagues further explain:

> Competition is no longer seen as a game with a zero-sum outcome, but as a positive-sum relationship in which new mechanisms for providing resources develop in tandem with advances in knowledge. At the core of this relationship is a vital need to access relevant knowledge: knowledge of a sort that is sophisticated and widely dispersed and not easily produced or captured inside the boundaries of a firm.

Powell et al., *supra* note 97, at 143 (citation omitted).

129 ELLICKSON, *supra* note 127, at 167.

plays a key role in choosing a partner for a joint endeavor, particularly because these arrangements are fraught with uncertainty.[130] Organizations that develop better reputations as collaborators will attract higher-quality partners, and it thus becomes valuable to maintain a strong reputation in the industry.[131] In a tightly knit community such as that formed by university scientists, news about companies' prior destructive behavior spreads quickly, and other scientists are eager to impose punishment. As Robert Ellickson explains, the spread of reputational information through gossip or a newsletter, for example, "deter[s] future uncooperative behavior by increasing an actor's estimates of the probability that informal enforcers would eventually catch up with him."[132]

The important role that close connections play in encouraging cooperative behavior perhaps best can be examined by looking at the behavior of a company upon exiting a tightly knit research community. DuPont, for example, began asserting against universities its rights to an exclusively licensed technology immediately after it stopped doing research in molecular biology.[133] Once it no longer had to rely on cooperative interactions with other molecular biologists, DuPont had "little to lose and revenue to gain when [it] sacrifice[d] the goodwill of that community."[134]

2. *Threat of Sanction: Reputation with the General Public*

Another factor that prevents companies from aggressively asserting their patent rights against universities is the necessity of maintaining a good reputation with the public.[135] Suing a university is unlikely to win a large pharmaceutical company much goodwill among consumers or government officials, regardless of the merits of the case. Even when a university is infringing a patent holder's property rights, the public may be sympathetic to its cause. As John Tehranian notes, "We have largely achieved a social consensus that the theft of material property is morally and legally wrong. However, even in the heart of capitalism, much doubt abounds as to whether the same can be said for the piracy of intellectual property."[136] The public may

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130 Powell, *supra* note 52, at 210.

131 *Id.* (noting that "[c]ollaboration becomes a process of identity construction").

132 ELLICKSON, *supra* note 127, at 232.

133 Walsh et al., *supra* note 47, at 326.

134 *Id.*

135 *See, e.g.*, *id.* at 325 ("Many firms claim to be reluctant to enforce their patents against universities to the extent that the university is engaging in noncommercial research, because of the low damage awards and bad publicity that suing a university would entail.").

136 John Tehranian, *All Rights Reserved? Reassessing Copyright and Patent Enforcement in the Digital Age*, 72 U. CIN. L. REV. 45, 60 (2003). Tehranian states that the "tenuous

view the suing firms as greedy, particularly because of the nonrivalrous nature of the intellectual property and the ease of its reproduction.[137] Guarding against a loss of reputation is particularly important for firms involved in controversial areas of research. For companies developing genetically modified foods, for example, creating a strong, trusting relationship with the public is an important precursor to the successful commercialization of their products.[138] Thus, companies will spend substantial amounts of money, and may forego otherwise beneficial litigation, in an effort to develop and maintain a positive public image.

3. *Cost-Efficiency*

In addition to the other structural rationales discussed above, practicalities deter companies from litigating infringements by university researchers. First, companies often are not aware of the violations that take place within the confines of the "ivory towers." Many patents take the form of research tools that can be manufactured without any proprietary materials, so university researchers can make these technologies in their own laboratories. Particularly when the patented technology is not incorporated into the end-product, it may be impossible for industry researchers to determine when their patent has been infringed.[139] Even if infringing behavior can be detected, companies may choose not to sue because the potential damage award is so

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nature of our national social consensus on intellectual property rights" was demonstrated in the wake of the recent anthrax scare. *Id.* Within days of the first anthrax-related death, American politicians were calling for the compulsory licensing of Cipro, the leading treatment for anthrax. That position was diametrically opposed to the one taken by the United States government in supporting "thirty-nine pharmaceutical companies in their suit against the government of South Africa for patent infringement of HIV drugs." *Id.*

137 *See id.* at 60–61.

138 In an effort to combat the growing public resistance to genetically modified organisms (GMOs), the largest biotechnology companies are investing millions of dollars in a sustained public relations campaign designed to transform the public's image of the companies and the products they sell. David Barboza, *Biotech Companies Take on Critics of Gene-Altered Food*, N.Y. TIMES, Nov. 12, 1999, at A1. The stakes in the contest for public opinion are high: Billions of dollars in investment by the biotechnology industry and American farmers, who adopted the GMOs, could be at risk if the technology does not achieve widespread acceptance. *Id.* As a result, biotechnology companies like Monsanto are taking drastic steps to cultivate a strong public image, including pledging to "'behave honorably, ethically and openly'" and contributing a significant amount of genetic data to international researchers concerned with growing rice to feed the world's poor. Justin Gillis, *Cultivating a New Image: Firms Give Away Data, Patent Rights on Crops*, WASH. POST, May 23, 2002, at E1 (quoting Hendrik A. Verfaillie, President and Chief Executive of Monsanto).

139 Walsh et al., *supra* note 47, at 324 ("[I]f research tool patents have created a minefield, they are mines with fairly insensitive triggers.").

low.[140] As one commentator explained, "An isolated use of a patented invention in purely academic research with no commercial implications might have little impact on the profitability of the patent, assuming that in the absence of an exemption the researcher would forego use of the invention rather than obtaining a license."[141] Given the high price of litigation, both monetary and reputational, companies rationally refrain from aggressively pursuing their intellectual property rights against universities in most instances.

IV
THE SUFFICIENCY OF AN "INFORMAL" RESEARCH EXCEPTION

Part III established the existence of an "informal" research exception that allows universities to use patented technologies for noncommercial research more liberally than what the legal exception, narrowly interpreted by courts and further constricted by *Madey*, would suggest. This Part looks at whether this informal solution is sufficient to protect university research from the harm predicted by many commentators after *Madey*. First, this Part will discuss the continued viability of the informal exception. After proposing many reasons to believe that the informal exception will continue to operate in the foreseeable future to protect noncommercial university research, this Part then will address the problems inherent in relying on the extralegal solution.

A. The Continued Viability of the Extralegal Solution

The informal research exception that has evolved in research and development, and particularly within the biotechnology community, can serve to counteract the failure of the legal system to provide a

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[140] Note, however, that the Patent Act permits courts to award treble damages. 35 U.S.C. § 284 (2000). Enhanced damages typically are used to punish willful infringements. MUELLER, *supra* note 1, at 330–31. However, potential damage awards against public universities have been limited by two recent Supreme Court cases, *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, 527 U.S. 627 (1999), and *College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board*, 527 U.S. 666 (1999), which held that state actors cannot be held monetarily liable for past royalties.

[141] Eisenberg, *supra* note 42, at 1035. However,

> [F]or inventions with significant markets among researchers, such as patented laboratory techniques and other research tools, exempting even purely academic researchers from the patent monopoly could deprive patent holders of a portion of the monopoly profits they might otherwise expect to earn and thereby reduce incentives to make and disclose such inventions in the future.

Id.

viable experimental use defense.[142] Extralegal solutions have been adopted successfully in other situations, particularly within tightly knit communities, when the legal regime has failed to provide a workable default solution. Because ties between companies and universities appear, if anything, to be getting stronger, these working arrangements will continue to provide a viable alternative to the legal codification of the experimental use exception.

If the experimental use exception is primarily intended to facilitate noncommercial activities—including basic research, peer review, and teaching activities—an informal exception tracks this goal closely. As discussed above, companies usually will ignore infringing behavior or enter into licensing arrangements on favorable terms when universities are acting in the domain of noncommercial research.[143] When universities are engaged in noncommercial research, the costs to a patent holder of bringing suit are most prohibitive: The costs to their reputation, both within the research community and with the general public, will be the highest; the possibility of detection is the most remote; and the resulting research may be the most valuable. When universities use unlicensed patented technologies in research that has potential commercial applications, however, a company may have a greater incentive to bring suit, as detection is easier, the likelihood of public backlash is lower, and the potential damage awards are larger.

This Note argues that the informal exception plays a role in protecting university research to a degree previously unrecognized by legal scholarship in this area. Extralegal norms often take on an importance underemphasized by legal scholars. In his influential book, *Order Without Law: How Neighbors Settle Disputes*, Robert Ellickson remarks that "[l]aw-and-economics scholars and other legal instrumentalists have tended to underappreciate the role that nonlegal systems play in achieving social order."[144] In explaining how substantive norms often supplant the laws that officially govern society, Ellickson cites numerous examples of communities that have developed their own social order absent binding law.[145] A Norwegian statute granting housekeepers entitlement to overtime pay, for example, was violated in nearly ninety percent of households studied, yet not one person instituted a lawsuit under the statute for the first

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142 The lack of a codified experimental use exception could be the result of the relative influence of pharmaceutical companies and other private organizations, as compared to that of nonprofit academic institutions, in lobbying Congress.

143 *See supra* Part III.

144 ELLICKSON, *supra* note 127, at 137–40 (explaining "legal-centralist" tradition of most legal scholars).

145 *Id.* at 141–43.

two years of its existence.[146] After investigating the cause of the housekeepers' failure to invoke legal protection, researchers found that a nonlegal mechanism—the housekeepers' power to exit the relationship—was the primary way that housekeepers controlled abuse by their employers.[147] Similarly, companies have been found to be far more generous toward their customers than is required by law,[148] presumably because they want to build goodwill that can translate into future sales. The importance of nonlegal norms also can be seen in a laboratory setting. One experiment showed that in two-person games where one person was given a higher initial monetary entitlement, the players were inclined to split equally the proceeds from a game, particularly when they knew they would play against each other multiple times.[149]

In the past, academic institutions have demonstrated their ability to evade legal rules that otherwise would prevent them from obtaining materials they regard as necessary. The fair use provisions of the Copyright Act of 1976, as interpreted by authoritative law, arguably prevent many acts of photocopying that are commonplace among teachers and professors. The Guidelines,[150] for example, impose a 2500 word limit on photocopied materials[151] and require, among other things, that photocopying occur only when it is "unreasonable to expect a timely reply to a request for permission."[152] Under these standards, a professor photocopying a long article and distributing it to her class would violate the law. In a situation directly parallel to

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146 *Id.* at 141–42.

147 *Id.*

148 *See id.* at 142 (reporting finding that "a mass retailer of household appliances in Denver was significantly more solicitous of complaining customers than the law required" and "would often refund a buyer's money without questions, even when it was not legally compelled to do so" (citing H. Laurence Ross & Neil O. Littlefield, *Complaint as a Problem-Solving Mechanism*, 12 LAW & SOC'Y REV. 199 (1978)).

149 *Id.* at 143. Expecting only to observe Pareto-superior trades, the authors of the study termed this behavior "'Lockean ethics.'" *Id.* (quoting Elizabeth Hoffman & Matthew L. Spitzer, *Entitlements, Rights, and Fairness: An Experimental Examination of Subjects' Concepts of Distributive Justice*, 28 J. LEGAL STUD. 259 (1985)).

150 The "Guidelines" are formally named the AGREEMENT ON GUIDELINES FOR CLASSROOM COPYING IN NOT-FOR-PROFIT EDUCATIONAL INSTITUTIONS WITH RESPECT TO BOOKS AND PERIODICALS, H.R. REP. NO. 94-1476, at 68–70 (1976), *reprinted in* 1976 U.S.C.C.A.N. 5659, 5681–83, and are the result of an agreement between the Ad Hoc Committee on Copyright Law Revision, the Authors League of America, Inc., and the Association of American Publishers, Inc. *See* Ann Bartow, *Educational Fair Use in Copyright: Reclaiming the Right to Photocopy Freely*, 60 U. PITT. L. REV. 149, 159–60 (1988). Though Congress specifically declined to adopt the Guidelines as binding law, courts generally have held that use of copyrighted materials meeting the Guidelines' delineated standards constitutes fair use. *Id.* at 160.

151 H.R. REP. NO. 94-1476, at 68, *reprinted in* 1976 U.S.C.C.A.N., at 5682.

152 *Id.* at 69, *reprinted in* 1976 U.S.C.C.A.N., at 5682.

the case of experimental use, however, university professors engage in "rampant unconsented photocopying" with few repercussions despite the "daunting legal backdrop."[153] Two notable cases have challenged the ability of universities to engage in photocopying for academic purposes without the permission of copyright holders—*Basic Books, Inc. v. Kinko's Graphics Corp.*[154] and *Princeton University Press v. Michigan Document Services*.[155] In both cases, copyright-holding publishers chose to sue commercial entities that indirectly engaged in infringing behavior—off-campus copy centers that compiled course packets at the direction of university professors. The professors, on the other hand, were left unscathed, presumably because they had the power to retaliate against the suing publishers by withdrawing their business.[156]

Reliance on these kinds of informal exemptions seems particularly appropriate because the ties that bind together universities and commercial entities only seem to be strengthening. A recent study analyzing interorganizational collaboration in the biotechnology industry concluded that firms increasingly are relying on external collaboration for research and development, and that organizations are becoming more adept at selecting appropriate partners based on reputation.[157] Another study predicts that "research collaboration among geographically separated institutions will become the normal way of conducting research."[158] As commentators note, given the "'diminishing role for corporate laboratories as the wellspring of innovation,'" commercial reliance on university research no doubt will increase.[159]

B. The Imperfect Solution

Although the informal research exception serves to protect noncommercial academic research in the absence of a robust legal regime, it nonetheless may be unsatisfactory in some respects. Relying on a

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153 ELLICKSON, *supra* note 127, at 260.

154 758 F. Supp. 1522 (S.D.N.Y. 1991) (holding that copy center's photocopying of copyrighted materials for use in university course packets did not constitute fair use).

155 99 F.3d 1381 (6th Cir. 1996) (holding that copy center's photocopying of copyrighted materials for use in university course packets did not constitute fair use).

156 ELLICKSON, *supra* note 127, at 263–64; *see also id.* at 264 (noting that "copy centers, because they buy few books, cannot informally retaliate against a publisher's overzealous enforcement of the Guidelines").

157 Powell et al., *supra* note 97, at 143.

158 Diana M. Hicks & J. Sylvan Katz, *Where is Science Going?*, 21 SCI. TECH. & HUM. VALUES 379, 394 (1996).

159 Powell & Owen-Smith, *supra* note 99, at 257 (quoting Richard S. Rosenbloom & William J. Spencer, *The Transformation of Industrial Research*, 12 ISSUES SCI. & TECH. 68 (1996)).

nonlegal research exception imposes costs on society and deters progress in science because it is not enforceable under the law. Companies can, and do, attempt to enforce their patent rights against universities.[160] Moreover, the mere threat of litigation, no matter how distant, can be enough to force universities into time-consuming and expensive attempts to obtain authorization before using any patented material.[161] Alternatively, researchers may decide to engage in a less valuable line of research or perform duplicative work to invent around the patent in question. The social costs associated with this de facto exception can be quite substantial; besides the additional administrative burden placed on university officials, the value of "lost" research opportunities may be incalculable and particularly devastating in the area of basic research.

In addition, companies can require university researchers to submit to onerous conditions before agreeing to license their patented materials. Most often, firms require researchers to submit to restrictions or delays in publication so they can review drafts prior to dissemination or apply for a patent.[162] Although the NIH recommends that universities allow corporate sponsors to delay publication for no longer than two months, far longer delays are common.[163] One survey, for example, found that fifty-eight percent of life-science companies sponsoring academic research required publication delays of more than six months.[164] Firms also are able to demand rights in future intellectual property developed from the patented material, even though university officials fear that this will make it more diffi-

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[160] In addition to bringing suit, companies can pursue less drastic methods of enforcement, including sending letters to a university in an attempt to stop infringing behavior. *But see* Walsh et al., *supra* note 47, at 317 (suggesting that receiving such letters is relatively uncommon and that letters are typically ignored).

[161] *Id.* at 314–17 (noting that significant number of industry participants reported delays and costs associated with research tool patents). The authors also suggest that the transaction costs associated with licensing are substantial, reporting a thirty-three percent increase in the resources devoted to the "transaction costs" of filing, enforcing, and contracting for patents between 1995 and 2000. *Id.* at 316–17.

[162] *See* MAURER, *supra* note 91, at 14; Press & Washburn, *supra* note 82, at 41–42. Over thirty-five percent of major engineering research centers told researchers that they "would allow corporate sponsors to delete information from papers prior to publication." *Id.* at 42.

[163] MAURER, *supra* note 91, at 14; REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS (1998) [hereinafter NIH REPORT], *at* http://www.nih.gov/news/researchtools/index.htm (noting that most universities will agree to delays of thirty to ninety days to permit provider of licensed material opportunity to request deletion of confidential information or to apply for patent).

[164] Press & Washburn, *supra* note 82, at 41–42 (citing 1994 survey conducted by Massachusetts General Hospital). Another survey revealed that "nearly one in five [university scientists] had delayed publication for more than six months to protect proprietary information." *Id.* at 42 (citing 1997 Journal of the American Medical Association survey).

cult to obtain future funding.[165] This practice may conflict with universities' fundamental purpose of developing science for the public benefit if industry scientists are able to assert control over the direction of future research.[166]

Arguably, legal decisions like *Madey* that establish a narrow experimental use exception help to erode this informal arrangement. Prior to *Madey*, firms may have been more cautious in enforcing their patent rights against universities because of the legal uncertainties surrounding the potential claims. Post-*Madey*, it is unlikely that any university successfully could rely on experimental use as a defense to patent infringement.[167] Besides clarifying this narrow interpretation of the experimental use exception, the *Madey* decision also focused national attention on the potential illegality of a host of common university behaviors. Industry players, newly sensitized to the fact that they can bring suit successfully against universities and other nonprofit entities, may be emboldened to do so in the future.[168]

Another factor that could limit the operation of the informal exception is the changing character of university science. As universities become more active in commercializing their research, the public may begin to see them more as commercial entities than as nonprofit institutions and consequently could put less pressure on companies to refrain from suing them.[169] Industry, too, may respond to the changing face of university research. Though firms wishing to maintain their connections with universities will be hesitant about aggres-

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[165] NIH REPORT, *supra* note 163 (reporting that "many universities fear that precommitments to license future discoveries to providers of research tools will undermine opportunities for future research funding from other firms, interfere with future technology transfer to other firms, and conflict with the university's stewardship of its inventions for the public benefit").

[166] *See, e.g.*, Press & Washburn, *supra* note 82, at 41–46, 50–51.

[167] *See supra* text accompanying notes 30–40.

[168] *See* Walsh et al., *supra* note 47, at 335 (noting that *Madey* will "sensitiz[e] both faculty and university administrations to the possible illegality of—and liability for—[unauthorized] uses of [intellectual property]," which could "chill some of the 'offending' biomedical research that is conducted in university settings").

[169] Since passage of the Bayh-Dole Act, almost every major university has established a technology transfer office, and the number of university-generated patents since has increased by approximately 2000%. Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at US Universities*, 284 JAMA 2203, 2203 (2000) (reporting that number of university patents granted has increased from approximately 250 per year in 1980 to more than 4800 in 1998); Press & Washburn, *supra* note 82, at 46 (noting recent prevalence of technology-licensing offices).

sively enforcing their legal rights, it is entirely possible that firms on the fringe of the networked community will be more litigious.[170]

The informal solution is imperfect: A codified exception undoubtedly would protect experimental research more efficiently and with more certainty than this nonlegal working arrangement. Nonetheless, at the current time, neither statutory protection nor a strong legislative movement toward statutory protection exists. And the immense political power possessed by large pharmaceutical companies makes it unlikely that a statutory change will be made in the near future. Given this political backdrop, it becomes essential to recognize the important function that this informal exception plays in protecting universities from attack when conducting experimental research. Despite the predictions of some commentators that *Madey* will have a significant "chilling effect"[171] on university research, the structural connections that serve to align interests of universities and corporations in some respects counsel that such a result is unlikely to occur. Yes, *Madey* moves the experimental use exception in the wrong direction normatively and may lead to some inefficiencies: Corporations with more bargaining power may be able to demand more restrictive publication delays, and at the margin, some may choose to move portions of their research overseas. But the system of university research will not collapse without a formal experimental use exception: Companies have far too much at stake to allow that to happen.

CONCLUSION

University research undoubtedly is becoming more applied, with corporate connections becoming increasingly frequent. While many see these commercial connections as a threat to the impartiality of university science, this Note suggests that the connections also serve to protect noncommercial university science—including basic research, peer review, and teaching activities—from litigation. Recent decisions have construed the experimental use defense so narrowly as to provide no real legal protection to universities charged with patent infringement, even with regard to noncommercial research. Thus, this extralegal solution—the informal research exception—while not without flaws, can help to protect the noncommercial university research recognized by most commentators as essential to the innovative process.

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[170] *See supra* Part III. Companies that eschew the typical model of external innovation and are able successfully to develop their own research and development capabilities will have less to lose from retaliation by universities.

[171] *See supra* note 5 and accompanying text.