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Scientific Research and the Experimental Use Privilege in Patent Law

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Summary

Congress has identified research and development (R&D) as important contributors to technological progress. The performance of R&D may have intellectual property ramifications, however. To the extent that researchers use patented inventions without authorization, they may face infringement liability. Although the courts recognize an exception to patent infringement known as the "experimental use privilege," this judicially created doctrine has been described as very narrow and rarely applied. In particular, the experimental use privilege applies only to uses done for amusement, to satisfy idle curiosity or for strictly philosophical inquiry. This doctrine does not excuse uses that are in keeping with the accused infringer's business objectives.

In 2002, the U.S. Court of Appeals for the Federal Circuit applied these principles in the case of *Madey v. Duke University*. The court held that the experimental use privilege does not apply to activities that are "in keeping with the alleged infringer's legitimate business" — even though the business of the defendant, Duke University, was nonprofit research. This ruling has raised concerns among some representatives of universities and research institutions, who fear that their basic R&D activities will subject them to patent infringement lawsuits.

Competing views have arisen over the significance of the *Madey v. Duke University* case. Some commentators believe that a limited experimental use privilege may best encourage technological advancement by rewarding successful researchers with robust patent rights. Others argue that the restricted nature of the experimental use privilege may in fact limit researcher access to state-of-the-art technologies and thus discourage further technological development. Still others assert that this issue is not of great practical importance, as few patent owners will likely file costly and time-consuming lawsuits against researchers who are not making commercially important uses of patented inventions.

The judicially created, "common law" experimental use privilege is complemented by a limited statutory experimental use privilege for patents on pharmaceuticals, medical devices, and certain other products regulated by the Food and Drug Administration. This provision, enacted as part of the 1984 Hatch-Waxman Act, applies to firms seeking to market generic equivalents of brand-name products. In addition, Congress has enacted other intellectual property legislation that incorporates provisions shielding researchers from infringement liability.

Should congressional interest continue in this area, a variety of options are available. If the current scope of the common law experimental use privilege is deemed to be appropriate, then no action need be taken. Alternatively, Congress could enact legislation confirming the limited experimental use privilege recognized in *Madey v. Duke University* and predecessor cases. Introduction of a broader form of the experimental use privilege into U.S. patent law is an additional possibility. The report will be updated if events warrant such action.

Contents

Scientific Research and the Experimental Use Privilege in Patent Law

Congress has identified research and development (R&D) as important contributors to technological advance.[1] Technological improvements are in turn acknowledged to be a driving force in the long-term economic expansion of the United States. The federal government plays a role in funding R&D in the United States, having appropriated an estimated $126 billion for federal R&D in 2004.[2] Legislation has further encouraged technical cooperation among government, academia, and the private sector during their R&D efforts.[3]

Although the issue has not commonly arisen, R&D activities may have intellectual property implications. To the extent that researchers use another's patented invention without authorization, they may face liability for patent infringement. While the courts recognize an exception to patent infringement known as the "experimental use privilege,"[4] this judicially created doctrine has been described as "very narrow"[5] and "only sparingly applied."[6] The experimental use privilege allows a researcher to use a patented invention without permission from or compensation to the patent owner. However, such a use must be "merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the [patented invention] to produce its described effects."[7] If the purpose of the research falls outside these parameters, the "common law" experimental use privilege is inapplicable, and the researcher may face liability for patent infringement.

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[1]*See* CRS Report 95-50, *The Federal Role in Technology Development*, by Wendy H. Schacht.

[2]*See* CRS Issue Brief IB10129, *Federal Research and Development Funding: FY2005*, by Michael E. Davey, coordinator.

[3]*See* CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by Wendy H. Schacht; and CRS Report RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship*, by Wendy H. Schacht.

[4]Janice M. Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools," 76 *Washington Law Review* (2001), 1.

[5]Michelle Cai, "*Madey v. Duke University*: Shattering the Myth of Universities' Experimental Use Defense," 19 *Berkeley Technology Law Journal* (2004), 175.

[6]*Douglas v. United States*, 181 U.S.P.Q. (BNA) 170, 176 (Ct. Cl. Tr. Div. 1974), *aff'd on other grounds*, 184 U.S.P.Q. (BNA) 613 (Ct. Cl. 1975).

[7]*Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C. Mass. 1813).

Congress has supplemented this "common law" experimental use privilege with a statutory research exemption to patent infringement. Introduced as part of the Hatch-Waxman Act,[8] this exemption is limited to patented pharmaceuticals, medical devices and certain other products regulated by the Food and Drug Administration ("FDA"). It exempts from patent infringement clinical studies and other activities performed in order to obtain FDA marketing approval.

Despite relatively limited judicial application of patent law's experimental use privilege, vigorous debate on the topic has persisted for many years.[9] The 2002 judicial opinion in *Madey v. Duke University* reinvigorated this discussion.[10] Here, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") rejected an experimental use defense to a patent infringement lawsuit against Duke University. The Federal Circuit held that the experimental use privilege does not apply to infringing activities that are "in keeping with the alleged infringer's legitimate business" — even though Duke University's "business" consisted of serving as a nonprofit research institution. Although the experimental use privilege was not formally eliminated in *Madey v. Duke University*, some commentators believe that this infringement exception is so limited that it is practically nonexistent.[11] This decision has in turn raised concerns among some representatives of universities and research institutions, who fear that their basic research activities will subject them to patent infringement lawsuits.[12]

Both supporters and detractors of an expansive experimental use privilege believe that this doctrine bears upon the fundamental goal of the patent system, the promotion of innovation. A more narrow exception will result in broader intellectual property rights. Robust patent rights potentially provide innovators with strong incentives to invest in research and development.[13] On the other hand, an overly restrictive experimental use exception might conceivably depress technological advancement by decreasing the ability of researchers to experiment with state-of-the-art technology.[14] Debate over the appropriate scope of the experimental use exception has been particularly vigorous with respect to patents on cell lines, assays,

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[8]*See* CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas.

[9]*See* Katherine J. Strandburg, "What Does the Public Get? Experimental Use and the Patent Bargain," 2004 *Wisconsin Law Review* 81.

[10]307 F.3d 1351 (Fed. Cir. 2002).

[11]*See* Jennifer Miller, "Sealing the Coffin on Experimental Use," 2003 *Duke Law & Technology Review* (May 7, 2003), 12.

[12]Lawrence M. Sung & Claire M. Maisano, "Piercing the Academic Veil: Disaffecting the Common Law Exception to Patent Infringement Liability and the Future of a Bona Fide Research Use Exemption After *Madey v. Duke University*," 9 *Journal of Health Care Law and Policy* (2003), 256.

[13]Jordan P. Karp, "Experimental Use as Patent Infringement: The Impropriety of a Broad Exception," 100 *Yale Law Journal* 2169 (1991).

[14]Rebecca S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 *University of Chicago Law Review* 1017 (1989).

and other "research tools" used primarily for the purpose of conducting biotechnology research.[15]

This report will explore the intellectual property laws and policies concerning the patent law's experimental use privilege. It begins with a review of patent policy and procedures. The report then discusses current statutes and judicial precedent governing the common law experimental use in patent law, as well as the potential impact of this doctrine upon innovation policy. The report next reviews the statutory experimental use privilege with respect to the Hatch-Waxman Act and other, more specialized intellectual property statutes. This report closes with a summary of congressional issues and alternatives.

Introduction to the Patent System

Patent Policy

The goal of the patent system is to promote the production and dissemination of technological information. Some observers believe that absent a patent system, individuals and firms would be less likely to engage in research and development. Without the availability of patent protection, new inventions could be easily copied by "free riders" who incurred no cost to develop and perfect the technology involved, and who would therefore be able to undersell the original inventor. The resulting inability of inventors to capitalize on their inventions would lead to an environment where too few inventions are made. By providing individuals with exclusive rights in their inventions for a limited time, the patent system allows inventors to realize the profits from their inventions.[16]

Other commentators believe that if the patent system were unavailable, individuals would maintain their inventions as trade secrets so that competitors could not exploit them. Trade secrets do not enrich the collective knowledge of society, however, nor do they discourage others from engaging in duplicative research. The patent system avoids these inefficiencies by requiring inventors to consent to the disclosure of their inventions in issued patent instruments.[17]

Additional explanations for the patent laws have been offered. The Patent Act may stimulate technological advancement by inducing individuals to "invent around" patented technology. Issued patent instruments may point the way for others to develop improvements, exploit new markets or discover new applications for the

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[15]*See, e.g.*, David C. Hoffman, "A Modest Proposal: Toward Improved Access to Biotechnology Research Tools By Implementing a Broad Experimental Use Exception," 89 *Cornell Law Review* (2004), 993.

[16]Roger E. Schechter & John R. Thomas, *Principles of Patent Law* § 1.3.1 (Thomson West 2004).

[17]*See, e.g., Grant v. Raymond*, 31 U.S. 218, 247 (1832).

patented technology.[18] Moreover, the patent system may encourage patentees to commercialize their proprietary technologies during the term of the patent. The protection provided by a patent's proprietary rights increases the likelihood a firm will continue to refine, produce and market the patented technology.[19] Finally, the patent law has been identified as a facilitator of markets. Absent patent rights, an inventor may have scant tangible assets to sell or license, and even less ability to police the conduct of a contracting party. By reducing a licensee's opportunistic possibilities, the patent system lowers transaction costs and makes technology-based transactions more feasible.[20]

The patent system has inspired numerous critics, however. Some detractors have asserted that the patent system is unnecessary due to market forces that already suffice to create an optimal level of invention. The desire to gain a lead time advantage over competitors, as well as the recognition that technologically backward firms lose out to their rivals, may well provide sufficient inducement to invent without the need for further incentives.[21] Others observe that the inventions that fueled many dynamic sectors of modern industry, such as biotechnologies and computer software, arose at a time when patent rights were unavailable or uncertain.[22]

While these justifications and criticisms have varying degrees of intuitive appeal, none of them has been empirically validated. No authoritative study conclusively demonstrates that society obtains more rapid technological development with patents than it would without them. As a result, the rationales for, and criticisms of, the patent system remain open to challenge.[23]

Patent Acquisition and Enforcement

As mandated by the Patent Act of 1952,[24] U.S. patent rights do not arise automatically. Inventors must prepare and submit applications to the U.S. Patent and Trademark Office ("USPTO") if they wish to obtain patent protection.[25] USPTO

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[18]R. Polk Wagner, "Information Wants to Be Free: Intellectual Property and the Mythology of Control," 103 *Columbia Law Review* (2003), 995.

[19]F. Scott Kieff, "Property Rights and Property Rules for Commercializing Inventions," 85 *Minnesota Law Review* (2000), 697.

[20]*See* Robert P. Merges, "Intellectual Property and the Costs of Commercial Exchange: A Review Essay," 93 *Michigan Law Review* (1995), 1570.

[21]*See* Frederic M. Scherer & David Ross, *Industrial Market Structure and Economic Performance* (Rand McNally & Co., 3d ed. 1990).

[22]*See, e.g.,* Pamela Samuelson, Benson *Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program — Related Inventions*, 39 *Emory Law Journal* (1990), 1025.

[23]CRS Report RL31951, *Innovation, Intellectual Property, and Industry Standards*, by John R. Thomas.

[24]Pub. L. No. 82-593, 66 Stat. 792 (codified at Title 35 United States Code).

[25]35 U.S.C. § 111 (2000).

officials, known as examiners, then assess whether the application merits the award of a patent.[26] The patent acquisition process is commonly known as "prosecution."[27]

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[28] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[29] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must be useful, novel and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[30] To be judged novel, the invention must not be fully anticipated by a prior patent, publication or other knowledge within the public domain.[31] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[32]

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[33] The term of the patent is ordinarily set at twenty years from the date the patent application was filed.[34] Patent title therefore provides inventors with limited periods of exclusivity in which they may practice their inventions, or license others to do so. The grant of a patent permits the inventor to receive a return on the expenditure of resources leading to the discovery, often by charging a higher price than would prevail in a competitive market.

Patent rights are not self-enforcing. A patentee bears responsibility for monitoring its competitors to determine whether they are using the patented invention or not. Patent proprietors who wish to compel others to observe their intellectual property rights must usually commence litigation in the federal district courts.[35] The U.S. Court of Appeals for the Federal Circuit possesses exclusive national jurisdiction over all patent appeals from the district courts,[36] while the U.S. Supreme

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[26]35 U.S.C. § 131 (2000).

[27]John R. Thomas, "On Preparatory Texts and Proprietary Technologies: The Place of Prosecution Histories in Patent Claim Interpretation," 47 *UCLA Law Review* (1999), 183.

[28]35 U.S.C. § 112 (2000).

[29]*Ibid.*

[30]35 U.S.C. § 101 (2000).

[31]35 U.S.C. § 102 (2000).

[32]35 U.S.C. § 103 (2000).

[33]35 U.S.C. § 271(a) (2000).

[34]35 U.S.C. § 154(a)(2) (2000).

[35]35 U.S.C. § 281 (2000).

[36]28 U.S.C. § 1295(a)(1) (2000).

Court possesses discretionary authority to review cases decided by the Federal Circuit.[37]

The Common Law Experimental Use Privilege

General Principles

Under the Patent Act of 1952, any individual who makes, uses, sells, offers to sell, or imports into the United States a patented invention without the authorization of the patent owner faces liability for infringement.[38] Although the Patent Act authorizes a number of defenses to a charge of patent infringement — such as that the patented invention does not meet the statutory standards for patentability and was improvidently awarded a patent by the USPTO[39] — the statute does not expressly authorize a generally applicable experimental use privilege. The federal courts have nonetheless developed a "common law" experimental use privilege using their judicial powers.

Judicial decisions from the nineteenth century established the scope of the experimental use privilege. In the first of these opinions, the 1813 case of *Whittemore v. Cutter*,[40] Justice Joseph Story explained that "it 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 sufficiency of the machine to produce its described effects."[41] Later, in *Sawin v. Guild*,[42] Justice Story explained that an unauthorized manufacture of a patented invention was not an infringement unless it constituted "making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification." The 1861 decision in *Peppenhausen v. Falke* further explained:

> It has been held, and no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee.[43]

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[37] 28 U.S.C. §1254(1) (2000).

[38] 35 U.S.C. § 271(a) (2000).

[39] 35 U.S.C. § 282 (2000).

[40] 29 F.Cas. 1120 (C.C.D.Mass.1813) (No. 17,600).

[41] 29 F. Cas. at 1121.

[42] 21 F. Cas. 554 (C.C.D. Mass 1813) (No. 12, 391).

[43] 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861).

This judicial conception of the experimental use privilege has been described as "crabbed,"[44] "narrowly construed"[45] and "rarely sustained."[46] As explained in numerous judicial opinions, the experimental use exception applies only to uses done for amusement, to satisfy idle curiosity or for strictly philosophical inquiry.[47] Any use that is commercial in nature is not subject to the doctrine.[48]

The opinion of the Court of Claims in *Pitcairn v. United States* provides one example of judicial views concerning the experimental use privilege.[49] In that case, the U.S. government was accused of infringing 59 patents relating to helicopters. The government contended that various aircraft used only for purposes of testing and demonstration should be held not to infringe. The court disagreed, explaining:

> Defendant urges the court to exclude from compensation any aircraft used by the defendant for testing, evaluational, demonstrational or experimental purposes. Use for such purposes is use by or for the Government and is compensable. Obviously every new helicopter must be tested for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors. Tests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency. Experimental use is not a defense in the present litigation.[50]

This language further suggests that if the use furthers the user's "legitimate business" objectives, even in a tangential way, then it is not experimental.[51]

A 2002 decision on the experimental use privilege, *Madey v. Duke University*,[52] reflects this narrow sense of the experimental use privilege. Here, Duke University recruited Dr. John M.J. Madey from Stanford University in order to serve as a research professor and director of a laser laboratory. A dispute ultimately led to Madey's resignation from Duke. After he left the university, Madey brought suit for

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[44]James Boyle, "Foreward: The Opposite of Property," *Law & Contemporary Problems* (Winter/Spring 2003), 27.

[45]Kevin Sandstrom, "How Much Do We Value Research and Development: Broadening the Experimental Use Exemption to Patent Infringement in Light of *Integra Lifesciences I Ltd. v. Merck KGaA*, 30 *William Mitchell Law Review* (2004), 1067.

[46]Rebecca S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," 97 *Yale L. J.* 177, 220 (1987).

[47]*See, e.g., Radio Corp. of America v. Andrea*, 15 F.Supp. 685, 30 USPQ 194 (E.D. N.Y. 1936), modified, 90 F.2d 612, 34 USPQ 312 (2d Cir. 1937).

[48]*See, e.g., Cimotti Unharing Co. Derboklow*, 87 F. 997, 999-1000 (C.C.E.D.N.Y. 1898).

[49]547 F.2d 1106 (Ct. Cl. 1976).

[50]547 F.2d at 1125-26.

[51]*See also, e.g., Embrex Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).

[52]307 F.3d 1351 (Fed. Cir. 2002).

infringement of two patents relating to the operation of specialized equipment used in the Duke laser laboratory.[53]

Responding to Madey's charges of patent infringement, Duke sought to take advantage of the experimental use privilege. Duke explained that it was a non-profit educational institution dedicated to teaching, research and the advancement of knowledge. Duke further argued that it does not undertake research or development work principally for the purpose of obtaining patents or designing products for the marketplace. The district court agreed that the experimental use privilege applied and ruled in favor of Duke.[54]

On appeal, the Federal Circuit reversed the district court's experimental use determination. The Court of Appeals characterized the experimental use privilege as "very narrow and strictly limited."[55] In particular, the Federal Circuit observed that the experimental use privilege "does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[56] It further explained that:

> Major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. The projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.[57]

As a result, the Federal Circuit held that the district court had resolved the case based upon an inappropriately expansive view of the experimental use privilege. It remanded the litigation back to the district court, with instructions to resolve the issue in light of the Federal Circuit's decision.[58]

Many patent law experts agree that following the *Madey v. Duke University* case, colleges, universities and other academic institutions are unlikely to be able to rely upon the common law experimental use privilege as a defense to a charge of patent infringement.[59] Co-authors Lawrence Sung, then a member of the University of Maryland Law School faculty, and attorney Claire M. Maisano explained that the "decision in *Madey* leaves grave doubt that the common law exemption to patent infringement liability can act as a safe harbor for any academic

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[53]307 F.3d at 1352-53.

[54]266 F. Supp. 2d 420 (M.D.N.C. 2001).

[55]307 F.3d at 1361.

[56]307 F.3d at 1362.

[57]*Ibid.*

[58]307 F.3d at 1362-63.

[59]*See* Tom Saunders, "Renting Space on the Shoulders of Giants: *Madey* and the Future of the Experimental Use Doctrine," 113 *Yale Law Journal* (2003), 261 (concluding that *Madey* "reformulated the experimental use doctrine and cast considerable doubt on its continued viability as a defense in patent infringement cases involving universities").

research effort."[60] Commentator Michelle Cai further opined that "practically any project conducted by a research university, even one without any commercial implications, would be in keeping with the university's legitimate business interests and hence would not qualify for the experimental use defense."[61]

Observers generally agree that *Madey v. Duke University* either retains, or perhaps restricts to an even greater degree, the quite limited nature of the common law experimental use privilege as it might be applied outside of academic settings.[62] Attorneys Paul Devinksy and Mark G. Davis concluded that the opinion is consistent with previous judicial interpretations of the common law experimental use privilege. As a result the privilege "lives on as a narrow defense to a claim of infringement."[63] Other observers would go further. Ms. Cai states, for example, that the decision "has essentially destroyed any practical meaning to the experimental use defense."[64] Attorneys Cathryn Campbell and R.V. Lupo are in accord, stating that after *Madey v. Duke University* "the Experimental Use Exception would appear to provide little, if any protection in today's world."[65]

Experimental Use and Innovation Policy

Although the experimental use privilege has been part of the patent law for many years, the *Madey v. Duke University* opinion has renewed dialogue over the propriety and scope of this infringement exemption. Proponents and detractors of a broad experimental use privilege, as well as those who do not believe the doctrine is important as a practical matter, have expressed diverse opinions. This report summarizes these competing views.

Some commentators believe that a broad experimental use privilege is inappropriate as a matter of technology policy. Under this view, a liberal experimental allowance would greatly ease the ability of competitors to "design around" the invention or develop competing technologies. Patent owners in turn would be less able to appropriate the returns of their investments in research and development, this account continues, and would therefore be discouraged from

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[60]Sung & Maisano, *supra* note 10.

[61]Cai, *supra* note 5.

[62]*See* Michael R. Taylor & Jerry Cayford, "American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change," 17 *Harvard Journal of Law & Technology* (2004), 321 ("In a recent decision, the U.S. Court of Appeals for the Federal Circuit narrowed the [common law experimental use] exemption to the point of eliminating it for practical purposes.").

[63]Paul Devinksy & Mark G. Davis, "2003 Patent Law Decisions of the Federal Circuit," 53 *American University Law Review* (2004), 773, 883.

[64]Cai, supra note 5.

[65]Cathryn Campbell & R.V. Lupo, "Exemption to Patent Infringement Under 35 U.S.C. Section 271(e)(1): Safe Harbor or Storm A-Brewing?," 5 *Sedona Conference Journal* (2004), 29.

making future investments in research and development.[66] As attorney Jordan Karp concludes: "Rather than spurring increased innovative activity, a broad experimental use exception would have just the opposite effect."[67]

For some observers, a broad experimental use privilege is inappropriate even when research takes place within an academic research setting. This is because university research is often not isolated from the private sector, but instead may have significant commercial implications.[68] As stated by two senior officers of the USPTO, the *Madey v. Duke University* decision "recognized a basic economic truth underlying research performed by large universities — it is a business, and universities derive substantial commercial value from that research."[69]

Indeed, some commentators believe that university research is increasingly likely to have commercial implications. This shift is believed to be due in part to federal legislation commonly known as the Bayh-Dole Act.[70] The Bayh-Dole Act aims to encourage the commercialization of basic research by allowing universities and small businesses to procure patents on inventions that result from federally funded research. Since the passage of the Bayh-Dole Act, many research universities have developed patent portfolios and garnered significant royalties from intellectual property licensing.[71] Because academic institutions are increasingly benefitted from the patent system, some observers reason, they should also be held accountable when they infringe the patents of others.[72]

In contrast, others believe that the common law experimental use privilege is overly narrow. They assert that the current scope of this doctrine too greatly restricts the ability of innovators to "tinker" with the developments of others.[73] Under this view, research may be chilled if scientists cannot experiment upon state-of-the-art technology free from charges of patent infringement. By limiting the tools with which researchers can work, these commentators say, the patent system could ultimately depress, rather than promote innovation.[74]

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[66]Karp, *supra* note 13.

[67]*Ibid.*

[68]Cai, *supra* note 5.

[69]Stephen G. Kunin & Linda S. Therkorn, "Workship on Future Public Policy and Ethical Issues Facing the Biotechnology Industry," 86 *Journal of the Patent and Trademark Office Society* (2004), 503.

[70]Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015.

[71]*See* Schacht, *supra* note 3.

[72]*See* Traci Dreher Quigley, "Commercialization of the State University: Why the Intellectual Property Restoration Act of 2003 Is Necessary," 152 *University of Pennsylvania Law Review* (2004), 2001.

[73]*See* Eisenberg, *supra* note 14.

[74]*See* Maureen A. O'Rourke, "Toward a Doctrine of Fair Use in Patent Law," 100 *Columbia Law Review* (2000), 1177.

Other observers believe that limiting the experimental use privilege with respect to universities and nonprofit institutes could impede academic research. Some university-based scientists believe that, unlike some of their counterparts in the private sector, academic researchers have all but ignored the patent system.[75] In order to avoid patent infringement, universities may have to devote scarce resources to perform costly patent searches and engage in licensing negotiations with patent holders. To a greater extent than profit-seeking firms, educational institutions may find that these obligations weigh heavily on their frequently tight budgets.[76]

Several legal scholars have suggested that the holding of *Madey v. Duke University* raises particular concerns with regard to patented research tools. A "research tool" is an invention, such as a particular cell line, reagent, or antibody, that is used exclusively or primarily for the purpose of conducting scientific research.[77] Some observers believe that patents are too frequently granted on research tools, particularly in biotechnology, and that such patents may impede future advancement. For example, two members of the University of Michigan Law School faculty, Michael A. Heller and Rebecca S. Eisenberg, have concluded that researchers might someday need to obtain numerous patent licenses in order to conduct basic research.[78] The costs and complications of engaging in numerous patent transactions may potentially create an "anti-commons": an environment where resources that could be committed towards further research and development are inefficiently under-utilized.[79] Under this view, the narrowly cabined experimental use privilege contemplated in *Madey v. Duke University* strengthens patents on research tools and might make research and development more difficult to accomplish.[80]

Notably, other scholars contest these theories. For example, F. Scott Kieff, a member of the law faculty of Washington University in St. Louis, asserts that this scenario is incorrect as a matter of individual incentives.[81] Rational patent holders should always encourage others to research with their technologies, Kieff explains, so as to increase the number of applications for their inventions and hence their own profits. Wesley M. Cohen, an academic at the Fuqua School of Business at Duke University, has also conducted empirical research suggesting that although the "anti-

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[75]John P. Walsh et al., "Working Through the Patent Problem," 299 *Science* 1021, 1021 (2003) ("[Research universities] have largely ignored the growing number of patents covering technology that their scientists use without license and without apology.").

[76]Miller, *supra* note 11.

[77]Natalie M. Derzko, "In Search of a Compromised Solution to the Problem Arising From Patenting Biomedical Research Tools," 20 *Santa Clara Computer & High Technology Law Journal* (2004), 347.

[78]Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 *Science* 698 (1998).

[79]*Ibid.*

[80]Strandburg, *supra* note 9.

[81]F. Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science — A Response to Rai and Eisenberg," 95 *Northwestern Law Review* (2001), 691.

commons" environment posited by Heller and Eisenberg may be theoretically possible, to date it has not actually occurred.[82]

Other commentators believe that "scientists recognize the benefits of sharing materials freely whenever possible and have developed informal norms to achieve broad dissemination of research tools."[83] For example, the National Institutes of Health ("NIH") has issued "Principles and Guidelines" in order to promote the broad use of patented research tools in biotechnology. [84] In particular, the NIH encourages patent proprietors to license their proprietary research tools in such a way as to minimize restrictions upon their use. Although the Principles and Guidelines formally apply only to recipients of federal funding, the NIH has urged the entire biotechnology community to adopt similar policies "so that all biomedical research and development can be synergistic and accelerated."[85]

Finally, a third set of commentators remain agnostic about the propriety of an experimental use privilege, but believe that this issue is not of great importance for practical reasons. Patent infringement litigation is widely regarded as costly, time-consuming and complex.[86] There may be insufficient economic justification to commence litigation against individuals who are not making commercially important uses of patented inventions. As a result, patent infringement suits may only rarely be brought against hobbyists, philosophers and noncommercial defendants, regardless of how narrowly or broadly the experimental use privilege is defined. [87]

It is also important to remember that the patent law may, in certain circumstances, provide researchers with the ability to use products even though they have been patented by others. One of these principles is known as the "exhaustion" doctrine. Under this legal rule, once a patent owner has sold a patented product, he cannot control the use of that particular product. Any patent rights in that specific physical item are said to have been "exhausted" by this initial sale. Sometimes the exhaustion principle is termed the "first sale" doctrine.[88]

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[82]J. Walsh, A. Arora and W.M. Cohen, "The Patenting and Licensing of Research Tools and Biomedical Innovation," Mimeo, National Academy of Sciences, October, 2001.

[83]Heather Hamme Ramirez, "Defending the Privatization of Research Tools: An Examination of the "Tragedy of the Anticommons" in Biotechnology Research and Development," 53 *Emory Law Journal* (2004), 362.

[84]Department of Health and Human Services, National Institutes of Health, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources," 64 Fed. Reg. 72,090 (Dec. 23, 1999).

[85]*Id.* at 72,090.

[86]*See, e.g.*, Kimberly A. Moore, "Are District Court Judges Equipped to Resolve Patent Cases?," 15 *Harvard Journal of Law and Technology* (2001), 1.

[87]Andrew J. Caruso, "The Experimental Use Exception: An Experimentalist's View," 14 *Albany Journal of Law, Science & Technology* (2003), 217.

[88]CRS Report RL32400, *Patents and Drug Importation*, by John R. Thomas.

For example, suppose that a pharmaceutical firm wished to analyze a drug that had been patented by another. That firm might wish to confirm the drug's biological activity, identify new medical indications, or compare its pharmacological profile to those of other compounds. If the firm is able simply to purchase the patented drug on the open market, then no issues of patent infringement will ordinarily arise. Any patent on the drug is exhausted once the drug has been sold, allowing the purchasing firm to use the patented drug as it wishes. The scope of the experimental use privilege is irrelevant in this scenario.[89]

On the other hand, suppose that a patented drug is not available for purchase within the market. In order to experiment with that compound, a pharmaceutical firm must synthesize it within its own laboratories. This step would be an act of patent infringement, however, because the right to make a patented invention is exclusive to the patent owner.[90] In this case the experimental use privilege would, at least theoretically, come into play as a possible defense to patent infringement.

Statutory Experimental Use Privileges

The existence, possible scope and importance of the common law experimental use privilege in patent law remains the subject of considerable debate. However, it should be noted that the Patent Act of 1952 includes a limited statutory experimental use privilege for patents on pharmaceuticals, medical devices, and certain other products regulated by the Food and Drug Administration (FDA). This provision, enacted as part of 1984 legislation known as the Hatch-Waxman Act,[91] applies to firms seeking to market generic equivalents of brand-name products. In addition, Congress has enacted other intellectual property legislation that incorporates provisions shielding researchers from infringement liability. This report considers these topics in turn.

The Hatch-Waxman Act

The Hatch-Waxman Act for the first time introduced a statutory experimental use privilege into the patent laws. This privilege applies only to certain products — notably specific kinds of pharmaceuticals and medical devices — that are regulated by the FDA. Firms must obtain FDA approval in order to market these products. Ordinarily the FDA will approve only of those products that have been proven to be safe and effective through laboratory, animal and clinical investigations.[92] Such

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[89]Edward T. Lentz, "Pharmaceutical and Biotechnology Research After *Integra* and *Madey*," 23 *Biotechnology Law Report* (2004), 265.

[90]35 U.S.C. § 271(a) (2000).

[91]Pub. L. No. 98 — 417, Title II, 98 Stat. 1585 (Sept. 28, 1984).

[92]CRS Report RL30989, *The U.S. Drug Approval Process: A Primer*, by Blanchard Randall IV.

studies can be costly and time-consuming. In some cases, the effort to obtain FDA marketing approval requires many years to complete.[93]

Many firms wish to sell drugs or medical devices that are "generic" — that is to say, equivalent to a product that was first developed and sold under a brand name by a different company. Prior to Hatch-Waxman Act, generic firms faced two notable difficulties in getting their products to market. First, generic firms ordinarily had to conduct the same sort of expensive and lengthy clinical investigations as their brand-name counterparts in order to obtain FDA marketing approval. This requirement existed even in circumstances where the generic drug was chemically identical to a brand-name drug of widely acknowledged safety and effectiveness.[94]

Second, generic firms had to account for the patents owned by their brand-name competitors. As of the early 1980's, legal uncertainty existed as to whether a generic firm could conduct clinical trials at all if a brand-name firm held patents on the drug or medical device. As part of the FDA marketing approval process, the generic firm would need to both make and use the patented drug or device — activities that under the intellectual property laws are exclusive to the patent proprietor.[95] The result was that a generic firm could be sued for patent infringement and, at least until the relevant patents expired, enjoined from engaging in the activities it needed to perform in order to satisfy FDA marketing approval requirements.

Some generic drug and medical device firms sought to rely upon the common law experimental use privilege in this situation. Their position was that activities performed in order to fulfill FDA marketing approval standards were merely experimental in nature, and as a result should be exempted from patent infringement.[96] Whether the courts would uphold this argument remained an open legal question for many years.

Eventually this issue came before the Federal Circuit, which in 1984 issued its decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[97] Here the Federal Circuit conclusively held that the common law experimental use privilege did not shield generic firms engaged in FDA marketing approval activities from charges of patent infringement. In this case, Roche Products, Inc. ("Roche") marketed a prescription sleeping pill under the trademark "Dalmane." Roche also was the proprietor of a patent claiming a chemical compound, flurazepam hcl, that was the

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[93]*See* Shashank Upadhye, "Understanding Patent Infringement Under 35 U.S.C. § 271(e)(1): The Collisions Between Patent, Medical Device, and Drug Laws," 17 *Santa Clara Computer & High Technology Law Journal* (2000), 1.

[94]*See* Janet A. Gongola, "Prescriptions for Change: The Hatch-Waxman Act and New Legislation to Increase the Availability of Generic Drugs to Consumers," 36 *Indiana Law Review* (2003), 787.

[95]35 U.S.C. § 271(a) (2000).

[96]Alfred B. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," 39 *IDEA: Journal of Law and Technology* (1999), 389.

[97]733 F.2d 858 (Fed. Cir. 1984).

active ingredient in Dalmane. Bolar Pharmaceutical Co. ("Bolar"), a manufacturer of generic drugs, grew interested in marketing a generic equivalent of Dalmane. Prior to the expiration of Roche's patent, Bolar obtained a supply of flurazepam hcl from a foreign manufacturer. It began to form the flurazepam hcl into dosage form capsules to obtain stability data, dissolution rates, bioequivalency studies and blood serum studies necessary to obtain marketing approval from the FDA.[98]

The Federal Circuit concluded Bolar's activities infringed the Roche patents, and that the experimental use defense did not apply. The Court of Appeals reasoned:

> Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the [Roche] patent. Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use de minimus. It is no trifle in its economic effect on the parties even if the quantity used is small. It is not a dilettante affair such as Justice Story envisioned. We cannot 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 has definite, cognizable, and not insubstantial commercial purposes.[99]

Congress responded to *Roche v. Bolar* by enacting the statute commonly known as the Hatch — Waxman Act. The statute introduced a number of changes to both the patent law and the food and drug law.[100] Among them was an accelerated marketing approval process for generic products.[101] In addition, the Hatch-Waxman Act created a statutory exemption from patent infringement for activities associated with regulatory marketing approval. As originally enacted and codified in 35 U.S.C. § 271(e)(1), the Hatch-Waxman Act exempted from patent infringement "uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." Through the Generic Animal Drug and Patent Term Restoration Act, which became effective on November 16, 1988, Congress extended this provision to cover regulated veterinary drugs and biological products as well.[102]

A number of significant judicial opinions have interpreted the Hatch-Waxman Act's experimental use privilege. The U.S. Supreme Court opinion in *Eli Lilly and*

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[98]733 F.2d at 860.

[99]733 F.2d at 863.

[100]*See* CRS Report RL30756, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act")*, by Wendy H. Schacht and John R. Thomas.

[101]21 U.S.C. § 355(j) (2000).

[102]Pub. L. No. 100-670, 102 Stat. 3971.

Co. v. Medtronic clarified the sorts of products that are covered by this statute.[103] In that case, Eli Lilly, which owned a patent claiming a cardiac defibrillator, filed an infringement action against Medtronic for its use of a similar device. Medtronic in turn pointed to 35 U.S.C. § 271(e)(1), arguing that Medtronic's use of the defibrillator was reasonably related to obtaining data for FDA approval. Eli Lilly in turn argued that the wording of 35 U.S.C. § 271(e)(1) — as it was at the time — only expressly referred to "drugs," not "medical devices."[104]

The Supreme Court sided with Medtronic, concluding that all of the products eligible for patent term extension under the Hatch-Waxman Act fall within the scope of the 35 U.S.C. § 271(e)(1) experimental use privilege. Justice Scalia concluded that the statutory phrase "a Federal law which regulates the manufacture, use, or sale of drugs" meant the entirety of the Food, Drug and Cosmetic Act, which regulates drugs but also covers medical devices and other products. As a result of the *Eli Lilly and Co. v. Medtronic* holding, 35 U.S.C. § 271(e)(1) extends to a range of subject matter, including pharmaceuticals, medical devices, food additives, color additives, and biological products. A generic firm may therefore use these products during the term of another's patent without fear of infringement liability, as long as the use is reasonably related to obtaining data for FDA approval.[105]

Other noteworthy judicial opinions have considered the nature of the activities that are exempted by the Hatch-Waxman Act privilege. The leading decision in *Intermedics, Inc. v. Ventritex, Inc.* interpreted the statutory exemption generously.[106] According to the *Intermedics* decision, "[w]here it would have been reasonable, objectively, for an accused infringer to believe that there was a decent prospect that the use in question would contribute (relatively directly) to the generation of information that was likely to be relevant in the processes by which the FDA would decide to approve the product,"[107] then the court should apply the 35 U.S.C. § 271(e)(1) infringement exemption. Following *Intermedics*, a number of other decisions have found that the accused infringer's activities fall within the statutory experimental use exemption.[108]

The Hatch-Waxman experimental use privilege is not without limit, however. A 2003 Federal Circuit decision, *Integra Lifesciences, I, Ltd. v. Merck*,[109] held that the 35 U.S.C. § 271(e)(1) experimental use exemption did not apply under the facts before the court. Here, Integra sued Merck for infringement of several patents

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[103]496 U.S. 661 (1990).

[104]496 U.S. at 665-66.

[105]*See* Patricia Nussle, "*Eli Lilly & Co. v. Medtronic Inc.*: A Case of Statutory Interpretation," 54 *Ohio State Law Journal* (1992), 645.

[106]775 F.Supp. 1269 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed.Cir.1993).

[107]775 F. Supp. at 1280.

[108]*See, e.g., Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997); *Glaxo, Inc. v. Novopharm, Ltd.*,110 F.3d 1562 (Fed. Cir.1997); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F.Supp.2d 104 (D. Mass.1998).

[109]331 F.3d 860 (Fed. Cir. 2003).

relating to compounds thought to eliminate tumor growth and for treating a variety of other diseases. In turn, Merck asserted 35 U.S.C. § 271(e)(1) as a defense. The district court held that the Scripps-Merck activity did not fall under the 35 U.S.C. § 271(e)(1) exemption.[110]

The Federal Circuit affirmed the district court on appeal. The Federal Circuit observed that Merck's experiments did not supply information for submission to the FDA. Rather, Merck conducted these experiments in order to determine which of several compounds was the best drug candidate to subject to future testing.[111] The court then reasoned that such activities were not conducted "solely for purposes reasonably related to the development and submission of information under federal law," as the statutory exemption required. Rather, they were early-stage, exploratory experiments performed merely to identify promising pharmaceutical compounds.[112] The *Integra Lifesciences* decision makes clear that the 35 U.S.C. § 271(e)(1) exemption does not apply to all exploratory research, but is instead a "narrowly tailored" exemption intended to have a "*de minimis* impact on the patentee's right to exclude."[113]

Other Statutes

Although the Hatch-Waxman Act awards limited experimental use privileges with respect to patents on certain drugs, medical devices, and other products regulated by the FDA, the Patent Act of 1952 does not provide for a more broadly oriented experimental use privilege. However, Congress has enacted a number of specialized intellectual property statutes that expressly incorporate a more comprehensive experimental use doctrine. For example, the Plant Variety Protection Act allows the Department of Agriculture to issue plant variety certificates on sexually reproducible plants.[114] These certificates provide their owner with the exclusive right to "exclude others from selling the variety, or offering it for sale, or reproducing it, importing, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom."[115] The statute does include a research exemption, however, stipulating that "[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter."[116]

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[110] *Integra Lifesciences I Ltd. v. Merck KGaA*, 50 USPQ2d 1846 (S.D. Cal. 1999).

[111] 331 F.3d at 863.

[112] 331 F.3d at 866.

[113] 331 F.3d at 867.

[114] Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified at 7 U.S.C. §§ 2321-2583). *See* CRS Report RL31568, *Plants, Patents and Seed Innovation in the Agricultural Industry*, by John R. Thomas.

[115] 7 U.S.C. § 2483(a).

[116] 7 U.S.C. § 2544 (2000).

Another specialized intellectual property statute, the Semiconductor Chip Protection Act of 1984,[117] allows individuals to claim exclusive rights in "mask works" — circuitry designs used on a computer or other semiconductor chip.[118] It is an act of infringement either to reproduce these mask works, or to sell or import a semiconductor chip embodying a protected mask work.[119] However, this legislation expressly exempts those individuals who "reproduce the mask work solely for the purpose of teaching, analyzing, or evaluating the concepts or techniques embodied in the mask work or the circuitry, logic flow, or organization of components used in the mask work."[120]

A third example is provided by the Vessel Hull Design Protection Act.[121] This legislation, which allows designers of an original boat hull to register their designs with the federal government, incorporates an experimental use privilege similar to that of the Semiconductor Chip Protection Act. Under the Vessel Hull Design Protection Act, individuals who make, use, sell or import the protected design without the authorization of the registered design owner may be subject to infringement liability.[122] Yet the statute expressly exempts from infringement those uses "solely for the purpose of teaching, analyzing, or evaluating the appearance, concepts, or techniques embodied in the design, or the function of the useful article embodying the design."[123]

Legislative Issues and Alternatives

Should congressional interest continue in this area, a variety of options are available. If the current scope of the common law experimental use privilege is deemed to be appropriate, then no action need be taken. Alternatively, Congress could enact legislation confirming the narrowly cabined view of the experimental use privilege as set forth in *Madey v. Duke University* and predecessor cases.

If reform of the experimental use privilege is deemed prudent, however, another possibility is the introduction of some additional form of the experimental use privilege into the Patent Act of 1952. This infringement exemption could supplement or replace the narrow experimental use privilege introduced by the Hatch-Waxman Act. One option is to incorporate a generally applicable privilege of the sort contemplated by the proposed, but unenacted Patent Competitiveness and

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[117]Pub. L. No. 98-620, 98 Stat. 3347.

[118]17 U.S.C. § 901 (2000).

[119]17 U.S.C. § 905 (2000).

[120]17 U.S.C. § 906(a)(1) (2000). *See* Lee Hsu, "Reverse Engineering Under the Semiconductor Chip Protection Act: Complications for Standard of Infringement," 5 *Albany Law Journal of Science and Technology* (1996), 249.

[121]Pub. L. No.105-304 , 112 Stat. 2905.

[122]17 U.S.C. § 1308 (2000).

[123]17 U.S.C. § 1309(g) (2000). The Digital Millennium Copyright Act provides another example of a statutory experimental use privilege. *See* 17 U.S.C. § 1201 (2000).

Technological Innovation Act of 1990. H.R. 5598 was introduced before the 101st Congress on September 12, 1990. Section 402 of that bill provided:

> It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention.

H.R. 5598 was reported by the House Judiciary Committee on October 26, 1990. Other intellectual property statutes, including the Plant Variety Protection Act, Semiconductor Chip Protection Act, and the Vessel Hull Design Protection Act, also provide examples of the manner in which a generally applicable statutory experimental use privilege could be drafted.

A more limited statutory experimental use privilege presents another law reform option. Such a privilege might be limited to patented inventions that arise in particular technological fields, in the fashion of the proposed, but unenacted Genomic Research and Diagnostic Accessibility Act of 2002. H.R. 3967 would have exempted from patent infringement the use of genetic sequence information for purposes of research. In addition, this bill would have limited the remedies that the owner of a patent on genetic diagnostic testing could obtain during infringement litigation. Following its introduction in the 107th Congress on March 14, 2002, H.R. 3967 was referred to the Subcommittee on Courts, the Internet and Intellectual Property on May 6, 2002, but no further action was taken.

Another possibility would be to limit the experimental use privilege to patented research tools, in whatever technological field they might arise. Yet another option is to grant an experimental use privilege in favor of universities or non-profit research institutions, but retain the current law of experimental use with respect to for-profit enterprises.

Consideration of any sort of statutory reform with respect to experimental use privilege should take into account the Agreement on Trade-Related Aspects of Intellectual Property Rights.[124] The United States is a signatory to the so-called "TRIPS Agreement," which is a component of the international agreements that form the World Trade Organization (WTO). The TRIPS Agreement in part requires its signatories to grant patent owners the right to exclude others from making, using, offering for sale, selling, or importing a patented invention.[125] Further, under Article 27 of the TRIPS Agreement, such rights must be "enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

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[124]Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994) ("TRIPS Agreement").

[125]TRIPS Agreement, Article 27(1).

The TRIPS Agreement does allow member states to limit patent rights under certain circumstances, however. As stated in Article 30 of the TRIPS Agreement:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 30 presumably allows its signatories to provide for a generally applicable experimental use privilege. Many WTO members, including Germany,[126] Japan[127] and the United Kingdom,[128] already incorporate such a privilege into their patent statutes. However, a more limited form of the experimental use privilege may raise concerns under the non-discrimination provision of Article 27. To the extent that the experimental use privilege is available for some sorts of inventions and not others, it may conflict with the Article 27 obligation not to discriminate as to the "field of technology" in which a patentable invention arises.[129]

Finally, the experimental use privilege need not be an all-or-nothing proposition. Another option is to grant researchers the ability to experiment with the patented inventions of others — provided they compensate the patent holder at a specified royalty rate. This regime would effectively amount to a "compulsory license" available to researchers.[130] Janice Mueller, a member of the faculty of the University of Pittsburgh Law School, posits that this approach would ensure "a royalty award of sufficient amount to maintain incentives for the development and patenting of new research tools, yet [alleviate] the access restrictions and up-front

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[126]German Patent Act, Article 11, § 2. *See* Klinische Versuche (Clinical Trials) II (Case X ZR 68/94), Federal Supreme Court of Germany, BGHZ 135, 217, [1998] R.P.C. 423.

[127]Japanese Patent Act § 69(1), available at [http://www.jpo.go.jp/shoukaie/patent.htm].

[128]United Kingdom Patent Act, 1977, ch. 37, § 60(5)(b) (Eng.), *reprinted in* U.K. Patent Office, Manual of Patent Practice (1999), available at [http://www.patent.gov.uk/-patent/reference/mpp/s60_71.pdf] (providing a defense to infringement for actions "done for experimental purposes relating to the subject-matter of the invention").

[129]Notably, a Canadian law modeled after the Hatch-Waxman Act was challenged before a WTO tribunal on precisely this ground. The WTO dispute resolution panel upheld the Canadian experimental use privilege based upon the particular circumstances created by the marketing approval and patenting procedures. *See* Canada — Patent Protection of Pharmaceutical Products, WTO Panel Report, WT/DS114/R (Mar. 17, 2000). Some commentators believe that Article 30 was "certainly interpreted narrowly by the WTO Panel." *See* Sol Picciotto, "Private Rights vs. Public Interests in the TRIPS Agreement," 97 *American Society of International Law Proceedings* (April 2-5 2003), 167. Whether other narrowly tailored experimental use privileges would survive scrutiny under the TRIPS Agreement remains uncertain.

[130]*See* CRS Report RL31132, *Multinational Patent Acquisition and Enforcement: Public Policy Challenges and Opportunities for Innovative Firms*, by John R. Thomas.

costs currently associated with acquisition and use of many proprietary research tools."[131]

In weighing this approach to the experimental use issue, it is also important to note that the TRIPS Agreement places some restrictions upon the ability of WTO members to grant compulsory licenses. Article 31, which is among the more detailed provisions in the TRIPS Agreement, in part requires that each application for a compulsory license be considered on its individual merits; that the proposed user must have made efforts to obtain a license from the patent owner; and that the legal validity of such a license be subject to review by the courts or other independent authority.[132] Deliberations over a "compulsory license" approach to the experimental use privilege may wish to account for these obligations.

Concluding Observations

Whether the patent law's experimental use privilege should be retained as a narrowly confined doctrine of limited availability, or expanded to encompass additional experimental activities, technologies, and researchers, continues to be the subject of active discussion in the scientific and legal communities. A limited experimental use privilege may best encourage technological advancement by rewarding successful researchers with patent rights that are not easily circumvented. However, some commentators believe that the circumscribed nature of the experimental use privilege may in fact restrict researcher access to state-of-the-art technologies and thus discourage further technological development. Although the courts have relied upon existing law in order to reach their decisions in particular cases, whether a narrow experimental use privilege most appropriately serves the contemporary scientific research community remains open to policy debate

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[131] *See* Mueller, *supra* note 4.

[132] Schechter & Thomas, *supra* note 16 , at § 12.6.