

October 2004

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Recommended Citation

Judith L. Curry & Bruce E. O'Connor, *University Research-A New Defense Under the Patent Law*, 12 J. INTELL. PROP. L. 29 (2004).

Available at: <https://digitalcommons.law.uga.edu/jipl/vol12/iss1/2>

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UNIVERSITY RESEARCH—A NEW DEFENSE UNDER THE PATENT LAW

Judith L. Curry* & Bruce E. O'Connor**

I. INTRODUCTION

Basic, applied, and sponsored research at or under the auspices of a university results in the conception and reduction to practice of numerous patentable inventions. The benefit of these academic patents both to the research mission of universities and to the economy as a whole has been measured in the context of royalty income and tax revenues. A recent article in the *Quarterly Journal of the Licensing Executives Society* reported that royalty income to U.S. universities, hospitals and research institutes has grown from around seven million in 1980, when Bayh-Dole was enacted, to over one billion in 2001.¹ The same article, analyzing data produced by a 1996 study conducted by MIT, concludes that at the royalty levels of 2001, tax revenues would have been almost ten billion dollars—over one-third of the amount the federal government currently invests annually in university research.²

Notwithstanding the economic value that academic patents clearly have, judicial decisions have recently cast doubt on the viability of two concepts of patent law that have been of particular importance to universities conducting research leading to innovative developments.³ One is the “experimental use exception,” providing that, as long as experimentation continues, the university can seek patent protection even though the university violates the public use statutory bar to patentability incorporated in the patent law.⁴ The other is the “research exemption,” providing that the university has a defense to a claim of patent infringement if its activities are for philosophical experiments without intent to infringe on the patent rights of others.⁵

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¹ Ashley Stevens, *20 Years of Academic Licensing—Royalty Income and Economic Impact*, XXXVIII QUARTERLY JOURNAL OF THE LICENSING EXECUTIVE SOCIETY 133, 139 (2003).

² *Id.*; see also Press Release, Kenneth D. Campbell, TLO says Government Research Pays Off Through \$3 Billion in Taxes (Apr. 15, 1998) (on file with author).

³ See *Pfaff v. Wells Elec.*, 525 U.S. 55, 48 U.S.P.Q.2d (BNA) 1641 (1998); *Madey v. Duke Univ.*, 307 F.3d 1351, 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002).

⁴ *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1877).

⁵ *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813); *Sawin v. Guild*, 21 F. Cas. 554

II. THE EXPERIMENTAL USE EXCEPTION

The patent laws bar patent protection for any invention that is in public use or on sale in the United States more than one year prior to the filing of an application for U.S. patent for that invention.⁶ These “public use” and “on sale” bars to patentability have long been subject to the experimental use exception, which is found where the public use or sale is primarily for purposes of experimentation.⁷ The intent of the inventor is critical to this determination, and such intent can be inferred from the actions of the inventor.⁸ If the experimentation is designed and is reasonably necessary to determine the functional viability of the invention or whether further improvement is needed, then the intent of the inventor is primarily for purposes of experimentation.⁹ If the experimentation goes beyond what is needed to determine functional viability or the need for further improvements, and instead looks at the commercial viability of the invention, the intent of the inventor is primarily for commercial purposes and the exception is not met.¹⁰ In determining intent, the courts usually look to the totality of circumstances involving the allegedly experimental use.¹¹

The policy behind the public use and on-sale bars is to: discourage the removal of inventions from the public domain that the public believes are freely available (e.g., commercial), encourage the prompt and widespread disclosure of inventions, prohibit the inventor from commercially exploiting an invention for a longer period than that prescribed by statute (e.g., the term of the patent, which is measured from the application filing date), and to allow inventors reasonable time to determine whether an invention is worthwhile.¹²

Based on these policy considerations, courts have held that the experimental use exception did not apply where the inventor placed no limitations on use of the invention, failed to conduct any tests or experiments, failed to adjust or modify the invention during a period of commercial sale, and conducted for-profit demonstrations extending beyond those demonstrations reasonably

(C.C.D. Mass. 1813).

⁶ 35 U.S.C. § 102(b) (2002).

⁷ *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134 (1877).

⁸ *Id.* at 136.

⁹ *Id.* at 136-37.

¹⁰ *See In re Smith*, 714 F.2d 1127, 1136, 218 U.S.P.Q. (BNA) 976, 984 (Fed. Cir. 1983); *see also* *Baxter Int'l, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1060, 39 U.S.P.Q.2d (BNA) 1437, 1441-42 (Fed. Cir. 1996).

¹¹ *See Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120, 39 U.S.P.Q.2d (BNA) 1100, 1105 (Fed. Cir. 1996); *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 1198-1200, 31 U.S.P.Q.2d (BNA) 1321, 1325-26 (Fed. Cir. 1994).

¹² *Tone Bros.*, 28 F.3d at 1198.

necessary to demonstrate functionality.¹³ Courts have found experimental use where the inventor did place restrictions on disclosure of information relating to the invention, the inventor retained control over devices embodying the invention, and where the inventor limited testing to that necessary to evaluate functionality.¹⁴

Although the experimental use exception remains viable in relation to the public use bar, its applicability to the on-sale bar is uncertain at the present time. The case of *Pfaff v. Wells Electronics* held that the on-sale bar is present where the invention is the subject of a sale or offer to sell and the invention is “ready for patenting.”¹⁵ This latter requirement means that the inventor has either reduced the invention to practice or that the invention’s conception is far enough along so that the patent application will serve as a constructive reduction to practice.¹⁶ In either case, the inventor has determined the basic functionality of the invention, although further experimentation may be needed to demonstrate that such functionality is consistent and repeatable. In such circumstances, it is difficult for the inventor to establish that the sale was primarily for purposes of experimentation.

III. THE RESEARCH EXEMPTION

The second area of patent law that is threatened by recent case law is the research exemption. The patent law finds infringement of a U.S. patent by anyone “who makes, uses, offers to sell, or sells any patented invention” in the U.S.¹⁷ In the past, courts have subjected infringement to a judicially created research exemption, which applies wherever the manufacture, use, offer to sell or sale is free of commercial motivations and is “merely for experimental purposes.”¹⁸ As with the experimental use exception, the intent of the inventor is critical to this determination, and the court can infer such intent from the actions of the inventor.¹⁹

The policy behind the research exemption is to encourage the development of patented inventions, so as to meet the constitutional aim of the patent law,

¹³ See *Int'l Tooth-Crown Co. v. Gaylord*, 140 U.S. 55, 62-63 (1891); *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 254-57 (1887); *Hall v. MacNeale*, 107 U.S. 90, 97 (1883); *Egbert v. Lippmann*, 104 U.S. 333, 334 (1881); *In Re Smith*, 714 F.2d at 1134; *Lough*, 86 F.3d at 1120.

¹⁴ *Am. Nicholson Pavement Co.*, 97 U.S. at 133-37.

¹⁵ *Pfaff v. Wells Elecs.*, 525 U.S. 55, 65-66, 48 U.S.P.Q.2d (BNA) 1641, 1646-47 (1998).

¹⁶ See *id.* at 67-68.

¹⁷ 35 U.S.C. § 271(a) (2002).

¹⁸ *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713, 29 U.S.P.Q. (BNA) 400, 410 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35, 32 U.S.P.Q. (BNA) 227 (10th Cir. 1936).

¹⁹ *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813).

which is to promote scientific and technological progress.²⁰ Some argue that requiring university researchers to obtain a license to patented technology will not impede research progress.²¹ This might be true but for the fact that patent law in the United States does not provide for compulsory licensing.²² A university research thus can be enjoined from further activity in a specific field covered by a patent if the patent holder decides to enforce the right to exclude that is granted by the patent law. Consequently, in addition to the economic impact, the abolition of the research exemption has social implications in that it may deter innovation and improvement of existing technologies which are beneficial to the public health and welfare.

Courts have held that the research exemption applies where the alleged infringing activities were conducted for the purposes of philosophical experiment, or to gratify a philosophical taste, or for mere amusement; as part of educational activities and to further an educational mission of the inventor; with no intent to derive profits or practical advantage; merely for experimental purposes; with no intended commercial use of the invention; or free of any commercial motivations.²³

The viability of the research exemption is uncertain at the present time. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,²⁴ the Federal Circuit found that experiments conducted by a pharmaceutical company that are consistent with the business of the company, and not strictly for philosophical inquiry, are not protected under the research exception.²⁵ The recent case of *Madey v. Duke University* held that where the research was consistent with the infringer's business, regardless of the research's immediate or ultimate commercial implications, the research exemption could not apply.²⁶ Thus, an organization whose primary

²⁰ See U.S. CONST. art. I, § 8, cl. 8 (permitting the patent system to "promote the Progress of Science and useful Arts").

²¹ Stephen G. Kunin & Linda S. Therkorn, *Workshop on Future Public Policy and Ethical Issues Facing the Biotechnology Industry*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 501, 502 (2004).

²² JAY DRATLER, LICENSING OF INTELLECTUAL PROPERTY § 3.03(2)(a) (1994).

²³ See, e.g., *Poppenhusen v. Falke*, 19 Fed. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861); *Pfizer, Inc. v. Int'l Rectifier Corp.*, 217 U.S.P.Q. (BNA) 157, 161 (C.D. Cal. 1982); *Ruth*, 13 F. Supp. at 713.

²⁴ 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (Fed. Cir. 1984).

²⁵ *Id.* at 863. The *Roche Products* case was followed by the enactment of the Hatch-Waxman Act and Amendments, which provide a limited research exception to companies for the manufacture, use, or sale (with certain exceptions) "solely for uses reasonably related to the development and submission of information under a Federal law which regulate the manufacturer, use, or sale of drugs or veterinary biological products." Hatch-Waxman Act, 35 U.S.C. § 271(e)(1) (2003). For a discussion of this statute and related cases, see Pradip K. Sahu & K. Shannon Mrksich, *The Hatch-Waxman Act: When is Research Exempt from Patent Infringement?*, 22 No. 4 INTELLECTUAL PROPERTY LAW NEWSLETTER 23 (2004).

²⁶ 307 F.3d 1351, 1362, 64 U.S.P.Q.2d (BNA) 1737, 1746 (Fed. Cir. 2002).

purpose or “business” is research is subject to infringement charges with respect to research that is fundamental, basic, and not related in any way to any commercial products or services. Indeed, one might conclude from the *Madey* rationale that any research receiving federal funding would be “commercial” since a principal goal of the Bayh-Dole Act, the federal statute permitting universities to retain title to inventions arising from federally funded research, is “to promote the commercialization and public availability of inventions made in the United States.”²⁷ Moreover, the appellate court in *Madey* expressed the opinion that even education is the “business” of a university.²⁸ The lower court seized upon the appellate court’s opinion in its decision following remand of the case, finding that Duke had failed to meet its burden that it was entitled to summary judgment on the research exemption defense because Duke had conceded “that at least some of its uses of [Madey’s] patents ‘unmistakenly further [its] legitimate business objectives, including educating and enlightening students and faculty participation in these projects.’ ”²⁹

IV. THE RATIONALE FOR REFORM

The full economic impact of these court rulings may not be assessed precisely for decades, but without court action or legislative reform, it is beyond argument that only a small percentage of university research today would satisfy the criteria for exemption from infringement. Given the extremely important role that universities have in conducting basic research and contributing to the scientific knowledge base, the time may have come to consider a statutory research exemption similar to those in place in the United Kingdom and Europe.³⁰

As can be seen from the foregoing exposition, there are clear parallels (and not so subtle differences) between the experimental use exception and the research exemption. In both, the intent of the actor to engage in experimentation and the lack of commercialization have been the primary tests for determining whether the exception and the exemption have been met. These parallels, and the current uncertainty in the law as to the viability of the experimental use exception and the exemption, lead one to conclude that Congress or the courts should replace both the exception and the exemption with a single defense to statutory bars and infringement claims. This defense will provide metes and bounds that are clear and definite, logical, consistent with the constitution, and supportive of the basic goals of the patent law.

²⁷ 35 U.S.C. § 200 (2000).

²⁸ *Madey v. Duke Univ.*, 307 F.3d 1351, 1362, 64 U.S.P.Q.2d (BNA) 1737, 1746 (Fed. Cir. 2002).

²⁹ *Madey v. Duke Univ.*, No. 1:97CV01170, 2004 WL 2148935, at *7 (M.D.N.C. 2004).

³⁰ Patent Act, 1977, ch. 37, § 60(5)(b) (Eng.).

The U.S. Constitution states that the Congress shall have power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”³¹ It is difficult to reconcile the holding in *Madey v. Duke* with this constitutional statement of purpose. The patent law regarding infringement, as it has developed in the United States, would appear to preclude any innovation or improvement on a patented article or process by anyone other than the patentee.

Discoveries or “inventions” are not protectable as traditional property because they are in the form of intangible knowledge or information (except by contract and then only between the contracting parties).³² This proposition is illustrated from the fact that numerous persons may independently make the same invention and may each have the right to use that invention without accounting to the other.³³ In this scenario, the first or any other inventor has no right to control use of the invention by the other inventors.³⁴

Patent law, pursuant to the constitutional clause quoted above, transforms an invention into property by granting a selected inventor (the first to invent under current U.S. law) the right to exclude all others, for a limited time, from making, using or selling the invention.³⁵ The policy considerations behind the “authors and inventors” constitutional clause and its implementation in the patent law have been vigorously debated for many years.³⁶ The most cogent analysis seems to be based on economics. The economic costs to patenting include: the cost of the U.S. Patent and Trademark Office (USPTO); the cost of the judiciary in acting as an appellate body from decisions of the USPTO, and in enforcing patents; the cost to patent holders in obtaining, maintaining, and enforcing patents; the cost to others in avoiding or paying for infringement claims; a decreased supply of patented goods, in that they are available if at all, from a single source; depletion of resources, in that research and development resources are put into areas that can be patented (because of increased profit) instead of other areas, such as basic research, that cannot be patented; and deterrence of inventive activity in an area that is patented, again because of the control that can be exercised by the patentee.³⁷

On balance, however, the economic benefits of patenting have been thought to significantly outweigh the economic costs.³⁸ One principal economic benefit

³¹ U.S. CONST. art. I, § 8, cl. 8.

³² R. CARL MOY, *MOY'S WALKER ON PATENTS* § 1:27 (4th ed. 2003).

³³ *Id.*

³⁴ *Id.*

³⁵ 35 U.S.C. § 271 (2000).

³⁶ U.S. CONST. art. I, § 8, cl. 8; MOY, *supra* note 32, §§ 1:11, 1:28-29.

³⁷ *See id.* § 1:34.

³⁸ *Id.* § 1:36.

is the actual and potential increased profit that the patentee can obtain, given patenting of the invention and the consequent right to control in some way the invention and its commercialization.³⁹ Another principal economic benefit is the direct and indirect advantage that the public receives as a consequence of commercialization of a patented invention, resulting in less expensive and higher quality goods either employing or made by use of the invention.⁴⁰ Other benefits, although highly touted, are now believed to be illusory.⁴¹ The principal of these benefits is based on a bilateral contract theory, in which the inventor promises to make full disclosure of the invention in exchange for the promise by the government of a time-limited right to exclude.⁴² Commentators have pointed out that such disclosure is made primarily for the purpose of telling infringers what they can and cannot do, that commercialization in most cases results in disclosure anyway, and that trade secret law gives an even broader right (i.e., one that is not time-limited) than does the patent law.⁴³

The most viable and primary rationale for patenting that expressly recognizes its economic benefits is based on a theory of unilateral contract: The promise of a limited-term right to exclude is given for the performance of invention and innovation.⁴⁴ In other words, innovation can be viewed as a broader term extending from the conception of an invention, through its reduction to practice, to its commercialization. This rationale is based on the premise that inventors will not innovate, or at least not in an optimal manner, unless they are given the potential of substantially increased profits resulting from the limited-term right to exclude and the consequent ability to control the commercialization of their inventions.⁴⁵

This unilateral contract theory has been expressly recognized by the U.S. Supreme Court on many occasions.⁴⁶ The Court in its various pronouncements also continues to make reference to the disclosure goal, or bilateral contract theory, by stating that the rationale of fostering and rewarding inventions and

³⁹ *Id.* § 1:38.

⁴⁰ *Id.* § 1:34.

⁴¹ JOHN W. SCHLICHTER, PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 2:10 (2d ed. 2003).

⁴² MOY, *supra* note 32, § 1:42.

⁴³ Other comments include: giving just rewards to the inventor (but the potential rewards under the patent law far exceed those necessary to make the inventor whole for his or her efforts); and permitting the patent holder to control the orderly development of a new technology and its commercialization (but it is rare that a single patent or group of patents will dominate an entire technology). *Id.* § 1:37.

⁴⁴ *Id.* § 1:38.

⁴⁵ *Id.*

⁴⁶ *See, e.g.,* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262, 201 U.S.P.Q. (BNA) 1, 4 (1979); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81, 181 U.S.P.Q. (BNA) 673, 678 (1974); Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 229-30, 140 U.S.P.Q. (BNA) 524, 527.

stimulating innovation also includes the disclosure of inventions in a manner that allows the public to use the inventions after expiration of the patent.⁴⁷ The Court has stated an additional goal of setting forth stringent requirements for patentability in the patent law so that ideas and inventions in the public domain are left in the public domain and not patented.⁴⁸

The literal wording of the constitutional provision⁴⁹ (“to promote the Progress of Science and useful Arts”) and the primary rationale of the patent law (“to stimulate and foster invention and innovation”)⁵⁰ are clearly not met by a system in which researchers cannot patent their inventions and are also subject to infringement claims, notwithstanding their lack of commercialization or intent to commercialize.

V. THE PROPOSED RESEARCH DEFENSE

The time has come for an explicit recognition of a “research defense” that tolls the effect of the public use and on-sale bars, based on the acts of the researcher, and that defeats a claim for infringement relating to those acts based on the patent of a third party. This research defense should be established whenever the acts of the researcher are primarily for purposes of experimentation, and the acts of the researcher do not rise to the level of commercial exploitation. This approach is consistent with the law of the United Kingdom, for example, which defines experimental use for purposes of its research exemption to include acts “done for experimental purposes relating to the subject matter of the invention.”⁵¹ This language covers investigations seeking to improve or modify the invention, but would not apply to commercial trials, for example.⁵²

This rule brings the experimental use exception and the research exemption under one roof by employing a doctrine that is consistent with most of the case law pertaining to the experimental use exception. Most importantly, this rule is entirely consistent with the primary rationale of patent law, in that researchers will be able to complete their inventions without the threat of infringement claims or the loss of patent rights. Stimulation of invention and innovation is paramount, especially for an organization such as a university whose principal role and reason for existence is the preservation, expansion, and distribution of human knowledge.

⁴⁷ *Aronson*, 440 U.S. at 262.

⁴⁸ *Id.*

⁴⁹ U.S. CONST. art. I, § 8, cl. 8.

⁵⁰ *Aronson*, 440 U.S. at 262.

⁵¹ Patent Act, 1977, ch. 37, § 60(5)(b) (Eng.).

⁵² W.R. CORNISH, INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADEMARKS AND ALLIED RIGHTS 214 (3d ed. 1996).

It is beyond the scope of this Article to detail those acts constituting commercial exploitation that terminate the research defense. There should be no question that acts directed to basic research should always be subject to the research defense, since such acts have little or no relationship to commercialization. A question does arise with reference to acts directed to applied research, because the ties between such acts and commercialization are often evident, especially as to research that is sponsored by a company and directed to a specific technology that is being or will be commercially exploited by the company. One thing should be certain—that the acts of the university will not be commercial exploitation simply because they are in support of the “business” of the university.⁵³

How the research defense comes into existence depends to a large extent on the courts. Certainly, the constitutional basis for the defense, and its support in the primary rationale for the patent law, give the courts the authority to implement the defense without the need for legislation. Congress can, and should if needed, legislate the defense in support of its own constitutional mandate.

⁵³ A potential conflict with the “strict requirements” goal of the patent law is noted. See David W. Carstens & Craig Allen Nard, *Conception and the “On Sale” Bar*, 34 WM. & MARY L. REV. 393, 425 (1993); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1075-76 (1989). But the statutory bars relating to public use and sale have long been recognized as “patent loss” provisions, see Michael A. Cicero & Lance D. Reich, *Time’s Up! Inaction Causes Loss of Patent Rights*, 10 SOUTH CAROLINA LAWYER 32, 35 (1999) (in support of the early disclosure requirement), rather than pulling something from the public domain that is already there (otherwise, a tautology results!).

