

THE EVANESCENT EXPERIMENTAL USE EXEMPTION FROM UNITED STATES PATENT INFRINGEMENT LIABILITY: IMPLICATIONS FOR UNIVERSITY AND NONPROFIT RESEARCH AND DEVELOPMENT

Janice M. Mueller*

TABLE OF CONTENTS

I.	INTRODUCTION	918
II.	HISTORICAL DEVELOPMENT OF THE UNITED STATES EXPERIMENTAL USE DOCTRINE.....	923
	A. <i>No General Statutory Exemption for Unlicensed Experimental or Research Use of Patented Inventions</i> ...	923
	B. Development of a Robust Fair Use Doctrine in Copyright Law	925
	C. The Common Law Development of a Narrow Experimental Use Exemption from Patent Infringement Liability (1813-2000)	927
III.	THE PIVOTAL 2002-2003 FEDERAL CIRCUIT EXPERIMENTAL USE DEFENSE DECISIONS: <i>MADEY</i> AND <i>INTEGRA</i>	936
	A. <i>Madey v. Duke University</i>	936
	1. Facts	938
	2. Analysis	940
	B. <i>Integra v. Merck KGaA</i>	947
	1. Facts	948
	2. Analysis	956
IV.	PLACING THE FEDERAL CIRCUIT’S EXPERIMENTAL USE DECISIONS IN THE CONTEXT OF BROADER THEMES.....	961
	A. <i>Rise of Formalism</i>	963
	B. Federal Circuit Hostility to Judicial Limitations on Patentee Exclusivity	966
	C. Rising Tide of Statutory Incursions on Exclusivity	968

*Professor of Law, University of Pittsburgh School of Law. The author welcomes comments and can be contacted via email at mueller@law.pitt.edu. She gratefully acknowledges the research assistance of John Marshall Law School students Mark Lang and William Warmouth.

D.	Disinclination to Consider International Patent Law	
	Norms	969
V.	PROPOSED FACTORS FOR LEGISLATIVE CODIFICATION OF	
	THE COMMON LAW EXPERIMENTAL USE EXEMPTION	972
A.	Availability of Consensual Licenses	974
B.	Experimenting on or Experimenting with the Patented	
	Invention	975
C.	Extent to Which Use Is Necessarily Incident to	
	Subsequent Commercial Activity	977
D.	<i>The Balance of Harms</i>	978
VI.	CONCLUSION	979

I. INTRODUCTION

The well-developed fair use doctrine of copyright law provides that certain unlicensed but socially beneficial uses of copyrighted works such as reproduction for purposes of scholarly research, teaching, criticism, and reporting are not infringement.¹ Rather surprisingly, no direct parallel to the fair use doctrine exists in U.S. patent law. In contrast with all leading foreign patent law regimes, no statutory provision in the U.S. Patent Act provides a general exemption from infringement liability for unlicensed use of patented inventions in contexts such as scholarly research and scientific experimentation.²

Early U.S. judicial decisions spoke approvingly of a common law-based doctrine that would exempt unlicensed uses of patented technology for purposes of scientific experimentation or purely personal use. More recently, the U.S. Court of Appeals for the Federal Circuit, which since 1982 has exercised exclusive nationwide jurisdiction over patent-based appeals, has also recognized the experimental use doctrine. However, the court interprets it so narrowly that, for all practical purposes, the doctrine has become a nullity. In the Federal Circuit's four precedential decisions in which an accused infringer asserted a common law-based experimental use

¹ See 17 U.S.C. § 107 (2000).

² See *J.E.M. Agric. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 140 (2001) (noting, in context of discussing research exemption provided by the Plant Variety Protection Act, that "[t]he utility patent statute does not contain similar exemptions"). Nor is there any express exception for a *de minimus* amount of infringement in the U.S. Patent Act. See 35 U.S.C. §§ 1–376 (2000).

defense, not once has the Federal Circuit applied the doctrine to absolve liability.

This article will demonstrate the Federal Circuit's emasculation of the experimental use exemption by analyzing the court's two most recent experimental use decisions. In both, non-profit universities and research institutions sought, but failed, to obtain experimental use immunity from patent infringement liability. In its 2002 decision in *Madey v. Duke University*³ and its 2003 decision in *Integra Lifesciences I, Ltd. v. Merck KGaA*,⁴ the Federal Circuit severely constrained the already limited reach of the experimental use doctrine. Dissenting in *Integra*, Judge Pauline Newman charged that the majority's decision had "essentially eliminate[d] the common law research exemption."⁵ The *Integra* and *Madey* decisions cap a narrowing trend the Federal Circuit began with its foundational 1984 decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*⁶ and confirmed in 2000 with *Embrex, Inc. v. Service Engineering Corp.*⁷

Despite the Federal Circuit's seeming discomfort with the experimental use exemption, a narrowly defined but practically meaningful experimental use exemption is long overdue for the U.S. patent system. A number of commentators have previously advocated a more robust experimental use doctrine, or at least a clearer explication of the doctrine's boundaries.⁸

³ 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

⁴ 331 F.3d 860, 867 (Fed. Cir. 2003), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

⁵ *Id.* at 873 (Newman, J., dissenting).

⁶ *See generally* 733 F.2d 858 (Fed. Cir. 1984), *superseded in part by* 35 U.S.C. § 271(e)(1) (2000).

⁷ *See generally* 216 F.3d 1343 (Fed. Cir. 2000).

⁸ *See generally* John H. Barton, *Patents and Antitrust: A Rethinking In Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 457 (1997) (proposing revision of experimental use exemption "so as clearly to permit use of patented technology for technology improvement purposes without needing to obtain an explicit license"); Jon Cohen, *Chiron Stakes out Its Territory*, SCIENCE, July 2, 1999, at 26 (quoting Robert Merges' description of experimental use exemption's reach as "one of the great unsolved mysteries of contemporary patent metaphysics"); Natalie M. Derzko, *A Local and Comparative Analysis of the Experimental Use Exception – Is Harmonization Appropriate?*, 44 IDEA 1 (2003); John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 717–19 (2002) (noting that absence of experimental use exception in U.S. patent law may motivate industries concerned with developing improvements to existing patented technology to locate their research operations outside of the U.S.); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1020 (1989) (asserting that purpose and scope of experimental use defense are not well defined and that "this vaguely defined doctrine is

Without such an exemption, scientific research functions that require the use of patented inventions are more likely to be shifted offshore to legally hospitable forums. With an ever-growing number of professional and service sector jobs already being outsourced to foreign countries,⁹ a patent law rule whose effect is to add scientific research to the job exodus is one the United States can ill afford.¹⁰

becoming less satisfactory” as level of research utilizing patented materials continues to accelerate); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243 (1990); Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC’Y 617 (1985); 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 (1989); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 866 n.118 (1990) (characterizing precise contours of experimental use defense as unclear); Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369 (1992); Janice M. Mueller, *No “Dilettante Affair”*: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 10 (2001) (proposing liability rule scheme incorporating payment of reach-through royalties for unauthorized use of patented research tools in cases involving significant impediments to access); Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) (advocating that patent law adopt a copyright-like fair use doctrine in order to curb overbroad patent rights in the new technology economy, which doctrine would safeguard incentives to invent while providing a safety valve to ensure that innovation is not impeded); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 139 (1999) (suggesting broader interpretation of experimental use exception as one possible mechanism for reducing transaction and creativity costs associated with patenting basic scientific research); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 146 (2004) (proposing that experimenting on a patented invention should be broadly permitted without regard to commercial intent, but that experimenting with a patented invention (as in the case of research tools) should be subject to a two-tiered compulsory licensing scheme in which compulsory licenses would be available only after a limited period of patentee exclusivity).

However, not all commentators favor enhancement of the currently moribund experimental use exemption from patent infringement liability. See, e.g., Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991).

⁹See Jonathan D. Glater, *Offshore Services Grow in Lean Times*, N.Y. TIMES, Jan. 3, 2004, at C1; Steve Lohr, *Many New Causes for Old Problem of Jobs Lost Abroad*, N.Y. TIMES, Feb. 15, 2004, at 17 (citing 2002 Forrester Research study predicting that 3.3 million service jobs in the United States will move offshore by 2015, and that about 500,000 of these jobs will be in the computer software and services sector).

¹⁰For example, many leading U.S. high technology companies have established facilities in India, where a rapidly growing economy is enhanced by outsourced jobs. See Saritha Rai, *As India’s Economy Rises, So Do Expectations*, N.Y. TIMES, Jan. 30, 2004, at W1. A one-mile

A limited but meaningful experimental use exemption would further the patent system's constitutionally mandated goal of "promoting the progress of . . . the useful arts"¹¹ through the dissemination of new innovation. Most innovation necessarily builds on that which came before. Unrestricted use of the earlier innovation for experimental purposes can only enhance the process of creating new and improved inventions. The publication of information about a new invention in the form of an issued patent is of little use to society if that information is effectively kept "on ice" for seventeen-eighteen years¹² by means of a patent owner's unchecked right to exclude others from use for any purpose.¹³

stretch of road in southern Bangalore already includes offices of multinationals known for high technology innovation, including Oracle, I.B.M., Accenture, Hewlett-Packard, PeopleSoft, and Honeywell. *Id.*

One example of the way in which the lack of an experimental use exemption from patent infringement in the United States may shift research work offshore involves innovation in the field of computer software. Many of the professional-sector jobs already being outsourced to countries such as India are for computer programmers. See Steve Lohr, *Debate Over Exporting Jobs Raises Questions on Policy*, N.Y. TIMES, Feb. 23, 2004, at C1 (noting that "[t]ransplanting work, not just call center operations but also skilled professional labor like computer programming, to lower-cost nations is a manifestation of a change in the terms of trade in global competition. Such jobs can more easily be sent to India or China largely because of technology - inexpensive telecommunications and the Internet."). As outsourcing of jobs has increased in recent years, so too have patent systems become much more accommodating to the patenting of software-implemented inventions, including their constituent algorithms. See, e.g., U.S. Patent No. 6,526,440 (issued Feb. 25, 2003) (issued to Google, Inc. of Mountain View, California, for a method of "[r]anking search results by reranking the results based on local inter-connectivity"). As more firms protect their software innovation through patents, it becomes increasingly likely that the research effort necessary to develop new computer programs will require the use of software algorithms and programming techniques already patented by others. Software development firms will be motivated to outsource their programming research and development to foreign countries that recognize an experimental use exemption, which could potentially immunize the research activity. India is one such country. See Patents Act, 1970, 27 INDIA A.I.R. MANUAL 450, § 47(3) (1979), available at http://www.wipo.int/clea/docs_new/en/in/in004en.html (last visited Nov. 29, 2004). Section 47(3) provides the following:

The grant of a patent under this Act shall be subject to the condition that . . . any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research

Id.

¹¹U.S. CONST. art. I, § 8, cl. 8.

¹²The average pendency of a patent application filed with the United States Patent and

The patent system's goal of technology dissemination must, of course, be balanced against the incentivizing function of patents. The potential of a powerful exclusionary property right in an invention serves to draw out new inventions that might otherwise be suppressed. An experimental use exemption, like any incursion on the exclusivity of the patent owner's right to exclude others from her invention, must therefore be carefully defined and judiciously applied so as not to significantly compromise incentives for innovation.

In *Madey v. Duke University*¹⁴ and *Integra Lifesciences I, Ltd. v. Merck KGaA*,¹⁵ the Federal Circuit declined important opportunities to craft an appropriately nuanced standard through judicial decision. The increasingly negative tenor of the court's pronouncements concerning experimental use makes it unlikely that the court will ever do so.

Accordingly, this Article calls for the congressional enactment of a limited but balanced experimental use exemption in patent law, just as Congress did in enacting the Copyright Act's fair use provision in 1976. Part II of the Article places the need for a meaningful experimental use defense in context by comparing the historical development of a robust fair use exception to copyright infringement with the rather sporadic case law development and subsequent demise in the Federal Circuit of patent law's experimental use defense. Part III of the Article critiques the Federal Circuit's pivotal 2002-03 decisions in *Madey* and *Integra*, in which the court refused to apply the experimental use defense to research activity conducted in university and non-profit institutional settings. The Article contends that the court in *Madey* mapped an exceedingly (and excessively) limited role for the experimental use defense through a distorted application of the "legitimate business" criterion of *Pitcairn v. United States*¹⁶ to basic research conducted by university researchers. The Article further contends

Trademark Office (USPTO) is now approximately twenty-six months. See Sabra Chartrand, *Patents*, N.Y. TIMES, Feb. 9, 2004, at C2. The enforceable term of a U.S. patent is twenty years less the period of application pendency. See 35 U.S.C. § 154(a)(2) (2000). Hence the average enforceable life of a patent is between seventeen and eighteen years.

¹³ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., dissenting), amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

¹⁴ See generally 307 F.3d 1351 (Fed. Cir. 2002), cert. denied, 539 U.S. 958 (2003).

¹⁵ See generally 331 F.3d 860, amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

¹⁶ 547 F.2d 1106, 1125 (Fed. Cir. 1977).

that by narrowly construing the issues on appeal, the panel majority in *Integra* ducked the important questions raised by the *Integra* dissent's strong defense of the experimental use doctrine.

Part IV of the Article places the Federal Circuit's repeated refusals to apply an experimental use defense in the context of several broader themes that appear to be impacting the court's patent law jurisprudence. Part V concludes that in light of these judicial refusals, Congressional action is mandated. The Article proposes and applies a set of factors for inclusion in a legislative codification of the experimental use defense.

II. HISTORICAL DEVELOPMENT OF THE UNITED STATES EXPERIMENTAL USE DOCTRINE

A. *No General Statutory Exemption for Unlicensed Experimental or Research Use of Patented Inventions*

The U.S. Patent Act does not provide any general exemption from patent infringement liability for uses of patented inventions that are not authorized by the patent owner. Section 271(a), which governs acts of direct infringement, is determinative. The statute provides that: "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent."¹⁷

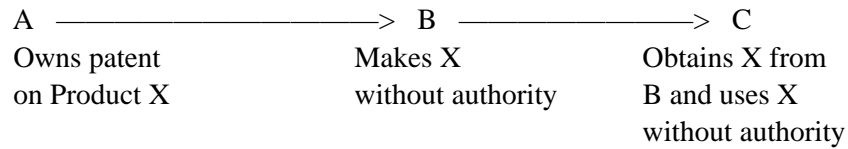
Two aspects of the statutory language are notable. First, the statute is written in the disjunctive, indicating that one can be an infringer if one merely uses an invention, even though one has not made or sold it. Second, no qualifiers modify the prohibition on unauthorized uses. The statute does not discriminate by purpose of the use, whether it be purely for making profit or entirely for non-commercial scientific research.¹⁸

To understand the broad literal scope of § 271(a), consider the following hypothetical in which party *A* owns a U.S. patent on product *X*. Party *B* manufactures *X*, without authority of *A*, in the United States during the term of *A*'s patent.¹⁹ Party *C* obtains *X* from *B* and uses *X* in the United States, again without authority of *A*.

¹⁷ 35 U.S.C. § 271(a) (2000).

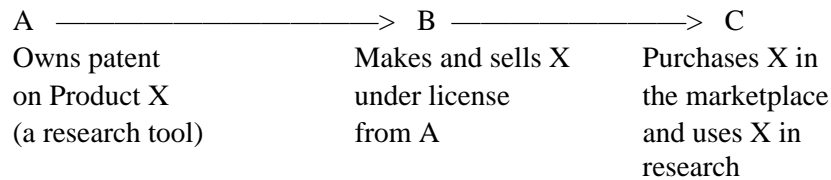
¹⁸ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984), *superseded in part* by 35 U.S.C. § 271(e)(1) (2000).

¹⁹ If the facts were changed such that *B* operated offshore and did not make the invention in



If one applies § 271(a) by its literal terms to this hypothetical, *B* and *C* will be held jointly and severally liable for infringement of *A*'s patent. Under the broad terms of the statute, this result is obtained regardless of the purpose of *C*'s use, whether it be for research, development, commercialization, or anything in between.

The above hypothetical must be distinguished from the case in which end user *C*'s use is with authority.²⁰ *C*'s use is not infringing if *C* has authority in the form of an express license or through operation of legal doctrines such as implied license and the first sale doctrine. For example, consider a modified scenario in which the patent of party *A*, a non-manufacturer, is directed to a research tool such as a chemical reagent.²¹ In this scenario party *B* makes and sells *X* under an express license from *A*. Party *C* is a researcher who is able to easily purchase *X* in the marketplace; i.e., *C* is an ordinary consumer of *X*.



The result here is that *B*'s making and selling is with authority under the terms of 35 U.S.C. § 271(a). Consequently, *C*'s purchase of the patented

the United States within the parameters of 35 U.S.C. § 271(a), then only *C* would be liable. *See Roche*, 733 F.2d at 860 (describing *Bolar*'s purchase of drug product from offshore source).

²⁰ *See* 35 U.S.C. § 271(a).

²¹ REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS, available at <http://www.nih.gov/news/researchtools/#background> (June 4, 1998) (noting that the National Institutes of Health (NIH) Working Group on Research Tools defines research tool as "embrac[ing] the full range of resources that scientists use in the laboratory"). Such resources include "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR [polymerase chain reaction]), methods, laboratory equipment and machines, databases and computer software." *Id.*

The meaning of research tool can vary with perspective, however. While researchers view the resources they rely on in the laboratory as tools, firms in the business of inventing, manufacturing, and selling these resources will consider them end products. *See id.*

research tool X from an authorized supplier *B* carries with it an implied license to *C* to use X.²² Under the first sale doctrine, *A*'s right to control the subsequent disposition of each particular tool X was exhausted upon the initial sale of the product X in the marketplace.²³

The second hypothetical is particularly important because it illustrates a scenario in which an experimental use exemption is not necessary. Purchase of the tool by the researcher, the target customer, implicitly carries with it an authorization permitting the researcher to use the tool for research purposes. Accordingly, this Article's proposal for a legislatively codified experimental use exemption excludes the case in which patented research tools are readily available for purchase in the marketplace.²⁴

B. Development of a Robust Fair Use Doctrine in Copyright Law

The absence of a statutory experimental use exemption in the U.S. patent law regime stands in sharp contrast to the well-developed fair use doctrine of copyright law, codified in the U.S. Copyright Act in 1976.²⁵ The Copyright Act provides a multi-factored standard by which courts are to judge whether a challenged unlicensed use is fair and hence non-infringing:

§ 107. Limitations on exclusive rights: Fair use.
Notwithstanding the provisions of §§ 106 and 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as

²²See generally *Aro Mfg. Co., Inc. v. Convertible Top Replacement Co. Inc.*, 365 U.S. 336 (1961).

²³See *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (explaining that the law is well settled that an authorized sale of a patented product places that product beyond the reach of the patent. The patent owner's rights with respect to the product end with its sale, and a purchaser of such a product may use or resell the product free of the patent.).

²⁴See Mueller, *supra* note 8, at 15 (limiting proposed liability rule for non-consensual use of patented research tools to those tools for which access is truly problematic, not tools widely available for purchase in the marketplace). This position was also asserted by the Solicitor General in his amicus brief in *Madey*. See Brief for the United States as Amicus Curiae, *Duke Univ. v. Madey*, 538 U.S. 959 (2003) (No. 02-1007), available at <http://www.usdoj.gov/osg/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.html> (last visited Nov. 29, 2004).

²⁵See MELVILLE B. NIMMER & DAVID NIMMER, *NIMMER ON COPYRIGHT* § 13.05 (2000) (noting that "in determining whether given conduct constitutes copyright infringement, the courts have long recognized that certain acts of copying are defensible as 'fair use'").

criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include:

- (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
- (2) the nature of the copyrighted work;
- (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
- (4) the effect of the use upon the potential market for or value of the copyrighted work. The fact that a work is unpublished shall not itself bar a finding of fair use if such finding is made upon consideration of all the above factors.²⁶

A robust jurisprudence stems from the federal courts' prolonged experience with application of this multi-factored standard in copyright cases; the courts' ability to apply the fair use exemption has benefited from repeated Supreme Court guidance.²⁷ Academic commentary concerning the fair use exemption is generally favorable.²⁸ The consensus view is that the fair use doctrine affords an important safety valve against over-inclusive application of copyright rights.²⁹

Although not added to the copyright statute until 1976, the fair use doctrine finds its U.S. origins in nineteenth century decisions of Justice

²⁶ 17 U.S.C. § 107 (2000).

²⁷ See generally *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569 (1994); *Stewart v. Abend*, 495 U.S. 207 (1990); *Harper & Row, Publishers, Inc. v. Nation Enters.*, 471 U.S. 539 (1985); *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417 (1984).

²⁸ See NIMMER, *supra* note 25, § 13.05.

²⁹ See, e.g., Wendy J. Gordon, *Fair Use as Market Failure: A Structural and Economic Analysis of the Betamax Case and Its Predecessors*, 82 COLUM. L. REV. 1600, 1601 (1982) (arguing that fair use doctrine is appropriately applied in market failure situations where "defendant could not appropriately purchase the desired use through the market . . . transferring control over the use to defendant would serve the public interest . . . the copyright owner's incentives would not be substantially impaired by allowing the user to proceed").

Joseph Story.³⁰ As early interdisciplinarian when it came to intellectual property law, Story also suggested a similar principle in patent law in the form of the experimental use doctrine, as discussed in the following section. However, the notion of a well-defined exemption from liability for certain uses of innovation protected by patents never received wide application or statutory codification as it did with respect to copyrighted works.³¹

C. The Common Law Development of a Narrow Experimental Use Exemption from Patent Infringement Liability (1813-2000)

The historical development of a common law experimental use exemption from patent infringement has been detailed elsewhere.³² This section provides a brief summary.

Authored by Joseph Story in 1813, *Whittemore v. Cutter* is the foundational U.S. decision approving an experimental use exemption from patent infringement.³³ The lawsuit involved allegations of infringement of a patent directed to a machine for manufacturing cards.³⁴ The patentee appealed the trial court's charge to the jury, which had effectively limited liability to those unauthorized uses of the defendant that were for profit: "The making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right, for which an action was given by the statute."³⁵ Story conceded that this definition of infringement favored the accused infringer,³⁶ and ventured that the jury charge "was adopted by the [trial] court from the consideration" that "it could never have been the intention of the legislature to punish a man, who constructed . . . a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."³⁷

³⁰ See *Folsom v. Marsh*, 9 F. Cas. 342 (C.C.D. Mass. 1841) (No. 4901).

³¹ See generally Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000). The potential applicability of copyright fair use principles to the experimental use exemption from patent infringement is considered further in Part V, notes 269-277 *infra* and accompanying text.

³² See, e.g., Mueller, *supra* note 8, at 17-32. For a thorough, international perspective on experimental use, see 16 DAVID GILAT, *EXPERIMENTAL USE AND PATENTS* (Max Planck Inst. for Foreign and Int'l Patent, Copyright and Competition Law 1995).

³³ 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

³⁴ *Id.* at 1123.

³⁵ *Id.* at 1121.

³⁶ *Id.*

³⁷ *Id.*

Story does not address further the factual question of the accused infringer's purpose, however, and remands the case to the trial court on other issues.³⁸ Thus, commentators have characterized the quoted passage as dicta not necessary for resolution of the case.³⁹

Whether or not dicta in *Whittemore*, Story did not consider his view of the experimental use doctrine mere surplusage. Story wrote approvingly of the same doctrine in the subsequent decision of *Sawin v. Guild*,⁴⁰ which involved the alleged infringement of a machine for cutting brad nails.⁴¹ He cited *Whittemore* as having established that patent infringement must concern:

[T]he making [of the invention] 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. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.⁴²

In Story's view, then, the profit motive driving the activity identifies those unauthorized makings or uses of patented inventions that deserve condemnation as infringement. Such acts potentially divert to the accused infringer a portion of the profits otherwise owed to the patent owner.⁴³ On

³⁸ *Id.* at 1123.

³⁹ See, e.g., Derzko, *supra* note 8, at 4; Duffy, *supra* note 8, at 717; Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, *supra* note 8, at 1023; Mark D. Janis, *Sustainable Agriculture, Patent Rights, and Plant Innovation*, 9 *IND. J. GLOBAL LEG. STUD.* 91, 106 (2001).

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

⁴¹ *Id.* at 554. The alleged infringer was a deputy sheriff who "having an execution in his hands against the plaintiffs for the sum of \$567.27 debt and costs, by virtue of his office, seized and sold, on said execution, the materials of three of said patented machines, which was at the time complete and fit for operation, and belonged to the plaintiffs." *Id.* Story concluded that the sheriff's act was a seizure of the materials from which the machines were made and not an infringing "sale" of the invention under the applicable patent statutes. See *id.* at 555. Story rejected the plaintiff's literal reading of the statute, under which it would be "practicable for a party to lock up his whole property, however great, from the grasp of his creditors, by investing it in profitable patented machines." *Id.*

⁴² *Id.* (citations omitted).

⁴³ This interpretation comports with Story's subsequent copyright fair use decision in *Folsom v. Marsh*, in which he condemned as unfair those uses that "supersede the objects" of the original. 9 F. Cas. 342, 348 (C.C.D. Mass. 1841) (No. 4901) (noting that in deciding the question of whether an unauthorized use of a copyrighted work is fair, courts "must often . . . look to the nature and objects of the selections made, the quantity and value of the materials used, and the

the other hand, uses which do not deprive the patentee of the lawful rewards of his discovery are exempt from infringement liability in Story's view. The making of a patented invention for "the mere purpose of philosophical experiment" is a paradigm example of exempted use.

The meaning of Story's adjective "philosophical," used in both *Whittemore* and *Sawin* to characterize exempted experimentation, is a critical aspect of his formulation. Multiple authorities confirm that in Story's day philosophical meant scientific. At that time the noun philosophy referred to natural philosophy, which in turn meant science generally.⁴⁴ Thus, under the experimental use doctrine as espoused by Story, scientific experiments which do not deprive a patent owner of his lawful rewards for having made his invention are exempt from infringement liability.

Story's formulation of a limited experimental use exemption from patent infringement liability gained general acceptance.⁴⁵ By 1861 courts deemed the law to be "well-settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity,

degree in which the use may prejudice the sale, or diminish the profits, or supersede the objects, of the original work").

⁴⁴ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 874 n.8 (Fed. Cir. 2003) (Newman, J., dissenting), amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237). "By 'philosophical' experiments Justice Story was referring to 'natural philosophy,' the term then used for what we today call 'science.' For example, in the volume on CLASSIFICATION OF SUBJECTS OF INVENTIONS ADOPTED BY THE UNITED STATES PATENT OFFICE, January 1, 1868 (GPO 1868), the section headed 'Philosophical Instruments—Class XXV' lists 'Philosophical Apparatus, Scales, Measures, and Instruments of Precision.'" Moreover, Professor Robinson's 1890 treatise provides that the interests of a patentee are not antagonized where the patented invention is "made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement . . ." William C. Robinson, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 (1890). Thus, Robinson, writing in 1890, also appears to equate philosophical with scientific. Other evidence of the early use of philosophical to mean scientific includes the founding of the American Philosophical Society. Launched in Philadelphia in 1743 at the urging of Benjamin Franklin, the Society pursued "all philosophical Experiments that let Light into the Nature of Things, tend to increase the Power of Man over Matter, and multiply the Conveniencies or Pleasures of Life." *About the American Philosophical Society*, at <http://www.amphilsoc.org/about/> (last visited Nov. 29, 2004). Early members of the Society "included doctors, lawyers, clergymen, and merchants interested in *science*, and also many learned artisans and tradesmen like Franklin." *Id.* (emphasis added).

⁴⁵ See Robinson, *supra* note 44, § 898 (1890) (stating that the interests of a patent owner are "not antagonized" where the patented invention is "made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement . . .").

or for mere amusement, is not an infringement of the rights of the patentee.”⁴⁶

Although well accepted as a matter of legal doctrine, the experimental use exemption was only infrequently applied in favor of an accused infringer.⁴⁷ A rare exception is *Ruth v. Stearns-Roger Manufacturing Company*, in which a Colorado district court in a 1935 decision absolved the unlicensed use of certain patented flotation machines and their parts by students and faculty of the Colorado School of Mines.⁴⁸ There the machines were “all used in the laboratory and . . . cut up and changed from day to day.”⁴⁹ In a second application of the exemption, the Court of Claims, a predecessor to the Federal Circuit, held in its 1958 decision *Chesterfield v. United States* that certain experimentation by the U.S. government was not infringement.⁵⁰ Assuming arguendo that the asserted patent claims to a metallic alloy were valid, the court concluded that the

⁴⁶*Poppenhusen v. Falke*, 19 F. Cas. 1049, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). An experimental use defense to infringement was also recognized in the contemporaneous judicial decisions of England. The Chancery Division stated the following:

[N]o doubt if a man makes [patented] things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition, and if it were, it is certainly not the subject for an injunction.

Frearson v. Loe, 9 Ch. D. 48, 66–67 (1878).

⁴⁷*See, e.g., Bonsack Mach. Co. v. Underwood*, 73 F. 206 (E.D.N.C. 1896). “In the present case, . . . the [accused] Underwood [cigarette making] machine has not been made simply as an experiment, but has been used for profit, that is, for the purpose of selling the patent [of Underwood].” *Id.* at 211.

⁴⁸13 F. Supp. 697, 703 (D. Colo. 1935) (finding that the parts used by the Colorado School of Mines were for “laboratory machines used for experimental purposes, and consequently did not contribute to an infringing use”), *rev’d on other grounds*, 87 F.2d 35 (10th Cir. 1936).

⁴⁹*Id.*

⁵⁰141 Ct. Cl. 838, 839 (1958) (adopting findings and opinion of trial commissioner Donald Lane).

government had not infringed them because its use was “only for testing and for experimental purposes.”⁵¹

Much more typical of the courts’ response to assertions of the experimental use defense is *Pitcairn v. United States*.⁵² The case stemmed from the government’s procurement of 2,200 helicopters acquired during 1946-64 at a total cost of over \$639 million.⁵³ These helicopters had been manufactured by third party contractors on the government’s behalf without authorization of the patent owner, leading to a twenty-year patent infringement litigation under 28 U.S.C. § 1498.⁵⁴ The government sought to lessen the very substantial damages base it faced by excluding the uses of certain helicopters as experimental.⁵⁵

The Court of Claims rejected the government’s experimental use defense, concluding that the helicopters at issue were not used by the government solely for experimental purposes.⁵⁶ The court contrasted the many other, truly experimental helicopters which the patentee had declined to charge as infringing. These helicopters were designed, developed, and manufactured in the course of numerous research and development contracts not at issue in the case at bar.⁵⁷

The *Pitcairn* court concluded that the government’s purported experiments could not be excused from patent infringement liability because they were merely a necessary precursor to the government’s ultimate, intended use of the helicopters in its “legitimate business” of military defense:

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*

⁵¹ *Id.*

⁵² *See generally* 212 Ct. Cl. 168 (1976).

⁵³ *Id.* at 176.

⁵⁴ *Id.* at 175–76.

⁵⁵ *Id.* at 198.

⁵⁶ *Id.* (concluding that “[i]n the present case there is no evidence in defendant’s offer of proof that any of the helicopters to which defendant’s ‘experimental use’ contentions pertain were built solely for experimental purposes”).

⁵⁷ *Id.* The court also distinguished *Chesterfield* as involving a governmental purchase and use of accused materials, rather than a government contracted-for manufacture as in the case at bar. *See id.* at 199.

*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.*⁵⁸

More than twenty-five years later, the Federal Circuit in *Madey v. Duke University*, detailed below,⁵⁹ would significantly distort *Pitcairn's* legitimate business formulation by applying it to truly scientific research activity conducted in a wholly different context; i.e., a nonprofit research university.

In an effort to reduce forum shopping and bring a greater measure of uniformity and consistency to U.S. patent law, the Federal Circuit was formed in 1982 through merger of the jurisdictions of the Court of Claims and the Court of Customs and Patent Appeals (CCPA).⁶⁰ The Federal Circuit adopted the prior decisions of those courts (thus including Court of Claims decisions such as *Pitcairn* and *Chesterfield*) as binding precedent.⁶¹ Its implementing legislation made the Federal Circuit the sole federal appellate court with jurisdiction over patent cases, supplanting the various federal regional circuits in that regard.⁶²

The Federal Circuit's first confrontation with an experimental use defense to patent infringement came in 1984 with *Roche Products, Inc. v. Bolar Pharmaceutical Co.*⁶³ Plaintiff Roche held a patent on the active ingredient in a sleeping aid sold commercially as Dalmane.⁶⁴ Defendant Bolar, a generic drug manufacturer, purchased five kilograms of the drug

⁵⁸ *Id.* at 199 (emphases added).

⁵⁹ See Part II.A. *infra*.

⁶⁰ See Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25.

⁶¹ See *S. Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982).

⁶² See 28 U.S.C. § 1295(a) (2000). This remained the rule until 2002, when in *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002), the Supreme Court clarified that in those cases where a patent law-based cause of action arises in a defendant's counterclaim rather than as part of a plaintiff patent owner's well-pled complaint, appeal is taken to the appropriate regional circuit rather than the Federal Circuit.

⁶³ See generally 733 F.2d 858 (Fed. Cir. 1984), *superseded in part by* 35 U.S.C. § 271(e)(1).

⁶⁴ See *id.* at 860 (noting that Roche patent was directed to the chemical compound flurazepam hydrochloride, which is the active ingredient in Dalmane).

from a foreign supplier.⁶⁵ Six months prior to the Roche patent's expiration date, Bolar used the drug in the United States to conduct tests and to gather data it needed to support an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration (FDA).⁶⁶ Bolar's ANDA sought authorization from the FDA to manufacture and sell a generic equivalent of Dalmane upon expiration of Roche's patent. Roche immediately filed suit, seeking to enjoin Bolar from any unlicensed use of the patented composition during the remaining (if short) life of the patent.⁶⁷

A federal district court denied the injunction on the ground that Bolar's use did not infringe because it was experimental, as well as de minimus.⁶⁸ The Federal Circuit reversed. The appellate court recognized the existence of a common law-derived experimental use exemption but held it to be "truly narrow," refusing to apply it to the facts at bar.⁶⁹ The *Roche* court cited *Pitcairn v. United States*⁷⁰ as the most persuasive of its predecessor court's experimental use cases, repeating (but generalizing) *Pitcairn*'s conclusion that "'tests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business of the . . . [alleged infringer]' are infringements for which '[e]xperimental use is not a defense.'"⁷¹ The Federal Circuit concluded that "Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."⁷² Bolar may have intended to conduct experiments, but performed them "with a view to the adaption of the patented invention to [Bolar's] business."⁷³ Bolar's unlicensed tests using the patented drug had "definite, cognizable, and not insubstantial commercial purposes."⁷⁴

From doctrinal and policy points of view, the Federal Circuit's denial of experimental use immunity in *Roche* was almost certainly correct. Bolar's experiments were not the truly scientific experiments Story contemplated, which would not deprive Roche of its just reward for inventing the active ingredient in Dalmane. Nor were the experiments performed in an attempt

⁶⁵ *See id.*

⁶⁶ *See id.*

⁶⁷ *Id.*

⁶⁸ *Id.* at 860–61.

⁶⁹ *Id.* at 863.

⁷⁰ 212 Ct. Cl. 168 (1976).

⁷¹ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

to find a new use for Roche's drug or to improve upon it; they added nothing new to the store of knowledge. Bolar's unlicensed use of Roche's invention was purely "superceding" in Justice Story's sense of the word.⁷⁵ Moreover, the experiments were simply a necessary incident to Bolar's intended goal of commercial sales of a generic equivalent of Dalmane. Proof of bioequivalency between a patented drug and its generic version is mandatory for FDA approval of the generic.⁷⁶ Bolar's immediate purpose in using the patented invention was clearly commercial.

Following *Roche* the Federal Circuit would not revisit the experimental use doctrine for over fifteen years. In June 2000 the court issued its opinion in *Embrex, Inc. v. Service Engineering Corp.*⁷⁷ The *Embrex* majority summarily denied the experimental use defense based on a district court's finding that the use was "expressly for commercial purposes,"⁷⁸ without exploring any other parameters of the nature of the accused infringer's unlicensed use. Thus, the *Embrex* panel missed a clear opportunity to clarify the vague boundaries of the experimental use doctrine.

Embrex's patent was directed to a method of inoculating chicks against diseases while still *in ovo* (before hatching).⁷⁹ The claimed method required administration of a vaccine within the "region defined by either the amnion or the yolk sac."⁸⁰ Accused infringer Service Engineering retained scientific consultants in an attempt to avoid infringement by designing around the *Embrex* patents.⁸¹ The scientists were unable to prevent injection into the region of the egg recited in the claim, however; thus, the experiments were unsuccessful.⁸² In view of the district court's finding that the experiments were conducted by Service Engineering chiefly to sell its

⁷⁵ See *Folsom v. Marsh*, 9 F. Cas. 342 (C.C.D. Mass. 1841) (No. 4901).

⁷⁶ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003) (noting Congressional understanding that 35 U.S.C. § 271(e)(1) safe harbor for regulatory data gathering permits limited testing so that "generic manufacturers can establish the bioequivalency of a generic substitute"), amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

⁷⁷ See generally 216 F.3d 1343 (Fed. Cir. 2000).

⁷⁸ *Id.* at 1349.

⁷⁹ See *id.* at 1346.

⁸⁰ *Id.*

⁸¹ See *id.* at 1346-47 (noting that defendant Service Engineering hired two scientists, one of whom suggested that the embryos be inoculated by injecting vaccine into the chorioallantoic sac rather than the amnion/yolk sac as recited in the claims of the *Embrex* patent).

⁸² See *id.* at 1347.

own *in ovo* injunction machines to potential customers, the Federal Circuit rejected the experimental use defense.⁸³

The facts of *Embrex* illustrate what should have been understood as a paradigm case of exempted experimental use: the use of a patented invention (here, a method) in an attempt to design around (i.e., avoid infringing) the patent. Any connection between these tests and Service Engineering's later sales of injection machines was remote at best.

Instead, the *Embrex* opinion is noted chiefly for the concurring views of Judge Rader, who took the position that after *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*,⁸⁴ U.S. patent law leaves no room for any sort of purpose—or intent—based exemption from infringement liability.⁸⁵ In Judge Rader's view, the issue is one of remedy rather than liability; i.e., true experimentation should be dealt with as a matter of potentially reduced damages rather than exemption from liability.⁸⁶

Judge Rader's remedy-adjustment framework ignores the exclusionary property right associated with a finding of liability. Although compensatory damages might be reduced, the unauthorized user of a patented invention might nevertheless be confronted with a permanent injunction against any future unlicensed use.⁸⁷ Another objection is that Judge Rader's framework requires litigation before the fact of liability and amount of compensatory damages can be determined.⁸⁸ Whatever the merits of Judge Rader's intent-free proposal, a different panel of the Federal Circuit expressly rejected it in *Madey v. Duke University*.⁸⁹ Judge Rader

⁸³ See *id.* at 1349.

⁸⁴ 520 U.S. 17 (1997).

⁸⁵ See *Embrex*, 216 F.3d at 1353 (Rader, J., concurring). Judge Rader's reading overstates the holding of *Warner-Jenkinson*, a case that did not involve an experimental use defense. See Mueller, *supra* note 8, at 30 (arguing that "*Warner-Jenkinson* merely establishe[d] that an accused infringer need not be aware of the plaintiff's patent in order to be liable for infringing it. In no way does *Warner-Jenkinson* hold or suggest that an accused infringer's experimental or research purpose is irrelevant to the question of infringement liability or remedy.>").

⁸⁶ See *Embrex*, 216 F.3d at 1352 (Rader, J., concurring) (contending that when "wholly non-commercial" infringement is proven, "the damage computation process provides full flexibility for courts to preclude large (or perhaps any) awards for minimal infringements").

⁸⁷ See Mueller, *supra* note 8, at 31.

⁸⁸ See *id.*

⁸⁹ See 307 F.3d 1351, 1360–61 (Fed. Cir. 2002) (Gajarsa, J., joined by Bryson, J., and Linn, J.) (refusing to view as "inescapable" the asserted "inconsistency" between the experimental use defense and the Supreme Court's holding in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 36 (1997), that intent plays no role in the application of the doctrine of equivalents).

nevertheless continued to espouse his position in *Integra Lifesciences I, Ltd. v. Merck KGaA*.⁹⁰

III. THE PIVOTAL 2002-2003 FEDERAL CIRCUIT EXPERIMENTAL USE DEFENSE DECISIONS: *MADEY* AND *INTEGRA*

In the first twenty years of its existence, the Federal Circuit confronted the experimental use defense only in the context of cases involving accused infringers who were commercial entities; i.e., in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* and *Embrex, Inc. v. Service Engineering Corp.*⁹¹ Much truer tests of the experimental use defense's viability came in 2002-03, when the Federal Circuit confronted two cases in which the accused activity involved scientific researchers in non-profit settings; i.e., a private university (Duke University) and a private research institution (the Scripps Research Institute). Despite the non-commercial settings, the court refused to apply the defense to absolve either defendant. The Federal Circuit's decisions in *Madey v. Duke University* and *Integra Lifesciences I, Ltd. v. Merck KGaA*⁹² are analyzed below.

A. *Madey v. Duke University*

The Federal Circuit's 2002 decision in *Madey v. Duke University*⁹³ marked the first time in the court's then-twenty year history that it had addressed the applicability of the experimental use exemption to an institution that might seem its most likely beneficiary: a non-profit research institution.⁹⁴ Despite the non-commercial nature of the Duke University

⁹⁰ See 331 F.3d 860, 864 n.2 (Fed. Cir. 2003) (asserting that "Judge Newman's dissent [does not] note that the judge-made doctrine is rooted in the notions of *de minimis* infringement better addressed by limited damages") (citing *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352-53 (Fed. Cir. 2000) (Rader, J., concurring)), amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

⁹¹ See generally 733 F.2d 858 (Fed. Cir. 1984); 216 F.3d 1343 (Fed. Cir. 2000).

⁹² See generally 307 F.3d 1351 (Fed. Cir. 2002); *Integra*, 331 F.3d 860.

⁹³ 307 F.3d at 1351.

⁹⁴ When it decided *Madey* in 2002, the Federal Circuit had previously issued two precedential decisions rejecting an experimental use defense to infringement. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the court held that a generic drug manufacturer was not entitled to immunity from infringement liability for its unlicensed use of patented drugs for purposes of testing and data-gathering to prepare an Abbreviated New Drug Application for submission to the FDA. 733 F.2d 858, 863 (Fed. Cir. 1984). In *Embrex, Inc. v. Service Engineering Corp.*, the court held that Service Engineering, a for-profit corporation, was not entitled to immunity for its activities that

research work at issue, the Federal Circuit refused to excuse it as experimental.⁹⁵ Rather, it characterized the researchers' experiments as within an extremely broad characterization of the legitimate business of the university, by strained analogy to the helicopter tests of *Pitcairn v. United States*,⁹⁶ discussed in Part II. C. *supra*.

The *Madey* decision raised what was for many the unsettling specter of research universities as potential patent infringer, and refocused attention to the question whether the seemingly moribund common law exemption for experimental use should be reinvigorated through legislative means.⁹⁷

Some commentators discount the *Madey* court's broad commentary about university research as unimportant dicta.⁹⁸ Most scientific researchers and university administrators are not schooled in the art of drawing fine distinctions between Federal Circuit holdings and dictum, however. The fact that the *Madey* decision is now on the books of published, precedential patent decisions should not be disregarded.

the district court had found were clearly commercial in nature. 216 F.3d 1343, 1349 (Fed. Cir. 2000).

⁹⁵ See *Madey*, 307 F.3d at 1362 (finding that where an "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" regardless of the profit or non-profit status of an institution).

⁹⁶ 212 Ct. Cl. 168 (1976). See *supra* notes 52–58 and accompanying text.

⁹⁷ Bernard Wysocki, Jr., *A Laser Case Sears Universities' Right to Ignore Patents*, WALL STREET J., Oct. 11, 2004, at A1 (reporting that "[t]he [Federal Circuit's] ruling in the Duke case is already reverberating, as universities fear that patent holders will come out of the woodwork demanding royalties and impeding research"). See generally Natalie M. Derzko, *In Search of a Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 347 (2004); Tom Saunders, *Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261 (2003); Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12 (2003); Matt Fleischer-Black, *Schools Dazed*, THE AMERICAN LAWYER, Oct. 3, 2003, available at <http://www.law.com/jsp/article.jsp?id=1063212099232> (last visited Nov. 29, 2004); Stephen B. Maebius & Harold C. Wegner, *The Looming Crisis Over the Research Use Exception to Patent Infringement: What Madey Taught Duke University* (2003), available at http://library.lp.findlaw.com/articles/file/00156/008583/title/Subject/topic/Education%20Law_Colleges/Universities/filename/educationlaw_1_145 (last visited Oct. 3, 2004); Stephen B. Maebius & Harold C. Wegner, *Ruling on Research Exemption Roils Universities*, NAT'L L.J., Dec. 16, 2002, at C3.

⁹⁸ See Maebius & Wegner, *The Looming Crisis Over the Research Use Exception to Patent Infringement: What Madey Taught Duke University*, *supra* note 97; see also Maebius & Wegner, *Ruling on Research Exemption Roils Universities*, *supra* note 97.

The *Madey* dispute holds the potential to significantly change the research practices of the U.S. scientific community. Prior to *Madey*, anecdotal evidence suggested that most U.S. university researchers believed they were immune from patent infringement liability so long as their use of others' patented innovation could be characterized as research rather than commercialization.⁹⁹ By suggesting in no uncertain terms that even purely non-commercial research can infringe patents, the *Madey* decision dispels those assumptions and issues a jolting wake-up call that researchers and administrators in the U.S. university and non-profit regime ignore patent rights at their peril.

1. Facts

Doctor John M.J. Madey, a prominent physicist,¹⁰⁰ was formerly the director of the Free Electron Laser (FEL) Laboratory¹⁰¹ at Duke University, a prestigious private university.¹⁰² The FEL Lab conducts basic research into nuclear physics; it is not involved in commercialization of its scientists' discoveries.¹⁰³ Madey was the named inventor and owner of two

⁹⁹ See Fleischer-Black, *supra* note 97 (stating that *Madey* ruling "[c]ame as a surprise to many university researchers and their lawyers, who believed that an almost 200 year old experimental use exemption protected them from suits . . . as long as they were conducting research in the name of science—not profits—professors and doctoral students thought they were free to use patented tools"); see also Wysocki, Jr., *supra* note 97 (describing Duke's belief that in using the patented lasers, "it had a solid defense" by "following a time-honored 'experimental use' exception whereby academics, in the name of research, could infringe on patents so long as they didn't sell the results in commercial markets").

¹⁰⁰ See *Madey*, 266 F. Supp. 2d at 421 (describing Madey as "an internationally known scientist and scholar in the field of electromagnetic radiation and its uses").

¹⁰¹ See Duke University, *Free Electron Laser Laboratory*, at <http://www.fel.duke.edu/> (last visited Nov. 29, 2004).

¹⁰² Because Duke is not a state university, no Eleventh Amendment immunity is available. Compare Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627 (1999).

¹⁰³ See Duke University, *Free Electron Laser Laboratory: DFELL Research*, at <http://www.fel.duke.edu/research/> (last visited Nov. 29, 2004) (describing laboratory's ongoing research projects in areas of nuclear physics and condensed matter); see also *Madey*, 266 F. Supp. 2d at 423 (noting Madey's concession "that the overwhelming majority of [Duke]'s uses of the patented devices were for academic or experimental purposes"); *Madey v. Duke Univ.*, No. 1:97CV1170, 1999 U.S. Dist. LEXIS 21379, at *4 (M.D.N.C. Dec. 1, 1999) (noting that Madey's lawsuit claimed that Duke improperly revised plans for construction of FEL Lab facilities "in order to accommodate the research interests of other professors in the field of nuclear physics").

U.S. patents that read on certain laser equipment in the FEL lab.¹⁰⁴ Because the equipment was not owned by Duke,¹⁰⁵ Duke did not have an implied license to use the patented inventions based on ownership of the physical assets.¹⁰⁶

Having directed the Duke FEL Lab since 1989, Madey was removed from that position in the wake of disputes with the university over control of the lab.¹⁰⁷ After Madey's resignation on August 31, 1998 and subsequent departure for another university, his former FEL colleagues continued to operate the laser equipment covered by Madey's patents.¹⁰⁸ Madey thereafter sued the university for patent infringement, also asserting several state law claims stemming from the employment dispute.¹⁰⁹

¹⁰⁴ See *Madey*, No. 1:97CV1170, 1999 U.S. Dist. LEXIS 21379, at *2-3 (M.D.N.C. Dec. 1, 1999). Before Madey joined the Duke faculty, he had obtained U.S. Patent No. 4,641,103 for microwave electron guns. *Id.* at *3. While still at Stanford, Madey had also developed the Mark III, a Free Electron Laser that he constructed using federal research funds, his own funds, and assistance from Stanford. *Id.* After joining the Duke faculty, Madey and E.B. Szarmes in 1992 were issued U.S. Patent No. 5,130,994 for the "Free Electron Laser Oscillator for Simultaneous Narrow Spectral Resolution and Fast Time Resolution Spectroscopy." *Id.* Madey later claimed that he was the sole owner of the 5,130,994 patent. *Id.* When Madey left Stanford to go to Duke, Stanford released all ownership interests in the Mark III and other FEL equipment, leaving Madey as the sole owner subject to the rights of the United States government. *Id.*

¹⁰⁵ The district court stated the following:

[T]he Research Agreement between [Madey] and Defendant Duke University provided that [Madey] would become a tenured faculty member of the Department of Physics as outlined in the Duke University Faculty Handbook, that [Madey] would locate his research in the FEL Lab constructed by Duke to house [Madey]'s patented equipment, that [Madey] would assist the University in obtaining research grants and serve as Principal Investigator of said grants, that [Madey] would be Director of the FEL Lab, and that [Madey] would be permitted to pursue research of interest to him using the laboratory's equipment and facilities.

See *id.* at *3-4.

¹⁰⁶ See *supra* notes 20-24 and accompanying text concerning implied licenses and the first sale doctrine.

¹⁰⁷ See *Madey v. Duke Univ.*, No. 1:97CV1170, 1999 U.S. Dist. LEXIS 21379, at *5-7 (M.D.N.C. Dec. 1, 1999) (detailing Madey's disputes with university over control of FEL Lab).

¹⁰⁸ See *id.* at *6 (noting that Madey's lawsuit alleges "that Defendants continue to use his FEL equipment").

¹⁰⁹ *Id.* (noting that Madey "brought claims for infringement of the [4,641,103 and 5,139,994] patents (Counts I and II), conversion of property and misappropriation of business opportunities (Count III), violation of 29 U.S.C. §§ 621-634 (Count IV), violation of [Madey]'s civil rights as

A North Carolina district court granted Duke summary judgment of no patent infringement based in part on the common law doctrine of experimental use.¹¹⁰ The Federal Circuit vacated the summary judgment, concluding that Duke was not entitled to judgment of non-infringement as a matter of law and that disputed fact issues remained.¹¹¹ Although the case has not been finally resolved as of this writing,¹¹² the clear tenor of the Circuit's decision is that the university's research work was not eligible for the common law experimental use exemption from infringement liability.

2. Analysis

Ideally, the Federal Circuit would have resolved *Madey* on its rather narrow and unique facts. A reasonable interpretation is that the Duke FEL scientists were using the patented equipment as research tools,¹¹³ for which they are the primary, intended consumers.¹¹⁴ The Duke scientists were

protected under 42 U.S.C. § 1983 (Count V), constructive fraud (Count VI), and breach of contract (Count VII)").

¹¹⁰*Madey*, 307 F.3d at 1352 (stating "[a]fter discovery, the district court granted summary judgment in favor of Duke on the remaining claims. For a first set of alleged infringing acts, it held that the experimental use defense applied to Duke's use of Madey's patented laser technology.").

¹¹¹*Id.* at 1364 (concluding that district court "incorrectly found that there was no genuine issue of material fact upon which Madey could prevail").

¹¹²*See generally* *Madey v. Duke Univ.*, No. 1:97CV01170, 2004 U.S. Dist. LEXIS 19182 (M.D.N.C. Sept. 20, 2004) (on remand). In light of the Federal Circuit's "extremely narrow conception" of the experimental use defense, the district court was compelled to deny Duke's motion for summary judgment of noninfringement based on the defense. *Id.* at *25–26. The district court observed that, per the Federal Circuit's direction in *Madey*, its task on remand was to determine "whether Duke has established that its alleged use of [Madey's] patented inventions was not in keeping with its legitimate business as an educational institution but was instead solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at *23. Because Duke had previously conceded that "at least some of its uses of [Madey's] patents 'unmistakably further [its] legitimate business objectives, including educating and enlightening students and faculty participating in these projects,'" the district court concluded that Duke had failed to demonstrate entitlement to the experimental use defense as a matter of law. *Id.* at *23–24. Although the district court held open the possibility that Duke might "marshal additional evidence on the experimental use defense," the court considered this doubtful. *Id.* at *25. If such evidence existed, the court stated, Duke would be free to offer it at a subsequent trial. *Id.* at *25–26.

¹¹³*See* REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS, *supra* note 21 (defining research tools).

¹¹⁴*See* Maebius and Wegner, *The Looming Crisis Over the Research Use Exception to Patent Infringement: What Madey Taught Duke University*, *supra* note 97; *see also* Maebius & Wegner, *Ruling on Research Exemption Roils Universities*, *supra* note 97.

experimenting *with*, rather than experimenting *on*, the claimed laser inventions.¹¹⁵ Their research used the lasers to study aspects of nuclear physics;¹¹⁶ the scientists were not studying the inventions embodied in the lasers, nor seeking to improve the operation of the lasers or find a new use for them. On this basis alone, the case could have been decided as one not qualifying for the experimental use exemption.

The Federal Circuit did not see fit to resolve the case on the basis of the Duke researchers' ordinary consumer status. Rather, by contorting the legitimate business qualification of *Pitcairn*,¹¹⁷ the *Madey* court mapped an exceedingly limited role for the experimental use exemption in the university and non-profit research system. The Federal Circuit stated:

Our precedent clearly does not immunize use that is in any way commercial in nature. *Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications.* For example, 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

¹¹⁵ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 878 n.10 (Fed. Cir. 2003) (Newman, J., dissenting) (stating that *Madey* "concerned the use of a patented laser device for the purpose for which it was made, not research into understanding or improving the design or operation of the machine"), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

¹¹⁶ See Duke University, *Free Electron Laser Laboratory: DFELL Research*, at <http://www.fel.duke.edu/research/> (last visited Nov. 29, 2004).

¹¹⁷ See *Pitcairn v. United States*, 212 Ct. Cl. 168, 199 (1976). Subsequent judicial decisions have applied *Pitcairn's* "legitimate business" criterion but not to facts involving research and development in a university or non-profit setting. See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (explaining defendant, a generic drug manufacturer, conducted "unlicensed experiments . . . with a view to the adaption of the patented invention to [defendant's] business"), *superseded in part by* 35 U.S.C. § 271(e)(1) (2000); *Deuterium Corp. v. United States*, 19 Ct. Cl. 624, 633 (1990) (finding that "DOE's participation was not strictly intellectual experimentation, but development of technology and processes for commercial applications. At the EIC pilot plant, DOE engaged in a demonstration project, not mere experimentation. Moreover the objective of the demonstration project was to develop an economically feasible commercial application of the '506 patent."); *Moore U.S.A. Inc. v. Standard Register Co.*, 144 F. Supp. 2d 188, 198 (W.D.N.Y. 2001) (finding that defendant's unlicensed manufacture and use of business forms was "commercial, not experimental, in nature").

participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

In short, regardless 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 non-profit status of the user is not determinative.¹¹⁸

Given this broad statement of what activity is *not* exempted, it takes considerable imagination to hypothesize *any* real-world case of experimentation that would win immunity from infringement liability under the stringent standard of *Madey*. A qualifying university researcher, for example, would need to be conducting amusement, curiosity or philosophical inquiry research that is *not* in keeping with the legitimate business of her institution. It is reasonable to query whether *any* research being conducted on the premises of a university, with university-provided tools, would ever qualify for the exemption.¹¹⁹

The most troubling part of the Federal Circuit's opinion in *Madey* is the court's out-of-context reliance on an isolated statement from *Pitcairn*. The "legitimate business" language of *Pitcairn*, a case involving the government's unlicensed use of helicopters destined for military assignment, does not cleanly transport to the university research realm. The purported experiments by the government in *Pitcairn* were the necessary predicate of the government's subsequent use of the helicopters in its legitimate business of national defense. Before the helicopters could be relied on in the field, they had to be tested for their ability to lift heavy loads, to maneuver, and the like. The experiments conducted using the patented lasers in *Madey*, by contrast, were conducted in the course of

¹¹⁸*Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (emphases added), *cert. denied*, 539 U.S. 958 (2003).

¹¹⁹Tom Saunders has persuasively argued that *Madey* draws an improperly artificial line between experiments conducted by individuals and those conducted by university researchers. *See* Saunders, *supra* note 97, at 265. Under *Madey*, the "educating and enlightening" purposes of individual researchers are transformed into "business objectives" when their experiments are conducted on campus. *See id.*

carrying out basic physics research. They were not a mere predicate for some other clearly non-experimental use.

A close reader of the *Madey* decision might contend that the framework of rules set forth there is not as harsh as may be perceived at first glance. This approach would read *Madey* quite literally and focus on the apparent conjunctive nature of the rule that the Federal Circuit set forth there. Under this textualist reading of *Madey*, immunity from infringement for research use of patented inventions will not be stripped unless *both* of two prongs are met: (1) the research is “in furtherance of the alleged infringer’s legitimate business”;¹²⁰ and (2) the research “is *not solely* for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”¹²¹

Applying this two-pronged literal interpretation, the result in *Madey* might be explained as primarily turning not on the interpretation of scientific research as falling within the university’s legitimate business, but rather on a perceived failure of Duke to meet the second, solely for amusement, curiosity or philosophical inquiry prong. Under this view, Duke really lost because its researchers were not conducting their research for strictly philosophical inquiry.¹²² Rather, the argument follows, their work involved some degree of commercialization.

Even accepting arguendo this reading of *Madey*,¹²³ the facts of record simply do not support a Duke loss under it. Before the district court, *Madey* had argued that Duke’s research in the FEL lab was commercial in its character and intent.¹²⁴ The district court found *Madey*’s purported “evidence” to be “mere speculation.”¹²⁵ The Federal Circuit did not disturb

¹²⁰ *Madey*, 307 F.3d at 1362.

¹²¹ *Id.* (emphases added).

¹²² Recall that the early experimental cases used philosophical to mean natural philosophy which translated more broadly as science or scientific. Thus, philosophical inquiry should be understood as meaning scientific inquiry. See *supra* Part II.C.; *supra* note 44.

¹²³ If *Madey* does in fact adopt a two-pronged test, i.e., “A and not B,” it is based on a misreading of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), *superseded in part by* 35 U.S.C. § 271(e)(1) (2000). The *Roche* court, after discussing *Pitcairn*’s “legitimate business” criterion, concluded that Bolar’s unlicensed use of the drug patented by Roche was “solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Id.* at 863. The court treated use solely for business reasons as antithetical to the concept of use for “amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Id.* Because Roche’s use was solely for business reasons, it therefore could not be “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Id.* Thus in *Roche*, the test was essentially “A or not A” rather than “A and not B” as in *Madey*.

¹²⁴ *Madey*, 307 F.3d at 1355.

¹²⁵ *Id.* at 1356.

this finding of fact. Rather, the Federal Circuit concluded that the lower court had erred as a legal matter in shifting the burden of proof to Madey to disprove that Duke's use was experimental.¹²⁶

A better way to view the outcome in *Madey* is that the FEL researchers' work simply was not of the nature eligible for immunity as solely philosophical inquiry, *i.e.*, purely scientific inquiry within Story's formulation. This is because the FEL work involved experimenting *with*, not *on*, the patented lasers. The lasers are research tools and the Duke scientists are the ordinary consumers or intended purchasers of such tools. Thus, to deny Madey his right to exclude would deprive him of his just reward for having invented the laser equipment used by the FEL researchers. This approach more cleanly resolves the case without having to determine whether the FEL experiments were in the legitimate business of Duke.

For better or worse, however, it is the legitimate business dictum of *Madey* that has garnered the attention of not only the university research community but also the U.S. Supreme Court. Duke's petition for certiorari contended that, in view of the Federal Circuit's broad statements in *Madey* pertaining to the legitimate business of the accused infringer, no research institution would ever be eligible for the protections of the experimental use defense, because all such institutions are in the business of conducting research and development.¹²⁷

Duke further argued in its certiorari petition that in the absence of a more robust experimental use doctrine, university research will be stunted by the combined effects of increasingly burdensome licensing demands of corporate patents owners; the transactions costs of licensing stacked patents; and the unavailability of non-exclusive licenses.¹²⁸

There is mounting evidence that supports Duke's argument. Universities have reported that in order to obtain licenses under corporate-owned patents, the universities must agree to comply with reporting requirements, assign improvements, and payment of reach-through royalties.¹²⁹ Recent scholarship also evidences the growing patent thicket

¹²⁶ *Id.* at 1361 (stating that it agreed with Madey "that the district court improperly shifted the burden to him").

¹²⁷ See Brief for the United States as Amicus Curiae at 10, *Duke Univ. v. Madey*, 538 U.S. 959 (2003) (No. 02-1007), available at <http://www.usdoj.gov/osg/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.html> (visited Sept. 25, 2004).

¹²⁸ See *id.*

¹²⁹ See Fleischer-Black, *supra* note 97 (noting that corporations have signed reach-through

through which universities must navigate.¹³⁰ The University of Iowa recently conducted an exercise to gauge the transactions costs associated with formally seeking freedom to operate for the research work of a university laboratory staffed by a handful of scientists who study rare ocular disease; the university spent \$24,000 in contacting seventy-one individuals, none of whom sought royalties for the university's possible use of their technology.¹³¹ Some commentators foresee a “tragedy of the anti-commons” in biotechnology patenting,¹³² although this dire outlook is not universally shared by all members of the university technology transfer community.¹³³

Although it ultimately denied certiorari, the Supreme Court took sufficient interest in the *Madey* case to invite the Solicitor General to

licenses with universities, which can give the corporations rights to control down-stream products that may be developed through the university's technology, and predicting that after *Madey*, corporations are sure to demand more such reach-through rights). Some corporations are asking for complete ownership of the innovations made by university professors, while others are demanding pre-approval of professors' publication of research results. *See id.* Certain corporations want universities to report “exactly who is conducting research with [the corporations' patented] tools, and what they are researching.” *Id.* (describing practice of E.I. du Pont de Nemours & Co.).

¹³⁰See Carl Shapiro, NAVIGATING THE PATENT THICKET: CROSS LICENSES, PATENT POOLS, AND STANDARD-SETTING (Competition Policy Center, Working Paper No. CPC00-011, 2000), available at <http://repositories.cdlib.org/iber/cpc/CPC00-011> (lasted visited Nov. 29, 2004) (noting the creation in key industries of a “patent thicket” of overlapping intellectual property rights that requires a firm to “hack its way through in order to actually commercialize new technology,” and asserting that the patent thicket problem is creating a patent system which is in “danger of imposing an unnecessary drag on innovation”); Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems With Patenting Research Tools*, 5 RISK 163, 168 (1994) (asserting that patents on research tools “can create obstacles to subsequent [research and development] and add to a thicket of rights that firms must negotiate their way past before they can get their products on the market”).

¹³¹See Wysocki, Jr., *supra* note 97.

¹³²See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); *see also* Mueller, *supra* note 8, at 7–8 (cataloguing instances of access problems in biotechnology patenting to conclude that “[t]he anti-commons theory is far from a merely academic construct”).

¹³³See, e.g., May Mowzoon, Comment, *Access Versus Incentive: Balancing Policies in Genetic Patents*, 35 ARIZ. ST. L.J. 1077, 1101 (2003) (contending that biotechnology industry “has resolved the problems of commercial access and patient access [to innovation protected in gene-related patents] through the use of contracts”).

submit an *amicus curiae* brief.¹³⁴ In recommending that the petition be denied, the Solicitor stressed the unique factual and procedural nature of the case.¹³⁵ *Madey* originated with an employment dispute, and the case was still in an interlocutory posture because the Federal Circuit had merely vacated the grant of summary judgment to Duke.¹³⁶

The Solicitor General also contended that the judicial creation of a blanket experimental use exemption for universities would ignore the rise of university patenting activity and collaborative university-corporate research endeavors. There is no dispute that since the 1980 enactment of the Bayh-Dole Act,¹³⁷ university patenting activity, both on the obtaining and enforcing sides, has increased dramatically. A 2002 survey by the Association of University Technology Managers (AUTM) reports that in 2002, 7,741 new U.S. patent filings were made by the 219 United States and Canadian universities participating in the survey, a marked increase from the 1,643 new applications filed by the 130 respondents in AUTM's first survey in 1991.¹³⁸ In 2002, some 218 respondent universities received adjusted gross income of \$1.267 billion from patent licenses and options.¹³⁹ In addition to exploiting their patents through licensing, several prestigious U.S. universities have recently asserted their patent rights in high-profile patent infringement litigation.¹⁴⁰ Hence, the argument that universities should be governed by the same rules as other players in the patent system is at least facially persuasive.

¹³⁴Brief for the United States as Amicus Curiae, *Duke Univ. v. Madey*, 538 U.S. 959 (2003), (No. 02-1007), available at <http://www.usdoj.gov/osg/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.html> (last visited Nov. 29, 2004).

¹³⁵*See id.* at 18.

¹³⁶*See id.* at 17.

¹³⁷Pub. L. No. 96-517, § 6(a), 94 Stat. 3019, 3019–28 (1980) (codified at 35 U.S.C. §§ 200-212) (2000).

¹³⁸*See* Association of University Technology Managers, *AUTM Licensing Survey: FY 2002*, at 11 (Table S-6), available at http://www.autm.net/index_ie.html (last visited Nov. 29, 2004).

¹³⁹*See id.* at 2 (Executive Summary).

¹⁴⁰For example, Columbia University has recently come under attack for seeking licensing fees from major biotechnology firms under a patent the university obtained in the 1970s on a technique “useful for genetically engineering animal cells to make them produce biotech drugs like interferon, which is used to treat multiple sclerosis.” Andrew Pollack, *3 More Biotech Firms File Suit Against Columbia Over Patent*, N.Y. TIMES, July 16, 2003, at B2. Columbia’s first patent on this technology, which issued in 1983, was “licensed by numerous companies and became one of the most lucrative ever held by a university, earning royalty payments of about \$100 million a year in its final years.” *Id.* Several major biotechnology firms have instituted federal court litigation to challenge the validity of the Columbia patent. *See id.*

The more persuasive point in the Solicitor General's argument, however, is that the more robust experimental use exemption sought by Duke represents a fundamental alteration of the patent bargain, and that this and other policy concerns raised by Duke's petition are better suited for legislative rather than judicial consideration.¹⁴¹ The Solicitor General conceded that the academic and scientific community had "raised weighty concerns about the potential effect of the patent laws on academic research."¹⁴² However, he contended, the courts should not engage in the kind of nuanced policy balancing necessary to craft a meaningful experimental use defense. Although the courts are equipped to do so under certain circumstances, here such an exercise would be difficult and ungainly.¹⁴³ The Solicitor General found it "improbable that a 190-year-old, judge-made defense with little rooting in any statutory text could anticipate the challenges of the modern academic and research environment and adequately accommodate the competing policy concerns raised by the parties in [*Madey*]."¹⁴⁴

The Federal Circuit refused in *Madey* to directly confront these policy concerns. Nor did it take the opportunity to do so in *Integra*, discussed in the following section. The Federal Circuit thus seems to share the Solicitor General's assessment of the courts' limited ability to craft a meaningful experimental use doctrine. Congressional action is necessary.

B. *Integra v. Merck KGaA*

The facts of *Integra Lifesciences I, Ltd. v. Merck KGaA*¹⁴⁵ make it a far more compelling candidate for application of the common law experimental use doctrine than those of *Madey*. The panel majority in *Integra* did not consider the common law experimental use issue to be properly raised on appeal, however, a conclusion sharply disputed by the dissent. Although the majority's opinion includes some sideline commentary on the issue, it

¹⁴¹ Brief for the United States as Amicus Curiae, *Duke Univ. v. Madey*, 538 U.S. 959 (2003) (No. 02-1007), available at <http://www.usdoj.gov/osg/briefs/2002/2pet/6invt/2002-1007.pet.ami.inv.html> (last visited Nov. 29, 2004).

¹⁴² *Id.* at 15.

¹⁴³ *See id.* at 16.

¹⁴⁴ *Id.*

¹⁴⁵ *See generally* 331 F.3d 860 (Fed. Cir. 2003), amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

resolves on other grounds¹⁴⁶ what could have been a key test case for resolution of questions concerning the experimental use exception. Whether the *Integra* case receives further judicial consideration now awaits Supreme Court consideration.¹⁴⁷

1. Facts

Integra Corporation owned several U.S. patents directed to peptides that contained RGD sequences of amino acids (RGD refers to the amino acid sequence of arginine—glycine—aspartic acid).¹⁴⁸ The patents asserted that

¹⁴⁶The *Integra* majority's primary focus was whether Merck's activities fell within the statutory safe harbor of 35 U.S.C. § 271(e)(1), a question beyond the scope of this Article. Section 271(e)(1) was added to the Patent Act in 1984 in order to overrule legislatively the specific ruling of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, as part of the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), popularly known as the Hatch-Waxman Act. The § 271(e)(1) safe harbor provides that use of a patented invention solely for purposes reasonably related to gathering data to support an FDA application for generic versions of previously approved drugs (i.e., an Abbreviated New Drug Application, or ANDA) is not patent infringement. See Mueller, *supra* note 8, at 25–27. In sharp contrast with the common law based experimental use exemption addressed in this Article, the § 271(e)(1) statutory safe harbor expressly exempts activity that is clearly commercial in purpose; i.e., government-mandated tests and data gathering that are a necessary precursor to commercial exploitation of the generic equivalent. The Federal Circuit clarified in *Madey* that the common law doctrine was not impacted by the enactment of 35 U.S.C. § 271(e)(1). See *Madey v. Duke Univ.*, 307 F.3d 1351, 1356 n.6 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

¹⁴⁷A petition for certiorari from the Federal Circuit's decision in *Integra* was filed in the Supreme Court on March 2, 2004. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237). On October 4, 2004, the Supreme Court asked the Solicitor General to file a brief expressing the government's views, as the court had previously requested in *Madey*. Brief for the United States as Amicus Curiae, *Merck KGaA v. Integra Lifesciences I*, 125 S. Ct. 237 (2004) (No. 03-1237), *available at* <http://supct.law.cornell.edu/supct/html/100404.ZOR.html>. The facts of *Integra* make it a more compelling case for the experimental use defense, but the Federal Circuit's resolution of *Integra* on the § 271(e)(1) issue may preclude the Supreme Court from addressing the common law experimental use doctrine.

¹⁴⁸See U.S. Patent No. 5,695,997 (issued Dec. 9, 1997) (describing methods for altering cell attachment activity of cells and for blocking cell surface receptors which mediate cell attachment activity by contacting the cells or cell surface receptors with a peptide including RGD_X, where X is an amino acid); U.S. Patent No. 4,988,621 (issued Jan. 29, 1991) (claiming methods comprising contacting the cells with a solution containing RGD sequence for promoting animal cell aggregation and inhibiting animal cell proliferation, and also methods for the detachment of cell lines from their substratum); U.S. Patent No. 4,879,237 (issued Nov. 7, 1989) (claiming

the use of these peptide sequences, through attachment to certain avB3 cell surface receptors, resulted in improved wound healing and adhesion of prostheses.¹⁴⁹ Integra was unsuccessful in commercializing the patents, however.¹⁵⁰

Defendant Merck KGaA, a German firm, began in 1988 to fund research work lead by Dr. David Cheresh at Scripps Research Institute, a non-profit, public benefit corporation located in California.¹⁵¹ Cheresh was a highly-recognized, tenured professor in Scripps' Immunology department.¹⁵² By screening and evaluating several different RGD peptides, Cheresh and his team found that use of certain cyclic forms of the RGD peptides¹⁵³ was effective to inhibit the growth of new blood vessels,

methods for controlling and preventing the Arg-Gly-Asp attachment of cells to substratum, as well as methods to harvesting cells by contacting the cells with a polypeptide consisting of RGD sequences, and for detaching cells from a substrate by contacting the cells with a solution containing a polypeptide consisting of Arg-Gly-Asp-Y); U.S. Patent No. 4,792,525 (issued Dec. 20, 1988) (describing a polypeptide including RGD sequences which alters the cell attachment activity of cells; also claiming methods to promote cell attachment activity utilizing the invention on a substrate, and also a method to inhibit undesirable cell attachment to a substrate and to enhance the phagocytic activity of the cells); U.S. Patent No. 4,789,734 (issued Dec. 6, 1988) (describing a method of isolating cell surface receptors which selectively bind to a peptide containing RGD sequence).

¹⁴⁹See U.S. Patent No. 5,695,997 (issued Dec. 9, 1997) (stating that the practical application can be found in "the derivatization of various prosthetic materials to promote bonding with surrounding tissues"); U.S. Patent No. 4,988,621 (issued Jan. 29, 1991) (stating that the invention is useful in the production of cell lines for research in diagnosis and therapy); U.S. Patent No. 4,879,237 (issued Nov. 7 1989) (noting that the invention is applicable to "the production of cell lines for research, in diagnosis and therapy"); U.S. Patent No. 4,792,525 (issued Dec. 20, 1988) (stating "invention is useful in surgery and therapeutic reconstruction and treatment of injuries"); U.S. Patent No. 4,789,734 (issued Dec. 6, 1988) (noting that the receptors would help "the bonding of a prosthesis, such as artificial skin"). See also *Integra*, 331 F.3d at 862-63 ("The RGD peptide sequence promotes cell adhesion to substrates . . . [B]y interacting with avB3 receptors on cell surface proteins called integrins. . . . In theory, inducing better cell adhesion and growth should promote wound healing and biocompatibility of prosthetic devices.").

¹⁵⁰See *Integra*, 331 F.3d at 873 (Newman, J., dissenting) (noting that the inventors failed to develop a commercially viable product, at which point the patents were sold to Integra).

¹⁵¹See *Integra Lifesciences I, Ltd. v. Merck KGaA*, No. 96-CV-1307, 1998 U.S. Dist. LEXIS 23215, at *2-3 (S.D. Cal. Dec. 22, 1998).

¹⁵²See *Integra Lifesciences I, Ltd. v. Merck KGaA*, No. 96-CV-1307, 1999 U.S. Dist. LEXIS 10380, at *2-3 (S.D. Cal. Feb. 9, 1999).

¹⁵³A hotly disputed issue in the ensuing patent litigation was whether Integra's patent claims were literally broad enough to encompass cyclic as well as linear forms of the RGD peptides. See *Integra*, 331 F.3d at 868. The Federal Circuit agreed with the district court that the term peptide is understood in the art to encompass differing structural forms of the peptide. *Id.* Based on its

and thus starve cancerous tumors.¹⁵⁴ Hence, Cheresch had discovered a new use for the peptides which could potentially confer a very significant public health benefit.¹⁵⁵

In 1995, Merck substantially increased funding for Scripps to identify potential drug candidates by testing efficacy, specificity, and toxicity of numerous RGD peptides.¹⁵⁶ After this testing, Scripps identified a particular cyclic RGD peptide as the best candidate for clinical development, in 1997.¹⁵⁷ In 1998, Scripps filed with the Food and Drug Administration an Investigatory New Drug Application on this RGD peptide.¹⁵⁸

After learning of the Merck-Scripps collaboration, Integra in 1996 sued Merck, Scripps, and Cheresch for patent infringement. Integra sought to

reading of the specification as describing both structural forms of peptide, the Federal Circuit refused to limit the claim term peptide to linear structures only, as suggested by *Merck*. *See id.*

¹⁵⁴ *See Integra*, 1998 U.S. Dist. LEXIS 23215 at *3. The court explained the following:

Since the late 1980's Dr. Cheresch's research has focused on integrins, proteins that span the cell membrane and serve as receptors on the surface of certain living cells. Among the compounds studied by Dr. Cheresch are monoclonal antibodies, linear peptides and homodetic cyclic peptides containing the amino acid sequence Arginine-Glycine-Aspartic Acid ("ARG-GLY-ASP" or "RGD"). Dr. Cheresch has allegedly discovered that by binding various molecules to receptors on the surface of certain cells, the growth of new blood vessels can be inhibited.

Id.

¹⁵⁵ A similar approach has been followed by biotechnology giant Genentech, which recently obtained FDA approval to market its anticancer drug Avastin. *See* Andrew Pollack, *F.D.A. Approves Cancer Drug from Genentech*, N.Y. TIMES, Feb. 27, 2004, at C1. The Genentech drug works by starving cancerous tumors. The author explained the following:

Avastin is the first drug to be approved that works by choking off the blood vessels that provide a tumor with oxygen and nutrients. That idea for fighting cancer, first proposed by Dr. Judah Folkman of Harvard and Children's Hospital Boston more than 30 years ago, has been difficult to get to work in practice.

Id.

¹⁵⁶ *See Integra*, 331 F.3d at 873 (Newman, J., dissenting). After Cheresch identified the inhibitory effect on blood vessels of Merck-provided peptide EMD 66203, Merck increased funding to study and synthesize various structures and compositions of cyclic RGD peptides. *See id.* at 873-74.

¹⁵⁷ *Id.* at 874 (explaining that in 1997, Scripps/Merck selected peptide EMD 121974, a derivative of EMD 66203, as the best candidate for clinical trials).

¹⁵⁸ *Id.*

enjoin any further work on Cheresch's discovery and to collect damages for the underlying research.¹⁵⁹

Merck responded by asserting that Integra's patents were invalid¹⁶⁰ and even if valid, then not infringed by Cheresch's use of the cyclic form of the RGD peptides.¹⁶¹ If the patents were valid and infringed, Merck contended, then the Cheresch-led work at Scripps was exempt under either (1) the common law experimental use doctrine or (2) the statutory safe harbor of 35 U.S.C. § 271(e)(1).¹⁶²

The *Integra* case was tried to a jury, which considered whether Cheresch's work from 1995-98 was immunized by the § 271(e)(1) safe harbor.¹⁶³ The district court did not instruct the jury on Merck's common law experimental use defense,¹⁶⁴ although the court previously had found a 1994 Cheresch experiment non-infringing under the common law defense.¹⁶⁵ The jury found the patents not invalid and infringed, and awarded Integra \$15 million in damages.¹⁶⁶

On appeal, the Federal Circuit panel split two-one in favor of Integra. In an opinion authored by Judge Rader and joined by Judge Prost, the majority noted that (1) the common law experimental use defense was not

¹⁵⁹ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, No. 96-CV-1307, 1999 U.S. Dist. LEXIS 10380, at *3 (S.D. Cal. Feb. 9, 1999). Integra sought damages from Merck and the issuance of an injunction against further unlicensed use of the peptides by Scripps and Cheresch. See *Integra*, 331 F.3d at 863.

¹⁶⁰ Merck obtained a summary judgment of invalidity under 35 U.S.C. § 102(b) on claim 2 of Integra's '621 patent. See *Integra*, 1999 U.S. Dist. LEXIS 10380, at *22-23. The Federal Circuit affirmed the invalidity ruling. *Integra*, 331 F.3d at 862.

¹⁶¹ See *Integra*, 331 F.3d at 868-69. Accused infringer Merck contended that the claims of the '525, '997, and '237 patents should be interpreted to encompass only the linear form of the RGD peptide, such that Merck's use of the cyclic form of the peptide did not infringe. See *id.* at 868. Merck separately argued that in the course of arguing the patentability of claims in a later-filed, unrelated application, Integra had admitted that the '525 and '997 patents did not teach cyclic peptides. See *id.* Hence, Merck contended, Integra was estopped from asserting the broader, cyclic interpretation in the case at bar. See *id.* at 868-69. The Federal Circuit rejected these arguments and affirmed the district court's broad construction of the claims as encompassing the cyclic as well as linear forms of the RGD peptides. See *id.* at 869.

¹⁶² See *id.* at 863 n.2.

¹⁶³ See *id.* at 863-64.

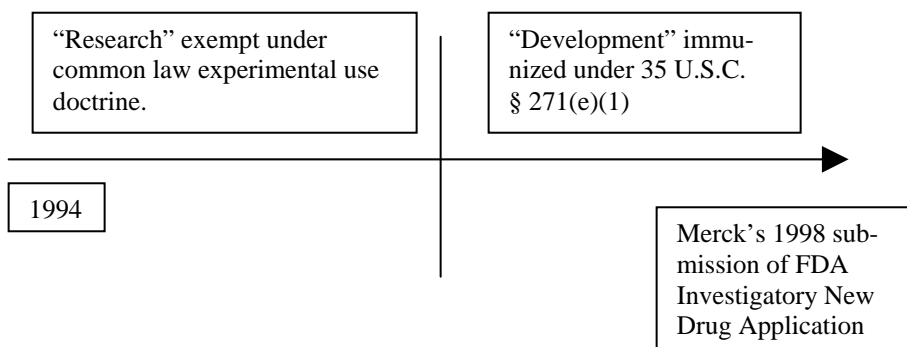
¹⁶⁴ See *id.* at 863-64 n.2.

¹⁶⁵ See *id.* at 878 (Newman, J., dissenting). No district court opinion explaining this finding has been published.

¹⁶⁶ See *id.* at 869. The jury found that Merck had infringed four of the patents in suit and awarded damages in the form of a reasonable royalty totaling \$15 million.

on appeal,¹⁶⁷ and (2) the Scripps research was general drug discovery, too unrelated or removed from FDA data gathering and submission to fall within the § 271(e)(1) safe harbor.¹⁶⁸ Thus, Merck infringed and that part of the district court's decision entered on the jury's infringement verdict was affirmed.

Dissenting Judge Newman charged that the majority had improperly ignored the common law experimental use defense raised by Merck. She contended that Scripps' basic research was within the common law exemption.¹⁶⁹ When that basic research crossed the line into development, the entirety of the work was immune from liability because the § 271(e)(1) safe harbor took up where the common law exemption left off. Judge Newman's dissenting position is depicted as shown below:



Viewing the question of a common law experimental use exemption as properly preserved on appeal, Judge Newman offered an extensive defense of it.¹⁷⁰ Under a proper interpretation of the research exemption, Judge Newman urged, the subject matter of patents may always be studied without liability.¹⁷¹ Such study is always permissible if made in order to

¹⁶⁷ *Id.* at 863 n.2. The *Integra* majority noted that the issue given to the jury was whether the defendant's pre-clinical experimentation fell within the safe harbor provided in 35 U.S.C. § 271(e)(1) (2000). *Id.* It concluded that "the common law experimental use exception is not before the court in the instant case." *Id.*

¹⁶⁸ *Id.* at 866.

¹⁶⁹ *See id.* at 874 (Newman, J., dissenting).

¹⁷⁰ *See id.* at 878. Judge Newman pointed to the district court's ruling that the common law exemption to infringement applied to a single Scripps experiment conducted in 1994. *See id.*

¹⁷¹ *See id.* at 875. In Judge Newman's view, information contained within patents is a primary source of scientific knowledge, the study of which is necessary for further progress in science and technology. *See id.* She observed that "the patent system both contemplates and

understand a patented invention, to improve it, to find a new use for it, to modify it, or to design around it.¹⁷² Only when the study of an invention crosses the line from research to development does the patent owner's right to exclude come into effect, under Judge Newman's calculus.¹⁷³

Although Judge Newman offered the "research" versus "development" distinction as a proposed dividing point between exempted and infringing uses, she declined to offer a specific test for distinguishing the two types of activity. Rather, Judge Newman observed that the following exists:

[A] generally recognized distinction between "research" and "development," as a matter of scale, creativity, resource allocation, and often the level of scientific/engineering skill needed for the project; this distinction may serve as a useful divider, applicable in most situations. Like "fair use" in copyright law, the great variety of possible facts may occasionally raise dispute as to particular cases. However, also like fair use, in most cases it will be clear whether the exemption applies.¹⁷⁴

Judge Newman's *Integra* dissent also recognized that the experimental use exemption must have limits in order to preserve incentives for innovation. If derogations from exclusivity are too severe, the economic value of a patent can be reduced to the point where it no longer serves its innovation-inducing function. Invoking notions of sequential or cumulative innovation, i.e., a recognition that most innovation builds upon earlier work,¹⁷⁵ Judge Newman recognized that "[i]t is the patentee who opened

facilitates research into patented subject matter," emphasizing that the study of patented information is not only permitted but encouraged in order to achieve scientific and technological advancement. *See id.* at 875–76.

¹⁷² *See id.* at 875.

¹⁷³ *See id.* at 876.

¹⁷⁴ *Id.* (citations omitted).

¹⁷⁵ *See* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 *BERKELEY TECH. L.J.* 813, 816, 853 (2001) (noting potential problems in negotiation of licenses between biotechnology firms that obtain patents on upstream research results and pharmaceutical firms that require use of the patented inventions in their own research and suggesting that patents on upstream inventions should be limited in their scope to encourage and preserve competition); Jerry R. Green & Suzanne Scotchmer, *On the Division of Profit in Sequential Innovation*, 26 *RAND J. ECON.* 1, 20 (1995) (noting that many products are the result of numerous improvements on previous inventions and stressing the importance of providing the first innovator with sufficient profits to maintain investment incentives while limiting the life of the initial patent); Suzanne Scotchmer, *Standing on the Shoulders of Giants:*

the door by providing the initial knowledge, without which there would be nothing to improve. . . . It is the initial inventor whose rights must receive primary consideration in an effective patent law, for the public interest starts with the threshold invention.”¹⁷⁶ Although the Scripps/Cheresh use of the Integra peptides for research purposes should have been exempt from liability in Judge Newman’s view, she acknowledged that “the threshold invention may (as here) exact tribute from or enjoin commercial and pre-commercial activity.”¹⁷⁷

The *Integra* majority (Judges Rader and Prost) responded to the merits of Judge Newman’s view of the experimental use exemption, despite their assertion that the common law experimental use defense was not before the court on appeal.¹⁷⁸ The majority noted that “the Patent Act does not include the word ‘experimental,’ let alone an experimental use exemption from infringement.”¹⁷⁹

Cumulative Research and Patent Law, 5 J. ECON. PERSP. 29, 30–31 (1991) (identifying patent breadth as primary means of adequately rewarding first generation inventors for their technological foundation and second generation innovators for their improvements and noting first generation inventors will only have sufficient incentive to invest if they “receive some of the social surplus provided by the second generation products” but concluding that second generation inventors must also be able to retain enough profit so as to encourage innovation at improvement stage).

¹⁷⁶ *Integra*, 331 F.3d at 876 (Newman, J., dissenting).

¹⁷⁷ *Id.*

¹⁷⁸ *See id.* at 863 n.2.

¹⁷⁹ *Id.* Contrary to the *Integra* majority’s assertion, the word “experimental” appears three times in the Patent Act, albeit not in connection with any exemption from liability for infringement of a utility patent. *See* 35 U.S.C. § 156(g)(5)(B)(i) (2000) (for purposes of patent term extension, defining regulatory period for a veterinary biological product as including “the period beginning on the date the authority to prepare an *experimental* biological product under the Virus-Serum Toxin-Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act”) (emphasis added); 35 U.S.C. § 201(b) (2000) (as part of Bach Dole Act codification, defining the term “funding agreement” as “any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of *experimental*, development, or research work funded in whole or in part by the Federal Government”) (emphasis added); *id.* § 201(b) (including within definition of “funding agreement,” “any assignment, substitution of parties, or subcontract of any type entered into for the performance of *experimental*, developmental, or research work under a funding agreement as herein defined”) (emphasis added).

The majority’s assertion that the Patent Act does not include an experimental use exemption from infringement, *Integra*, 331 F.3d at 863 n.2, is accurate if one treats the § 271(e)(1) safe harbor as outside the realm of experimental use in the sense of the common law exemption. To the extent that the unlicensed use of patented drugs for purposes of preparing FDA submissions is commercialization, this interpretation makes sense. *See Roche Prods., Inc. v. Bolar Pharm. Co.*,

The *Integra* majority invoked the current research tools debate to support its affirmation of the district court's decision that Cheresch's work was not exempt from infringement liability.¹⁸⁰ A research tool is generally understood as any resource commonly used by scientists in the laboratory to conduct research, and can include everything from a common chemical reagent to devices such as laboratory scales to mice or other laboratory animals genetically engineered for susceptibility to certain diseases.¹⁸¹ The

733 F.2d 858, 863 (Fed. Cir. 1984), (characterizing Bolar's use of patented drug to derive FDA required test data as having "not insubstantial commercial purposes"), *superseded in part* by 35 U.S.C. § 271(e)(1) (2000). It is contrary, however, to the legislative history of 35 U.S.C. § 271(e)(1), which compared that section to copyright's fair use exemption. *See* H.R. Rep. No. 98-857, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2714 (stating with respect to enactment of § 271(e)(1), "Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does.").

The only patent-related U.S. statute to specifically exempt research use of protected subject matter is the Plant Variety Protection Act (PVPA), 7 U.S.C. §§ 2401 et seq. (2000), which provides patent-like protection for sexually reproduced plant varieties. The PVPA provides 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." *Id.* § 2544 (titled "Research Exemption").

¹⁸⁰*See Integra*, 331 F.3d at 867. Although the *Integra* majority discussed research tools primarily in the context of explaining why the 35 U.S.C. § 271(e)(1) safe harbor does not immunize the Scripps-Merck activities, *see id.*, the vitiation argument as applied to patented research tools is equally relevant to analysis of the common law experimental use exemption.

¹⁸¹The NIH defines research tools as "the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as 'end products.'" REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS, *available at* <http://www.nih.gov/news/researchtools/#background> (June 4, 1998). Research tools include "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software." *Id.*

Patents on research tools have been the subject of significant recent commentary. *See* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 331-32 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (finding that drug discovery has not been impeded by increased incidence of patents on research tools because firms and universities have been able to develop working solutions to access problem); Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Medicine*, 66 LAW & CONTEMP. PROBS. 289 (2003) (observing problems that research tool patents held by publicly funded institutions can create and proposing that research sponsors should be able to restrict patenting when it would otherwise hinder subsequent research); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals*, 2001 U. ILL. L. REV. 173, 192-94 (2001) (contending that patents on early stage genomic research may impede progression of clinical development because of difficulties faced by pharmaceutical

Scripps work employed the patented RGD peptides as research tools to facilitate identification of new therapeutics, the majority contended.¹⁸² Under this view, Cheresch and his colleagues were ordinary consumers of such tools. Immunizing the Scripps-Merck activities from liability would effectively vitiate the statutory rights of owners of biotechnology research tool patents to exclude unlicensed use of such tools.¹⁸³

Judge Newman dismissed the majority's research tools argument as a red herring, at least as applied to Cheresch's work with the RGD peptides. She contended that "[t]he RGD-containing peptides of the Integra patents are not a 'tool' used in research, but simply new compositions having certain biological properties."¹⁸⁴ The syntheses and evaluations of new RGD peptides by Cheresch "were not use of the Integra products as a research tool."¹⁸⁵ To illustrate her point, Judge Newman contrasted the peptides at issue in *Integra* with the laser devices used in *Madey*. In her view, *Madey* "concerned the use of a patented laser device for the purpose for which it was made, not research into understanding or improving the design or operation of the machine."¹⁸⁶ *Madey*'s facts "do not invoke the common law research exemption, despite the broad statement in that opinion."¹⁸⁷

2. Analysis

The experimenting *on* versus experimenting *with* dichotomy offered by dissenting Judge Newman in *Integra* has been widely accepted by commentators as an important, if not entirely determinative, factor in

developers in negotiating for use of the "research tools"); Heller & Eisenberg, *supra* note 132 (discussing anticommons problem faced by inventor who requires access to multiple upstream patented research tool inventions in order to create a single useful product); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 224–25 (1988) (suggesting that if used too broadly, experimental use exception to patent infringement would eviscerate the value of patents on research tools and decrease the incentive to invent them).

¹⁸² See *Integra*, 331 F.3d at 872 n.4.

¹⁸³ See *id.* at 867.

¹⁸⁴ *Id.* at 878 (Newman, J., dissenting).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at 878 n.10.

¹⁸⁷ *Id.*

assessing experimental use.¹⁸⁸ When analyzing whether a particular use of a patented invention is exempt as experimentation, courts should distinguish between the use of patented inventions to study those very inventions, and the use of patented inventions to develop other, different inventions. Although not without some difficulties at the margin, the exercise of distinguishing the former, experimenting *on* or research into activity, from the latter experimenting *with* or research with activity, forms a critical foundation for any experimental use analysis.¹⁸⁹

Application of the experimenting *on* versus experimenting *with* distinction to the facts of *Integra*,¹⁹⁰ as well as to those of *Madey*,¹⁹¹

¹⁸⁸ See REPORT OF THE NATIONAL INSTITUTES OF HEALTH WORKING GROUP ON RESEARCH TOOLS App. D, available at <http://www.nih.gov/news/researchtools/appendd.htm> (June 4, 1998). The NIH Report states the following:

Foreign patent systems that recognize a research exemption typically distinguish between experimenting *on* a patented invention—i.e. using a patented invention to study the underlying technology or perhaps to invent around the patent, which is what the exemption covers—and experimenting *with* a patented invention to study something else, which the exemption does not cover. So construed, the exemption would not be available for researchers who make use of patented research tools in the course of investigating something else, as opposed to those who are studying the research tools themselves. This is a sensible distinction. It is difficult to imagine how a broader research exemption could be formulated without effectively eviscerating the value of patents on research tools. Researchers are ordinary consumers of patented research tools, and if these consumers were exempt from infringement liability, the patent holder would have nowhere else to turn to collect patent royalties. An excessively broad research exemption could eliminate incentives for private firms to develop and disseminate new research tools, which could on balance do more harm than good to the research enterprise.

Id. See also Eisenberg, *supra* note 39, at 1074. In her seminal article on the experimental use doctrine, Professor Eisenberg recommended that research should be exempt from liability if it is experimenting on a patented invention in order to check the adequacy of the patent's specification or the validity of its claims but should not be exempt if the researcher is an ordinary consumer of the patented invention. See *id.* at 1078.

¹⁸⁹ See Mueller, *supra* note 8, at 40 n.202 (questioning whether design-around activity, i.e., activity intended to produce a non-infringing alternative to the patented invention, can be clearly characterized as “experimenting on” the patented invention rather than “experimenting with” it).

¹⁹⁰ See generally *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

¹⁹¹ See generally *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), cert. denied, 539 U.S. 958 (2003).

strongly supports Judge Newman's view of the proper outcomes in those two cases. Dr. Cheresch and his Scripps colleagues in *Integra* experimented on the patented RGD peptides in order to discover a new use for those peptides; that new use (i.e., starving cancerous tumors) may ultimately lead to the development of important new therapeutics. In contrast, the Duke FEL researchers in *Madey* were experimenting with the patented laser devices in the ordinary course of conducting their physics research; they were not investigating any new use for the lasers, nor were they attempting to modify, improve, or design around the lasers.

Less uniformly accepted by commentators than the experimenting *on* versus experimenting *with* dichotomy is Judge Newman's broader assertion in *Integra* that it is not patent infringement to study "[t]he subject matter of patents . . . in order to understand it, or to improve upon it, or to find a new use for it, or to modify or 'design around' it."¹⁹² This claim must be understood in the broader context of Judge Newman's entire opinion. Judge Newman explains that in the *Integra* factual context of experimenting on a patented invention in order to find a new use for it "while [a] threshold invention may (as here) exact tribute from or enjoin commercial and pre-commercial activity, the patent does not bar all research that precedes such activity."¹⁹³ Thus, study of a patented invention, including attempts to develop a new use for it or to design around it, remains exempt from infringement liability until the primary purpose of the activity becomes commercial. When commercial purpose becomes the primary motivator for the activity, then the patentee's right to exclude comes into force. The patentee, from this point forward, can exact tribute in the form of royalties, or possibly even enjoin further activity.

Judge Newman's variegated view of experimental use comports with a 1992 resolution on experimental use issued by the International Association for the Protection of Intellectual Property (AIPPI),¹⁹⁴ the "world's leading non-governmental organization for research into, and formulation of policy for, the law relating to intellectual property."¹⁹⁵ The AIPPI position is that

[e]xperimental use includes any use of the patented invention to an extent appropriate to experimentation (as

¹⁹² *Integra*, 331 F.3d at 875 (Newman, J., dissenting).

¹⁹³ *Id.* at 876.

¹⁹⁴ See *Experimental Use as a Defense to a Claim of Patent Infringement*, AIPPI YEARBOOK 1992/III, at 282–83 (copy on file with author) [hereinafter *AIPPI Resolution*].

¹⁹⁵ Homepage of the International Association for the Protection of Intellectual Property, at <http://www.aippi.org/index.html> (last visited Nov. 29, 2004).

opposed to commercial use) which is for the purpose of improving the invention or making an advance over the invention or finding an alternative to the invention, but not the commercial exploitation of the subject of any improvement or advance.¹⁹⁶

Hence, basic research remains immunized, even though it involves the use of another's patented invention. The patentee's right to a reward accrues only when the fruits of that research are commercialized.

Judge Newman posits a "research" versus "development" divider for establishing a boundary between that activity for which a patentee may justly exact tribute and the earlier activity for which it may not.¹⁹⁷ Although Judge Newman does not expressly define when research ends and development begins, she contends that the terms have a common meaning and understanding in the technologic and scientific community.¹⁹⁸ Judge Newman would apparently include within the sphere of development those uses of patented inventions that are for pre-commercial, as well as commercial purposes.¹⁹⁹

Judge Newman's reliance on the existence in the scientific and technologic community of a general consensus on the meaning of the terms research and development is well founded. For example, the National Science Foundation (NSF) has promulgated definitions of research and development that are used by the NSF, the Office of Management and Budget, and United States federal agencies.²⁰⁰ The NSF defines research as "systematic study directed toward fuller scientific knowledge or understanding of the subject studied."²⁰¹ The NSF definitions further divide research between basic research, which has the objective "to gain more complete knowledge or understanding of the fundamental aspects of phenomena and of observable facts, without specific applications toward

¹⁹⁶ *AIPPI Resolution*, *supra* note 194, at ¶ 3.3.

¹⁹⁷ *See Integra*, 331 F.3d at 876 (Newman, J., dissenting).

¹⁹⁸ *Id.*

¹⁹⁹ *See id.* at 876.

²⁰⁰ *See American Association for the Advancement of Science, R & D Budget and Policy Program: Definitions of R&D and Other Key Terms*, available at <http://www.aaas.org/spp/rd/define.htm> (last visited Nov. 29, 2004) [hereinafter AAAS].

²⁰¹ National Science Foundation, *Definitions: Research, Development, and R&D Plant*, Federal Funds Survey, FY 1994, 1995, and 1996, Vol. 44, at <http://www.nsf.gov/sbe/srs/fedfunds/pubs/dst44/technote/research.htm> (last visited Nov. 29, 2004).

processes or products in mind,”²⁰² and applied research, which is intended to “gain knowledge or understanding necessary for determining the means by which a recognized need may be met.”²⁰³ The NSF defines development as “systematic use of the knowledge or understanding gained from research, directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.”²⁰⁴ Development excludes “quality control, routine product testing, and production.”²⁰⁵

Definitions seemingly clear in the abstract frequently become less certain when courts are called on to apply them to a particular set of facts. But that is the business of the judiciary. However one may define the boundaries of liability-free “research” and liability-causing “development” under Judge Newman’s framework, the more important point is her assessment that the courts are equipped to draw the necessary fine lines in appropriate cases, as they have long done in the copyright fair use context.²⁰⁶

Judge Newman’s confidence in the courts’ ability to apply an experimental use defense in practice is not necessarily inconsistent with the Solicitor General’s *amicus curiae* argument in *Madey*. There, the Solicitor General urged the Court not to grant certiorari on the ground that judicial crafting of a meaningful experimental use defense, given the somewhat unique facts of that case, would involve a difficult and ungainly balancing of weighty policy concerns.²⁰⁷ In view of the Federal Circuit’s repeated refusal to do so, it is clear that Congress must address the situation in the first instance by recognizing a narrowly defined but balanced experimental use defense through appropriate legislation. Such legislation should reflect

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ See *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 876 (Fed. Cir. 2003) (Newman, J., dissenting) (“Like ‘fair use’ in copyright law, the great variety of possible facts may occasionally raise dispute as to particular cases. However, also like fair use, in most cases it will be clear whether the exemption applies.”), amended by Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), petition for cert. filed, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

²⁰⁷ Brief for the United States as Amicus Curiae at 16, *Duke Univ. v. Madey*, 538 U.S. 959 (2003) (No. 02-1007), available at <http://www.usdoj.gov/osg/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.html> (last visited Nov. 29, 2004).

the factors proposed herein.²⁰⁸ The federal courts' successful experience with copyright law's fair use defense as codified in 1976 predicts that the judiciary is fully capable of applying a statutorily-codified patent law experimental use defense. Moreover, the line drawing necessary to determine whether an accused infringer's activity should be immunized under the experimental use defense should be no more difficult than other complex analytical tasks routinely faced by the federal courts in the various aspects of patent litigation.²⁰⁹ For example, validity determinations involving assertions of obviousness or non-enablement involve the application of multi-factored standards.²¹⁰

IV. PLACING THE FEDERAL CIRCUIT'S EXPERIMENTAL USE DECISIONS IN THE CONTEXT OF BROADER THEMES

The Federal Circuit has directly addressed the common law experimental use doctrine in only four precedential opinions in its twenty-two-year history.²¹¹ That the experimental use defense has been raised in only a handful of cases is not illogical. Patent cases are notoriously expensive and time-consuming to litigate.²¹² Most patent owners will

²⁰⁸ See *infra* Part V.

²⁰⁹ One of the many questions on which the Federal Circuit requested amici briefing in the claim interpretation referendum of *Phillips v. AWH Corp.* is whether it is appropriate for the court "to accord any deference to any aspect of trial court claim construction rulings." 376 F.3d 1382, 1383 (Fed. Cir. 2004) (en banc). The question may indicate a growing sense of confidence by the Federal Circuit in district court judges' abilities and could mean that the Federal Circuit is considering overruling *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), which held that claim interpretation is an entirely legal determination not involving any fact finding on which district courts would be owed deference.

²¹⁰ See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (setting forth factors underlying ultimate determination of non-obviousness under 35 U.S.C. § 103); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (setting forth factors underlying ultimate determination of enablement under 35 U.S.C. § 112, para. 1).

²¹¹ See generally *Integra*, 331 F.3d 860; *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2003), *cert. denied*, 539 U.S. 958 (2003); *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000); *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), *superseded in part* by 35 U.S.C. § 271(e)(1) (2000).

²¹² See Am. Intell. Prop. Law Ass'n, *2003 Report of Economic Survey*, 22 (2003) (reporting survey evidence showing that average cost of a patent infringement suit with more than \$25 million at risk was \$2.5 million through the end of discovery, and approximately \$4 million for all costs, including discovery, trial and appeal) [hereinafter AIPLA]; see also Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1502 (2001) (estimating that based on the 1999 AIPLA Economic Survey, about \$2 billion is spent on patent litigation annually, not including costs of judgment and indirect social costs such as judicial resources); Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J. L. & ECON. 463, 470 (1995)

institute infringement litigation only when it is economically rational to do so. The experimental use defense is most likely to be asserted when the alleged infringing activity arguably involved research or experimentation spurred by an immediate quest for profits. It is relatively rare that a patent case involving sufficient potential damages to warrant litigation centers around accused activity that is not plainly commercial on its face. Although juries awarded significant damages in *Integra* and in *Embrex*, both of those awards were vacated by the Federal Circuit and remanded for recomputation.²¹³

In each of four precedential decisions, the Federal Circuit rejected the accused infringer's experimental use defense on the facts or otherwise held the defense not available. Is there a coherent explanation for the court's continued refusal to exempt societally benign but unlicensed uses as experimental? A simplistic answer is that in none of the four cases did the accused activity fall within the exceedingly narrow confines of the amusement, curiosity, strictly philosophical inquiry or not legitimate business test as applied by the Federal Circuit.

The more interesting question is why the Federal Circuit has construed the experimental use doctrine so narrowly. Through its four experimental use decisions culminating in *Integra*, the Federal Circuit has effectively shrunk the availability of the experimental use defense to a practical nullity.²¹⁴ The doctrine as it stands today in 2004, post *Madey* and *Integra*, is even more constrained than that contemplated in 1813 by Justice Story in *Whittemore*.²¹⁵

It is doubtful that any single theory can satisfactorily explain the seeming hostility to a meaningful experimental use defense by a majority of the judges of the Federal Circuit. Rather, the court's narrow treatment of the defense should be viewed through the context of several broader themes, all of which, to some degree, have likely contributed to its virtual nullification. Each is discussed below.

(estimating that patent litigation within USPTO and federal courts begun in 1991 will lead to total expenditures of about \$1 billion in 1991 dollars).

²¹³See *Integra*, 331 F.3d at 872 (vacating \$15 million award based on reasonable royalty theory and remanding for further factual development and recalculation of damages); *Embrex*, 216 F.3d at 1350 (vacating \$500,000 award based on lost profits theory and remanding for recalculation on reasonable royalty basis).

²¹⁴See *Integra*, 331 F.3d at 873 (Newman, J., dissenting) (asserting that the majority's decision "essentially eliminates the common law research exemption").

²¹⁵See generally *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17, 600) (Story, J.); see also *supra* notes 33–39 and accompanying text discussing *Whittemore*.

A. *Rise of Formalism*

Patent law scholars have noted a rise of formalism in recent Federal Circuit decisions, evidenced by a preference for bright-line rules over more nuanced, multi-factored, “totality of the circumstances” standards.²¹⁶ A paradigm example of this formalistic approach is the Federal Circuit’s adoption of a complete bar rule of prosecution history estoppel as evidenced in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,²¹⁷ albeit later modified by the Supreme Court.²¹⁸ The Federal Circuit’s recent willingness to interpret language in patent claims without reference to the written description of the patent, let alone any other intrinsic or extrinsic evidence, provides another example.²¹⁹ This formalistic approach is contrary to the court’s previous holistic (or contextualist) approach in which the claims, written description, drawings and prosecution history were all considered as integrally connected and equally important sources of claim

²¹⁶See John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 792 (2003). Surveying developments in five areas of patent law jurisprudence, including on-sale bar, dedication to the public, prosecution history estoppel, patent eligibility, and obviousness issues, Professor Thomas demonstrates a trend towards adjudicative rule formalism and concludes that “[t]he Federal Circuit seems ever more prone to the pronouncement of categorical rules meant to govern future patent disputes.” *Id.* at 793. See also Timothy R. Holbrook, *The Supreme Court’s Complicity in Federal Circuit Formalism*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 1 (2003) (noting that Federal Circuit has recently formulated rules to promote predictability and certainty at the expense of fairness, specifically in the areas of patent claim construction and the doctrine of equivalents).

²¹⁷234 F.3d 558, 574 (Fed. Cir. 2000) (“[P]rosecution history estoppel acts as a complete bar to the application of the doctrine of equivalents when an amendment has narrowed the scope of a claim for a reason related to patentability.”), *vacated by* 535 U.S. 722 (2002).

²¹⁸535 U.S. 722, 737–38 (2002). In *Festo*, the Supreme Court rejected the Federal Circuit’s complete bar rule in favor of a rebuttable presumption of complete estoppel in the case of narrowing amendments made for purposes of patentability. *Id.* at 737–41. The Court elucidated on the circumstances that are sufficient to rebut the presumption:

The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

Id. at 740–41.

²¹⁹See *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1368–69 (Fed. Cir. 2004) (holding that because the “plain language of the claim” was clear, the district court erred in relying on anything beyond it).

term meaning.²²⁰ The Federal Circuit's narrowing of the experimental use defense through a distorted application of the *Pitcairn* "legitimate business" criteria to the university research at issue in *Madey v. Duke University* is yet another step in the court's movement towards per se rules.²²¹

The Federal Circuit may, to some extent, be taking its cue from the Supreme Court, which has also engaged in formalism in the patent law context.²²² For example, the Supreme Court rejected the Federal Circuit's substantially complete and totality of the circumstances standards for triggering the on sale bar of 35 U.S.C. § 102(b) in *Pfaff v. Wells Electronics, Inc.* in favor of a stricter "ready for patenting" rule.²²³ But, no Supreme Court complicity is evident with respect to the experimental use

²²⁰ See *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The court stated the following:

It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language. . . . [I]t is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication. As we have repeatedly stated, "Claims must be read in view of the specification, of which they are a part." The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.

Id. (citations omitted).

²²¹ *Madey v. Duke Univ.*, 307 F.3d 1351, 1363 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

²²² See Holbrook, *supra* note 216. Professor Holbrook observes that Supreme Court encouragement may influence the Federal Circuit's movement toward bright-line rules. *Id.* at 6. Holbrook points to four cases illustrating the Court's inclination to adopt bright-line rules in the substantive patent law cases that it hears. *Id.* at 6–9 (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 722 (1998); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002)). Holbrook concedes that the Court in *Festo* retreated from the trend of encouraging the Federal Circuit to adopt bright-line rules, but maintains that the Supreme Court favors such rules, albeit to a lesser extent than the Federal Circuit. *Id.* at 9.

²²³ 525 U.S. 55, 66–68 (1998).

defense to infringement, a subject which the Supreme Court has not yet addressed.

This movement by the Federal Circuit towards bright-line rules evokes the rules versus standards debate that is the topic of scholarly attention far beyond the confines of patent law.²²⁴ Interestingly, in view of the substantial intersection between patent law and antitrust law, the Federal Circuit's inclination toward formalism is contrary to the trend in modern U.S. antitrust law away from per se rules, i.e., away from virtually automatic condemnation of certain facially anticompetitive practices and towards a rule of reason analysis which considers the defendant's procompetitive justifications.²²⁵

Bright-line legal tests are laudable in that they tend to enhance certainty and predictability of outcome, but they may also result in unfairness and over-inclusiveness.²²⁶ Despite the seeming attractiveness of precise rules, nuanced and flexible standards are generally more appropriate for the dynamic innovation environment confronted by the Federal Circuit.²²⁷ The need for standards rather than rules is especially evident in cases of asserted experimental use. As detailed in Part V *infra*, analysis of an experimental use defense requires a multi-factored approach that carefully balances the defendant's purpose and motivation against the potential harm to incentives for future innovation. The analysis is not amenable to bright-line rules.

²²⁴ See Thomas, *supra* note 216, at 773–77; see also Louis Kaplow, *Rules versus Standards: An Economic Analysis*, 42 DUKE L.J. 557, 559 (1992) (characterizing the rules versus standards debate as one “that has received substantial attention from legal commentators”); Pierre Schlag, *Rules and Standards*, 33 UCLA L. REV. 379, 383–90 (1985) (examining the pros and cons of the rules versus standards debate in the context of deterrence, delegation, and communication/formalities/notice).

²²⁵ See generally *State Oil Co. v. Kahn*, 522 U.S. 3 (1997) (abandoning per se treatment of vertical maximum price fixing in favor of rule of reason analysis); *Broadcast Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1 (1979) (holding that issuance by performing rights societies of blanket licenses to copyrighted musical compositions at set fees should be analyzed under rule of reason rather than under per se rule normally applied to horizontal price fixing); *Cont'l T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36 (1977) (abandoning per se rule in favor of rule of reason treatment for vertical intrabrand non-price restrictions).

²²⁶ See Thomas, *supra* note 216, at 774.

²²⁷ See *id.* at 810.

B. Federal Circuit Hostility to Judicial Limitations on Patentee Exclusivity

The Federal Circuit's effective nullification of the common law experimental use defense to infringement in *Madey*²²⁸ and *Integra*²²⁹ can be seen as but a piece of a broader hostility to any judicial derogation of a patent owner's right to exclude others. Another example concerns the antitrust treatment of patent owners. The Federal Circuit has approved broad and controversial immunities from antitrust scrutiny for patent owners seeking to exploit their exclusionary rights.²³⁰ In *CSU, L.L.C. v. Xerox Corp.*, the court summarily rejected an accused infringer's assertion that a patent owner's refusal to license or sell its patented products constituted an antitrust violation or patent misuse.²³¹ CSU, an independent service organization for photocopiers, sued Xerox for violation of the antitrust laws based on Xerox's refusal to sell it Xerox-patented replacement parts.²³² Absent tying with market power²³³ or *Walker Process* fraud,²³⁴ the Federal Circuit concluded that a patent owner cannot lose its antitrust immunity when it asserts patent infringement.²³⁵

²²⁸See generally *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

²²⁹See generally *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237); see *supra* note 147.

²³⁰See Peter M. Boyle et al., *Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?*, 69 ANTITRUST L.J. 739, 739-40 (2001) (characterizing the Federal Circuit as having "taken on a new and controversial role in establishing the rules of the road at the IP-antitrust intersection" and noting Federal Circuit's incorporation into its reasoning in patent-antitrust matters as "a broad antitrust immunity enjoyed by patent owners").

²³¹203 F.3d 1322, 1329 (Fed. Cir. 2000).

²³²*Id.* at 1324.

²³³See 35 U.S.C. § 271(d)(5) (2000):

No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

Id.

²³⁴See *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) (holding that maintenance and enforcement of a patent knowingly procured through fraud on the

The Federal Circuit has also repeatedly rejected proposed infringement remedies that it considered tantamount to compulsory licensing, another derogation of patent exclusivity which involves a government compelled grant of a license to a patentee's competitor.²³⁶ For example, the court in *Smith International, Inc. v. Hughes Tool Co.* broadly asserted that "[w]ithout the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research."²³⁷ In *Hybritech, Inc. v. Abbott Laboratories*, the court similarly stressed in a preliminary injunction context that "because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole."²³⁸

Despite the Federal Circuit's hostility to the notion of compulsory licensing, this remedy is regularly required by the Federal Trade Commission and the Department of Justice in their enforcement of the antitrust laws. Compulsory licensing of particular patents is seen as necessary to appease competition concerns, especially in cases of mergers and acquisitions between firms with significant patent portfolios.²³⁹ Based

USPTO can form the predicate for an antitrust action asserting monopolization under § 2 of the Sherman Act, 15 U.S.C. § 2 (2000)).

²³⁵ *CSU*, 203 F.3d at 1327–28. The court concluded the following:

In the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws. We therefore will not inquire into his subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anticompetitive effect, so long as that anticompetitive effect is not illegally extended beyond the statutory patent grant.

Id.

²³⁶ Compulsory licensing takes away the patentee's right to injunctive relief but permits her monetary relief in the form of royalty payments. It is distinguishable from a complete exemption from infringement liability of the sort proposed herein for most experimental uses and applied in the copyright fair use context.

²³⁷ 718 F.2d 1573, 1578 (Fed. Cir. 1983).

²³⁸ 849 F.2d 1446, 1456–57 (Fed. Cir. 1988).

²³⁹ See Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 880–91 (2003) (detailing six case studies from the 1980's and 1990's in which the Federal Trade Commission ordered licensing of pharmaceutical patents under antitrust consent decrees), available at

on the post-licensing experiences of a sampling of firms compelled to license their patents by the government for antitrust compliance purposes, some recent scholarship rejects the historically-accepted categorical assumption that compulsory licensing harms the incentives for innovation that patents represent.²⁴⁰

C. *Rising Tide of Statutory Incursions on Exclusivity*

The Federal Circuit's general reluctance to derogate the exclusive rights of patent owners stands in sharp contrast to the growing number of statutory provisions that achieve that effect. The court's reluctance to carve out judicial exceptions to exclusivity, such as an experimental use defense, may reflect discomfort with an increasing number of legislative forays in this area, or simply a refusal to legislate judicially. These provisions include the Hatch-Waxman Act's exemption from infringement liability for regulatory data gathering, codified at 35 U.S.C. § 271(e)(1); governmental takings of patent licenses under 28 U.S.C. § 1498; compulsory licensing (march-in) rights under the Bayh-Dole Act, 35 U.S.C. § 200; prior user rights for business method inventions under 35 U.S.C. § 273; and the remedies exclusion for infringement of medical procedure patents under 35 U.S.C. § 287(c). At the constitutional level, the Supreme Court has interpreted the Eleventh Amendment as clothing state governments and instrumentalities with immunity from damages for acts of patent infringement.²⁴¹

This compilation of incursions on the exclusionary right of a patent owner is not set forth by way of urging that more is better when it comes to such enactments. Rather, the point is simply that if Congress were to enact a meaningful experimental use defense, it certainly would not be the first (and probably not the last) statutory enactment having the potential to reduce the scope of a patent owner's right to exclude.

<http://www.ssrn.com/abstract=486723> (last visited Nov. 29, 2004). Chien concludes that of the six companies subjected to compulsory licensing, only one exhibited a decline in patenting activity subsequent to the licensing event. *Id.* at 857.

²⁴⁰ See *id.* at 891–92 (rejecting the categorical assumption that compulsory licensing of patents harms the incentive function of patents).

²⁴¹ See *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 646–47 (1999).

D. Disinclination to Consider International Patent Law Norms

The Federal Circuit's decisions are rarely influenced by international patent law norms.²⁴² The court's four decisions involving an assertion of the experimental use defense are no exception. None of the opinions in those cases have noted that most foreign patent regimes have implemented a statutory exemption from liability for experimental or research uses of patented inventions. Admittedly, the principle of territoriality means that for the Federal Circuit's purposes, foreign laws have no relevance to disputed uses within U.S. borders of inventions patented under U.S. laws. Nevertheless, U.S. patent law policymakers should be aware that an experimental use exemption has become the international norm.

Most of the world's leading patent systems, including both civil and common law jurisdictions, have codified in their patent codes a general experimental use exemption from patent infringement liability.²⁴³ For example, Germany's patent law provides that "[t]he effects of the patent shall not extend to . . . acts done for experimental purposes relating to the subject matter of the patented invention."²⁴⁴ Japan's statutes provide that

²⁴²The Federal Circuit is not bound by the judicial decisions of foreign tribunals. But one might expect the Federal Circuit to look occasionally for interpretative guidance in foreign decisions involving equivalent legal issues in much the same way as the Federal Circuit occasionally references pre-1982 U.S. regional circuit decisions. This has not been the case. The Federal Circuit has cited foreign authority in only a small handful of decisions. For example, only two Federal Circuit opinions have cited or discussed British judicial decisions appearing in the *Reports of Patent Cases* (R.P.C.) reporter. See *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1251 (Fed. Cir. 2000) (referring to United Kingdom judicial decision in the course of interpreting the meaning of infringing offers to sell under 35 U.S.C. § 271(a)); *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1426 (Fed. Cir. 1994) (referring to United Kingdom judicial decision when analyzing issue of infringement under the doctrine of equivalents by *in vivo* or *in situ* conversion of chemical compounds).

²⁴³See John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 718 (2002) (noting that rather than following the United States on the experimental use issue, many nations "seem to be going in the other direction" and citing examples).

²⁴⁴German Patent Act, 1980, § 11.2, available at http://www.wipo.int/clea/docs_new/en/de/de081en.html (last visited Nov. 29, 2004). The German statute's reference to acts done "for experimental purposes relating to the subject matter of the patented invention" appears to reflect an acceptance of the experimenting on versus experimenting with dichotomy. *Id.* Experiments relating to the subject matter of the patent at issue would appear to mean experimenting on the patented invention to study it. See Wolfgang von Meibom & Dr. Johann Pitz, *Experimental Use and Compulsory License Under German Patent Law*, PAT. WORLD, June/July 1997, at 27.

Von Meibom and Pitz evaluate new criteria for determining the scope of the experimental use exception under § 11.2 as set forth by the Federal Supreme Court of Germany in *Klinische*

“[t]he effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.”²⁴⁵ The United Kingdom (U.K.) patent law provides that “[a]n act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if (a) it is done privately and for purposes which are not commercial; [or] (b) it is done for experimental purposes relating to the subject matter of the invention.”²⁴⁶

Developing country patent regimes have followed the approach of the industrialized nations’ patent systems. For example, India, a country whose patent laws are undoubtedly of growing interest to the many U.S. corporations outsourcing work there, also recognizes an experimental use exemption in its patent statutes.²⁴⁷

Versuche I, [1997] R.P.C. 623, 642 [hereinafter *Clinical Trials I*]. See von Meibom & Pitz at 29. The breadth of biotechnological patents often create problems when future inventions use the technology and depend on the prior patent. See *id.* at 30. The authors conclude that the experimental privilege approved by the Court in *Clinical Trials I* will work to limit the breadth of claims in biotechnological patents and lead to a strengthening of the dependent inventor’s position in negotiations for a license. See *id.* While the authors welcome the *Clinical Trials I* decision because of the Court’s movement away from the prior commercial v. private criteria for determining experimental use, they foresee future problems due to the failure to identify specific delimitation criteria. See *id.*

See also Gilat, *supra* note 32. Gilat evaluates the result of *Boehringer-Ingelheim Int’l GmbH v. Dr. Rentschler Arzneimittel GmbH & Co.* and concludes that conducting experiments which jeopardize the economic value of a product patent does not fall within the exception of § 11.2. See *id.* at 70. Gilat concludes that *Boehringer’s* holding does not accord with the competitive environment fostered by patent law. See *id.* Contrary to *Boehringer*, Gilat asserts that “trials aimed at finding new indications to patented products fall under the experiment exception and should be allowed, at least until the validity of the use patent is established.” *Id.* at 71.

²⁴⁵ Japan Patent Law, Law No. 121 of 1959, as amended by Law No. 220 of 1999, § 69(1), available at http://www.wipo.int/clea/docs_new/en/jp/jp036en.html (last visited Nov. 29, 2004).

²⁴⁶ Patents Act, 1977, c. 37, § 60(5) (Eng.), available at http://www.wipo.int/clea/docs_new/en/gb/gb001en.html (last visited Nov. 29, 2004).

²⁴⁷ India’s patent law provides the following:

The grant of a patent under this Act shall be subject to the condition that any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.

India Patents Act, 1970, 27 INDIA A.I.R. MANUAL 450, § 47(3) (1979), available at http://www.wipo.int/clea/docs_new/en/in/in004en.html (last visited Nov. 29, 2004).

All of these foreign legislative enactments appear to comport, at least facially, with the pertinent provision of the World Trade Organization-administered TRIPS Agreement.²⁴⁸ Article 30 of TRIPS provides that:

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 interest of the patent owner, taking account of the legitimate interests of third parties.²⁴⁹

Intellectual property scholars view Article 30's practical impact as allowing WTO member countries "to permit limited use for private and noncommercial purposes, for research and experimental or teaching purposes, and for preparation of individual medicines by pharmacies."²⁵⁰

In addition to legislation providing for an experimental use defense to patent infringement, foreign courts have developed a body of judicial decisions interpreting and applying the code.²⁵¹ While none of this

²⁴⁸ 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).

²⁴⁹ *Id.* at art. 30.

²⁵⁰ KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 178 (2000).

²⁵¹ A sampling of leading foreign judicial decisions on the experimental use defense includes the following: *Klinische Veruche II*, [1998] R.P.C. 423, 423–24 (holding that defendant's use of patented recombinant human erythropoietin in clinical trials for purposes of testing effectiveness and digestibility of defendant's product, as well as to supply data needed for government regulatory approval for defendant's marketing of that product, was exempted from infringement liability under German Patent Act § 11(2)); *Klinische Versuche I*, [1997] R.P.C. 623, 642 (holding that defendant's use of patented interferon-gamma as active substance in the conduct of clinical trials on human subjects for the purpose of finding new indications [i.e., whether interferon-gamma would treat cancer, AIDS, Allergies, Leukemia, asthma, and chronic hepatitis] was exempted from infringement liability under German Patent Act § 11(2), "in principle irrespective of whether, beyond the character of pure research, economic interests are also in the background."). Additionally, the court in *Monsanto Co. v. Stauffer Chemical Co.* stated the following:

Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions can fairly . . . be regarded as experiments[. . .] but trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or a body such as the PSPS [Pesticides Safety Precautions Scheme, operated

jurisprudence is binding on the Federal Circuit, it is available to inform the debate. The Federal Circuit, which might benefit from the experience of other jurisdictions that recognize an experimental use exemption, thus far has ignored it.²⁵²

V. PROPOSED FACTORS FOR LEGISLATIVE CODIFICATION OF THE COMMON LAW EXPERIMENTAL USE EXEMPTION

In view of the Federal Circuit's repeated refusals to recognize a meaningful experimental use standard, culminating with the court's 2002-03 decisions in *Madey*²⁵³ and *Integra*,²⁵⁴ this article urges legislative action. Congress should enact a general²⁵⁵ experimental use exemption from patent infringement as already exists in the law of many other countries.²⁵⁶ To preserve incentives for innovation, the statutory scheme called for must be narrowly defined and carefully structured. Within these confines, however, courts must be given the discretion to balance the potential public benefits flowing from unrestricted access to patented inventions for research

by U.K. Ministry of Agriculture] . . . that the product works as its maker claims are not to be regarded as acts done 'for experimental purposes.'

[1985] R.P.C. 515 (U.K. Ct. App. 1985) (applying Patents Act, 1997, c. 37, § 60(5)(b) (Eng.)). The Chancery Division stated, in dicta, the following:

[I]f a man makes [patented] things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent).

Frearson v. Loe, 9 Ch. D. 48, 66-67 (1878).

²⁵² See Craig Allen Nard, *Toward a Cautious Approach to Obeisance: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, 39 HOUS. L. REV. 667, 668-69 (2002) (suggesting that Federal Circuit should be "more receptive to empirical and social science scholarship," which could provide court with greater context for its decisions, i.e., a "window on the world").

²⁵³ *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

²⁵⁴ *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

²⁵⁵ The author uses "general" merely to contrast an industry specific, narrow exemption from liability for particular uses of inventions such as the regulatory data gathering safe harbor of 35 U.S.C. § 271(e)(1) (2000).

²⁵⁶ See Part IV.D, *supra* notes 243-251 and accompanying text.

purposes against the possible lessening of incentives for innovation that the patent law's exclusionary right provides.²⁵⁷

In formulating a limited but meaningful statutory defense to patent infringement for experimental use activity, members of Congress and other intellectual property law policymakers should consider at least the following factors gleaned from the preceding analysis of pertinent judicial authority and policy concerns:²⁵⁸ (1) the availability of consensual licenses; (2) whether the challenged use amounts to experimenting on a claimed invention or experimenting with it; (3) the degree to which the alleged experimental activity is necessarily incident to subsequent commercial exploitation; and (4) the balance of harms invoked in the granting or denial of an experimental use defense under the particular facts at hand. Each proposed factor is discussed separately below.

²⁵⁷ A recent study of the U.S. patent system sponsored by the National Academy of Sciences concludes that there is only a small likelihood that Congress will pass research-exception legislation and proposes instead an administrative approach to the problem. See NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., *A PATENT SYSTEM FOR THE 21ST CENTURY* 93–95 (Stephen A. Merrill et al. eds., 2004) [hereinafter *NAS Report*]. In particular, the *NAS Report* suggests that under an expanded application of the “authorization and consent” clause typically found in federal government procurement contracts, see 28 U.S.C. § 1498(a) (2000), the U.S. government “could assume liability for patent infringement by investigators whose work it supports under contracts, grants, and cooperative agreements.” NAT'L RESEARCH COUNCIL at 93. Federal research-sponsoring agencies could include an explicit “authorization and consent” clause in their funding instruments so that the federal government would assume any liability which might arise from research grantees' unlicensed use of third parties' patented inventions. *Id.* at 95. As the *NAS Report* authors recognize, however, this approach merely “shift[s] rather than remov[es] infringement liability.” *Id.* at 94. It also creates a bifurcated system under which research-use protections are available for federally-funded research but not for research undertaken in the corporate setting or in university work that is not federally funded. The *NAS Report*'s proposal also raises concerns with respect to expansion of the federal government's monetary exposure (not to mention its resource capacity to take on the additional litigation). Although infringing activity undertaken by or for the federal government cannot be enjoined (since it is deemed the taking of a license under the government's Fifth Amendment eminent domain power), it has the potential to trigger notoriously long-running and complicated litigation over the issue of reasonable compensation to the patentee. See *e.g.*, *Hughes Aircraft Co. v. United States*, 140 F.3d 1470, 1472–73 (Fed. Cir. 1998) (summarizing history of then-ongoing patent infringement litigation that had been commenced by patentee Hughes against the federal government in 1973).

²⁵⁸ The factors proposed herein are not intended to represent an exclusive list of judicial considerations. Other factors may be appropriate in particular cases.

A. Availability of Consensual Licenses

Based on the analysis in Part II.A *supra*, if a license to use a patented invention reasonably could have been obtained, either impliedly through operation of law or expressly through a transaction with the patent owner, the unlicensed use at issue is less likely to qualify for the experimental use exemption. In contrast, where a consensual license is not available through either of these means, the unlicensed use is more likely to be exempted from liability.

A sub-inquiry of this factor considers whether the patented invention is physically embodied in a product rather than in a process or method. Where the patented invention is embodied in a product, the first sale doctrine often alleviates the need for an experimental use exemption. Purchase of a particular product item will often—but not always—carry with it an implied license to use the invention embodied in the item, depending upon whether or not the purchase was made from the patent owner (or someone acting under the patent owner's authority).²⁵⁹ For example, purchase of a research tool such as a chemical reagent or a piece of laboratory equipment from the patent owner or other authorized source will generally carry with it an implied license to use the item in the course of conducting research.²⁶⁰

If the claimed invention is a process, however, the first sale doctrine does not come into play because the end user has not purchased any product from the patent owner. *Embrex, Inc. v. Service Engineering Corp.*, illustrates this point.²⁶¹ The invention used by Service Engineering without authority was a method for inoculating chicks before hatching.²⁶²

In addition to the availability of implied licenses, if express non-exclusive licenses to use a patented invention are easily accessible on commercially reasonable and non-discriminatory terms, this too argues

²⁵⁹ See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961) (holding that repair of patented convertible top by automobile purchasers was not direct infringement under 35 U.S.C. § 271(a) where top was manufactured by car company under express license with patentee). *But see* *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476 (1964) (holding that repair of patented convertible top by automobile purchasers was direct infringement where car was purchased from car company that did not possess a license from patent owner).

²⁶⁰ Recall that Duke University did not benefit from an implied license to use the laser equipment involved in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003), because Duke did not own the equipment in question. See Part III.A, *supra* notes 105–106.

²⁶¹ 216 F.3d 1343 (Fed. Cir. 2000).

²⁶² *Id.* at 1346.

against the exemption of an unlicensed use. The burden of transaction costs to gain access to the patented innovation is not a significant concern in such cases. For example, the Cohen-Boyer patents on gene cloning methodology are frequently cited as an example of a groundbreaking technology that has been widely licensed on reasonable terms to all comers.²⁶³

B. *Experimenting on or Experimenting with the Patented Invention*

In the formulation proposed by dissenting Judge Newman in *Integra* (detailed in Part III.B *supra*), a determination must be made as to whether the unauthorized use in question can be characterized as study of the patented invention for purposes of verifying its accuracy or utility, to improve it, find a new use for it (as in *Integra*), or to design around it.²⁶⁴ All of these experimenting on type uses of a patented invention are more likely to be exempted experimental uses.

On the other hand, when a putative infringer is using the patented invention as a tool to develop an unrelated invention, an unauthorized use is less likely to qualify for exemption. The facts of *Madey v. Duke University* exemplify this type of use.²⁶⁵

That scientific researchers should be less restricted in experimenting *on* patented inventions than in experimenting *with* them comports with the policies that U.S. patent law was designed to further. As implemented by the Framers, the constitutional mandate of promoting progress in the “useful arts”²⁶⁶ specifically contemplated the patenting of improvements of earlier inventions.²⁶⁷ The making of an improvement invention typically

²⁶³Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1710 (1996) (“The Cohen-Boyer patents have been widely licensed to biotechnology firms and pharmaceutical firms on terms that have been set low enough that they have generated few complaints from industry”).

²⁶⁴331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., dissenting), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

²⁶⁵307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

²⁶⁶U.S. CONST. art. I, § 8, cl. 8.

²⁶⁷*See* 35 U.S.C. § 101 (2000) (enumerating categories of potentially patentable subject matter which include improvements). The inclusion of improvements within the categories of patentable subject matter dates to the first U.S. patent law, the Patent Act of 1790, ch. 7, 1 Stat. 109 (1790). The Act provided that “upon the petition of any person . . . setting forth, that he, she, or they, hath or have invented or discovered any useful Art, Manufacture, Engine, Machine, or Device, or any improvement therein not before known or used, and praying that a patent may be

involves the study of information provided in the patent for the corresponding basic invention. That study likely requires experimenting on the basic invention in order to make an improvement that is a sufficiently novel and nonobvious variant to warrant an independent patent.²⁶⁸ Patent law rules that flatly prohibit unauthorized experimentation as a precursor to making improvement inventions contravene the cornerstone goal of promoting technological progress through improvement innovation.

Moreover, the experimenting on factor is consistent with policies underlying copyright law's fair use doctrine. As the author has previously suggested, judicial elevation of transformative character over commerciality in the copyright regime should serve as a model for similar treatment in the development of a meaningful experimental use standard in patent law.²⁶⁹ In a copyright fair use analysis, the commercial nature or for-profit motive of an accused infringer's unlicensed use of a copyrighted work is not fatal to her eligibility for the fair use defense.²⁷⁰ In *Campbell v. Acuff-Rose Music, Inc.*, the Supreme Court suggested that the commercialized nature of a disputed use is less important than whether its nature is transformative.²⁷¹ In contrast with a use that merely supercedes or supplants the original work, a transformative use is one that generally furthers the goals of copyright law, *i.e.*, to promote the progress of science through the creation and dissemination of copyrightable works.²⁷² When the challenged use "adds something new, with a further purpose or different character, altering the [copyright owner's work] with new expression, meaning, or message," the use is more likely to be held a fair one.²⁷³ By analogy, an experimenting *on* type use of a patented invention is more likely to add something new to the existing store of technological information concerning that invention, whether it be through the verification of the invention's utility or enablement, or the identification of a new, previously unrecognized use for

granted therefore," *Id.* § 1 (emphasis added), reprinted in EDWARD C. WALTERSCHEID, TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION 463–65, 1787–1836 (Rothman & Co. ed., 1998).

²⁶⁸ See *Integra*, 331 F.3d at 875 (Newman, J., dissenting) ("A rule that [the] information [in patents] cannot be investigated without permission of the patentee is belied by the routine appearance of improvements on patented subject matter, as well as the rapid evolution of improvements on concepts that are patented.").

²⁶⁹ Mueller, *supra* note 8, at 44.

²⁷⁰ *Id.* at 43.

²⁷¹ See 510 U.S. 569, 583–85, 590–91 (1994).

²⁷² See *id.* at 579.

²⁷³ *Id.*

the invention, or an improvement of the invention which is so significant that it may result in an independent patent.²⁷⁴

Favorable treatment of the experimenting *on* variety of use of patented inventions also promotes the goal of weeding out those patents that should not have been issued in the first instance.²⁷⁵ For example, no less than Thomas Edison conducted thousands of experiments falling within the broad scope of the Sawyer and Man patent claims to an incandescent lamp conductor in order to prove the claims invalid as non-enabled.²⁷⁶ Justice Story's seminal formulation of the experimental use doctrine explicitly contemplated unlicensed uses of inventions "for the purpose of ascertaining the sufficiency of the machine to produce its described effects."²⁷⁷

C. *Extent to Which Use Is Necessarily Incident to Subsequent Commercial Activity*

This factor considers whether or to what extent the unauthorized use at issue is linked to the putative infringer's subsequent commercialization or other for-profit business activity pertaining to the same invention. If the purported experiments are a mandatory predicate of intended commercial activity, as in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,²⁷⁸ or are a necessary precursor to "legitimate business" use of the invention as that term was originally employed in *Pitcairn v. United States*,²⁷⁹ the experiments are less likely to be entitled to immunity from infringement

²⁷⁴Not all aspects of copyright's fair use doctrine transfer cleanly to the patent sphere. For example, 17 U.S.C. § 107(3) (2000) mandates that a court consider "the amount and substantiality of the portion used [by the accused infringer] in relation to the copyrighted work as a whole." Because patents, unlike copyrighted works, include claims, *see* 35 U.S.C. § 112 para. 2 (2000), and because every limitation of a patent claim must be met either literally or equivalently in an accused device to establish patent infringement, *see Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988); *Lemelson v. United States*, 752 F.2d 1538, 1551 (Fed. Cir. 1985), the patent law experimental use analysis would not consider a comparable "portion used" factor.

²⁷⁵*See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) ("[T]he important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain").

²⁷⁶The Incandescent Lamp Patent, 159 U.S. 465 (1895).

²⁷⁷*Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.).

²⁷⁸733 F.2d 858, 863 (Fed. Cir. 1984), *superseded in part by* 35 U.S.C. § 271(e)(1) (2000), discussed in Part II.C, *supra* notes 63–76 and accompanying text.

²⁷⁹212 Ct. Cl. 168 (1976). *See* Part II.C, *supra* notes 53–59 and accompanying text.

liability.²⁸⁰ On the other hand, when the link between the challenged experiments and subsequent commercialization is more attenuated, as in *Embrex, Inc. v. Service Engineering Corp.*²⁸¹ and *Integra Lifesciences I, Ltd. v. Merck KGaA*,²⁸² this factor should weigh in favor of an experimental use exemption.

Placement of the unauthorized use activity on the research and development continuum, as suggested by dissenting Judge Newman in *Integra*,²⁸³ also informs this factor. The U.S. government and various U.S. scientific organizations have promulgated generally understood and accepted definitions for what constitutes research as opposed to development.²⁸⁴ The closer the experimentation is to research, the more this factor favors of an exemption from patent infringement liability.²⁸⁵

D. The Balance of Harms

Here, the courts must weigh the relative degree of harm to incentives for patenting if an experimental use exemption is granted versus the harm to the public's interest in unrestricted access to the invention if an exemption is denied. The potential harm to the public is most easily identified in cases where the experimentation that is being challenged as a patent infringement may lead to important health and welfare innovation, as was the case with Dr. Cheresch's unlicensed use of certain patented peptides in his attempts to find new cancer treatments in *Integra*.²⁸⁶

In certain cases where the potential harm to patenting incentives appears significant, courts may consider an alternative to fully exempting an experimental use from liability as proposed herein. Adoption of a liability rule²⁸⁷ would permit the experimental use to be made without injunction,

²⁸⁰ Gilat helpfully characterizes this as a distinction between market-oriented experiments and research-oriented experiments. See Gilat, *supra* note 32.

²⁸¹ 216 F.3d 1343 (Fed. Cir. 2000). See Part II.C, *supra* notes 77–91 and accompanying text.

²⁸² 331 F.3d 860 (Fed. Cir. 2003), *amended by* Nos. 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796 (June 6, 2003), *petition for cert. filed*, 72 U.S.L.W. 3568 (U.S. Mar. 2, 2004) (No. 03-1237).

²⁸³ *Id.* at 876 (Newman, J., dissenting).

²⁸⁴ See Part III, *supra* notes 200–205 and accompanying text.

²⁸⁵ *Id.*

²⁸⁶ 331 F.3d at 863.

²⁸⁷ Scholars have distinguished between property rules that protect legal entitlements against all non-consensual takings and liability rules that permit such takings but compensate the entitlement holder. See Ian Ayres & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement to Facilitate Coasean Trade*, 104 YALE L.J. 1027, 1036–37 (1995); Guido Calabresi

but require after-the-fact remuneration of the patent owner.²⁸⁸ This alternative would allow courts to guarantee a monetary reward to the patent owner while permitting the accused infringer's experimental use to go forward without threat of injunction.

However, the contours of adequate remuneration in a particular case of experimental use are not easily established. Although courts are adept at computing reasonable royalty compensation for past infringements,²⁸⁹ it is unclear that the same judicial expertise could be applied without significant modification to the case of prospective, ongoing experimental use. Such concerns are important but beyond the scope of this article.

VI. CONCLUSION

The time is long past for United States recognition of a meaningful experimental use defense to patent infringement. The continued absence of such a defense in the United States, in contrast with the world's other leading patent law regimes, can only catalyze the growing incidence of outsourcing of research and development to foreign forums.

In *Madey* and *Integra*, the Federal Circuit missed important opportunities to fully engage in reasoned debate over the policy bases and

& A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1115–16 (1972).

²⁸⁸ See Eisenberg, *supra* note 8, at 1078 (proposing that in the case of unauthorized use of patented invention for purpose of developing improvement or designing around to avoid infringement, patent owner should not be able to enjoin use but in some cases should be entitled to an after-the-fact reasonable royalty); Mueller, *supra* note 8, at 54–66 (proposing adaptation of Professor Eisenberg's framework that would permit unlicensed development use of patented biomedical research tools where tool is not available for anonymous purchase or licensing at commercially reasonable terms and suggesting that patent owner might be entitled to reach-through royalty payments in order to maintain adequate incentives for innovation in new research tools). But see F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 703 (2001) (arguing that enforcement of patent rights on a strictly property rule basis, rather than through liability rules, is essential to attaining the core goals of the patent system).

²⁸⁹ Courts are routinely called upon to compute damages for past patent infringement in the form of a reasonable royalty in accordance with the damages provision of the U.S. Patent Act, 35 U.S.C. § 284 (2000). That provision states, "Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." *Id.* A multi-factor framework for assessing the amount of reasonable royalty in the context of a hypothetical license negotiation was set forth in the seminal case of *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

parameters of a meaningful experimental use defense. The result of these decisions is that in the United States, the experimental use defense is for all practical purposes a nullity.

Accordingly, Congress should amend the U.S. Patent Act by enacting a narrowly defined, carefully balanced experimental use provision that preserves incentives for innovation while permitting unlicensed use of patented inventions in certain instances of legitimate scientific research. This article has suggested several important factors for inclusion in implementing legislation.