

MERCK KGAA v. INTEGRA LIFESCIENCES I, LTD.: JUDICIAL EXPANSION OF § 271(E)(1) SIGNALS A NEED FOR A BROAD STATUTORY EXPERIMENTAL USE EXEMPTION IN PATENT LAW

By Rebecca Lynn

In order to provide a narrow experimental use exemption for the regulatory approval of generic drugs, Congress enacted 35 U.S.C. § 271(e)(1) as part of the Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act.¹ The statutory exemption allows generic drug companies to begin the regulatory approval process for generic drugs before the brand name drug patent expires.² However, the scope of the exemption has been judicially expanded in a series of cases to encompass medical devices and activities far upstream from, and only tangentially related to, the FDA approval process.³

The latest example of the expansion of § 271(e)(1) occurred in *Merck KGaA v. Integra Lifesciences I, Ltd.*⁴ In *Merck*, the Supreme Court unanimously reversed the decision of the Federal Circuit and broadened the statutory experimental use exemption to include preclinical testing on patented products far upstream of FDA approval.⁵ The Court found that the use of patented inventions in preclinical research was exempt from infringement under the statute even when researchers did not submit their results to the FDA.⁶

Recognizing a need for a broad experimental use exemption in some instances, the Court has stretched § 271(e)(1) to cover issues that previously could have been addressed under the common law.⁷ *Merck* could not rely upon the common law experimental use exemption because the Federal Circuit eroded it in a series of cases until it was virtually non-existent.⁸ Additionally, while the court has expanded § 271(e)(1) in the

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1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68(b)-(c), 70(b) (1994); 21 U.S.C. §§ 301 n. 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

2. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-71 (1990).

3. *See infra* notes 47-60 and accompanying text.

4. 125 S. Ct. 2372 (2005).

5. *Id.* at 2384.

6. *Id.* at 2380.

7. *See infra* notes 45-59 and accompanying text.

8. *See infra* notes 15-32 and accompanying text.

areas of biotechnology and medical devices to reinstate the common law experimental use exemption to some extent, its full scope and application is uncertain. Thus, the Supreme Court's decision in *Merck* left pharmaceutical companies, researchers, and research tool companies with more questions than answers as to the boundaries of § 271(e)(1).

In response to the Supreme Court's continued broadening of the § 271(e)(1) experimental use exemption, this Note calls for an additional congressional enactment of a limited, but balanced, experimental use exemption in patent law. The recommendation is consistent with the common law experimental use exemption, the fair use doctrine in copyright, similar statutory enactments in the world's leading patent systems, and legislation already considered by Congress. Part I of this Note explores the background of the experimental use exemption including the history of the common law experimental use exemption and the introduction and judicial expansion of the § 271(e)(1) experimental use exemption. Part II of this Note delves into *Merck*, tracing the history of the decision from the district court through the Supreme Court. Part III of this Note provides an analysis of the Supreme Court's decision as well as a recommendation for a legislatively enacted experimental use exemption that applies across industries.

I. HISTORY OF THE EXPERIMENTAL USE EXEMPTION

This Part addresses the evolution of the common law and statutory experimental use exemptions. Section A covers the judicial creation of the common law exemption and explores its subsequent erosion in a number of Federal Circuit cases. Section B covers the creation of § 271(e)(1) and provides insight into the legislative history behind the exemption. Additionally, Section B details the subsequent judicial expansion of the exemption.

A. Common Law Experimental Use Exemption

In order to apply the proper analysis to the statutory experimental use exemption under § 271(e)(1), it is first necessary to explore the evolution of the experimental use exemption in the common law. Since 1813, a judicially-created common law experimental use defense has existed, although it finds little application in modern cases. In *Whittemore v. Cutter*,⁹ a jury trial for patent infringement, Justice Story explained that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described ef-

9. 29 F. Cas. 1120 (C.C.D. Mass. 1813).

fects.”¹⁰ Subsequently in *Sawin v. Guild*,¹¹ Justice Story cited *Whittemore* for having established that patent infringement must concern:

the 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 on the patent-right, and deprive the owner of the lawful rewards of his discovery.¹²

Thus, the intent of the accused infringer became a key factor in determining liability. The meaning of the term “philosophical” has caused some confusion and debate, but at the time of the opinion philosophical meant scientific.¹³ Hence, scientific experiments that were not made with the intent to deprive a patent owner of his rights and benefits for having made an invention were exempt from infringement liability under the common law experimental use doctrine.¹⁴

While the experimental use doctrine was well-accepted law by the end of the nineteenth century, courts rarely applied the doctrine in favor of an accused infringer.¹⁵ Rather, courts generally limited the experimental use defense to cases where there was no commercial activity or profit motive.¹⁶ In 1984, the newly-formed Federal Circuit dealt with the experimental use exemption for the first time in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*¹⁷ *Roche* proved to be the first in a series of cases in which the Federal Circuit chipped away at the foundation of the doctrine. The defendant in *Roche* wanted to market a generic version of a patented drug as soon as the patent expired.¹⁸ However, because FDA approval can take up to two years, the defendant obtained a quantity of the drug from a foreign source and began testing the drug approximately six months before the patent expired.¹⁹ The court held that the experimental use doctrine did

10. *Id.* at 1121.

11. 21 F. Cas. 554 (C.C.D. Mass. 1813).

12. *Id.* at 555 (citation omitted).

13. See Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 929 (2004).

14. *Id.*

15. See *id.* at 929-30.

16. Janice M. Mueller, *No “Dilettante Affair”:* Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76. WASH. L. REV. 1, 21 (2001).

17. 733 F.2d 858 (Fed. Cir. 1984).

18. *Id.* at 860.

19. *Id.*

not protect "limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent."²⁰ The court further restricted the common law exception by characterizing it as "truly narrow" and determining that it did not extend to any use of a patented invention that was "in keeping with the legitimate business of" an alleged infringer.²¹ The court stated that "argument[s] that the experimental use rule deserve[d] a broad construction [were] not justified," and that any activity, experimental or not, that had a commercial purpose fell short of the experimental use exception.²²

In 2000, the Federal Circuit noted in *Embrex, Inc. v. Service Engineering Corp.*,²³ that the experimental use exemption is construed very narrowly and denied the defense where the use was "expressly for commercial purposes."²⁴ The facts of *Embrex* present what should have been a paradigm case for exempted experimental use: use of a patented invention to design around a patent.²⁵ However, the opinion is chiefly noted for Judge Rader's concurring opinion which denied the possibility that even scientific or philosophical testing is an exempt experimental use. Specifically, Rader stated that "neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for experimentation . . ."²⁶ He went on to say that "the slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable."²⁷

In 2002, in *Madey v. Duke University*,²⁸ the Federal Circuit appeared to have put the final nail in the coffin for the experimental use exemption. In *Madey*, the court found that use of a patented laser by a university in

20. *Id.* at 861. After the decision, Congress quickly went into action to overrule the decision in the specific context of FDA approval of generic drugs by creating the 271(e)(1) experimental use exemption. Ruth E. Freeburg, *No Safe Harbor and No Experimental Use: Is It Time for Compulsory Licensing of Biotech Tools?*, 53 *BUFF. L. REV.* 351, 366 (2005).

21. *Id.* at 863 (quoting *Pitcairn v. United States*, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976)).

22. *Id.*

23. 216 F.3d 1343 (Fed. Cir. 2000).

24. *Id.* at 1349.

25. Mueller, *supra* note 13, at 935.

26. *Embrex*, 216 F.3d. at 1353 (Rader, J., concurring).

27. *Id.* (Rader, J., concurring).

28. 307 F.3d 1351 (Fed.Cir. 2002), *cert. denied*, 539 U.S. 958 (2003).

experimental research was not protected under the experimental use exemption.²⁹ The court concluded that:

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.³⁰

Had the court focused on the narrow issue in the case—whether using a research tool research constituted infringement—the case would not be controversial.³¹ The scientists were using the patented laser inventions for their intended purpose as research tools rather than *experimenting on* the claimed inventions (e.g., improving the lasers or finding a new use for them).³² However, the court instead took the opportunity to apply the same limited role for the experimental use defense in the area of university and non-profit research institutions as for other business applications.³³

B. Creation of the Statutory Experimental Use Exemption

While the Federal Circuit's decision in *Roche* was almost certainly correct from a doctrinal and policy perspective,³⁴ Congress reacted quickly in reaction to pressure from the public and generic drug companies and overturned *Roche* by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.³⁵ The Act provided two key provisions that dealt with unintended distortions at both ends of the seventeen year patent term due to the lengthy FDA approval process for pharmaceuticals.³⁶ At the beginning of the term, pharmaceutical companies were losing money because the FDA approval process consumed part of the patent term.³⁷ At the end of the term, pharmaceutical companies were enjoying an unintended extension after the

29. *See id.* at 1362.

30. *Id.*

31. *See* Mueller, *supra* note 13, at 941.

32. *Id.*

33. *Id.*

34. *Id.* at 933.

35. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68(b)-(c), 70(b) (1994); 21 U.S.C. §§ 301 n. 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

36. *Id.*; *see* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669 (1990).

37. *Medtronic*, 496 U.S. at 669-70.

expiration of their patent term because generic competitors could not begin the FDA approval process until the patent term expired.³⁸ Even though the two distorting effects were roughly offsetting, Congress chose to eliminate the distortions at both ends of the patent term.³⁹

Thus, the Hatch-Waxman Act satisfied both the pharmaceutical companies and generic manufacturers. First, pharmaceutical companies obtained an extension on the patent term to compensate them for time spent in the regulatory process.⁴⁰ Second, enacting an experimental use exemption allowed generic drug companies to begin the FDA approval process before the patent on the drug expired. This exemption, codified in 35 U.S.C. § 271(e)(1), states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs

Thus, the statutory experimental use exemption was born, and generic drug companies could begin marketing their products as soon as the pioneer drug's patent expired.

However, beyond the specific context of FDA approval for generic drugs, the boundaries of the statutory experimental use exemption remain unclear. While the statute specifically addresses generic drugs, the court has expanded its scope to include medical devices. The following Sections investigate the legislative history of the statutory experimental use exemption in order to shed light on the congressional intent behind the Act and map out the subsequent judicial expansion of the exemption leading up to *Merck*.

1. Legislative History of § 271(e)(1)

Congress's purpose behind § 271(e)(1) was to allow a limited experimental use exemption for the regulatory approval of generic drugs.⁴¹ According to the House Committee on the Judiciary, the purpose of the Hatch-Waxman Act was to allow "a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substi-

38. *Id.* at 669-71.

39. *Id.* at 672.

40. *Id.* at 669-71.

41. H.R. REP. NO. 98-857, pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

tute” prior to expiration of the drug patent.⁴² In specific reference to the facts of *Roche*, the House Committee on Energy and Commerce reiterated that the purpose of the exemption was to allow experimentation on a patented drug in preparation for commercial use after expiration of the patent.⁴³ Because drug companies would not market the generic drug until after the initial patent expired, the House Committee assumed that the impact on patent rights would be minimal.⁴⁴

However, the House Committee on the Judiciary also made sweeping comments that are susceptible to an interpretation that allows the Act to be applied outside the scope of generic drug approval:

[T]he committee . . . balance[d] the need to stimulate innovation against the goal of furthering the public interest. Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. This is all this bill does.⁴⁵

This statement, standing alone, could be construed to allow a broad experimental use exemption outside the narrow application of generic drug approval. However, the context of the rest of the House Report makes clear that courts should apply the Act only to generic drug approval. In passing the Act, Congress intended to overturn *Roche* and create a specific statutory experimental use exemption for generic drug approval because the unique regulatory issue confronted in the industry required it.⁴⁶

2. *Judicial Expansion of the Hatch-Waxman Act*

Contrary to the legislative purpose of the Hatch-Waxman Act, the courts expanded the statutory provisions of § 271(e)(1) to apply beyond regulatory approval for generic drugs.⁴⁷ Courts interpreted the phrase “un-

42. H.R. REP. NO. 98-857, pt. 2, at 8, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2692.

43. H.R. REP. NO. 98-857, pt. 1, at 45, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678.

44. H.R. REP. NO. 98-857, pt. 2, at 8, 30, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2714, 2792 (The House Committee on the Judiciary noted that the “nature of the interference with the rights of the patent holder” would not be “substantial,” but would be “de minimus [sic.]”); *see also* H.R. REP. NO. 98-857, pt. 1, at 46, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679 (“It is the [House Committee on Energy and Commerce’s] view that experimental activity does not have any adverse economic impact on the patent owner’s exclusivity during the life of a patent, but prevention of such activity would extend the patent owner’s commercial exclusivity beyond the patent expiration date.”).

45. H.R. REP. NO. 98-857, pt.2, at 30, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2714.

46. *Id.*

47. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Abtox, Inc. v. Exitron Corp.*, 122

der a Federal Act” to include not just drugs and medical devices but any product developed under federal guidelines.⁴⁸ Additionally, courts determined that the term “reasonably related” excluded infringing uses such as trade shows, demonstrations, and recruitment since these activities could be “reasonably related” to FDA approval.⁴⁹

In *Eli Lilly v. Medtronic, Inc.*,⁵⁰ the Court considered whether medical devices fell under the exemption. Although medical devices are not drugs, per the text of the exemption, they are subject to FDA regulation and approval under the Federal Food, Drug, and Cosmetic Act.⁵¹ The Federal Circuit ruled that the statutory exemption is not limited to drugs and extended it to medical devices that undergo the lengthy FDA approval process.⁵² The Supreme Court affirmed the decision, finding that “[t]he phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone.”⁵³ The Court dismissed the next part of the statute, which used the word “drugs,” as ambiguous and incomprehensible.⁵⁴ The Court further rejected any interpretation based upon legislative history.⁵⁵

From *Medtronic*, the path of expansion continued.⁵⁶ In 1993 and 1997, the Federal Circuit granted safe harbor to all medical devices, even those that do not undergo lengthy FDA approval.⁵⁷ Thus, the original rationale behind the Hatch-Waxman Act—eliminating a de facto patent term extension while the competitor went through the FDA approval process—was no longer relevant. Another extension occurred in 1993, when the Federal Circuit found that data from foreign sales and U.S. trade shows was “rea-

F.3d 1019 (Fed. Cir. 1997); *Chartex Int’l v. M.D. Personal Prods. Corp.*, 5 F.3d 1505 (Fed. Cir. 1993) (unpublished table decision).

48. Freeburg, *supra* note 20, at 371 (citing *Abtox*, 122 F.3d at 1030).

49. *Id.* at 370.

50. 496 U.S. at 661.

51. *See Medtronic*, 872 F.2d at 406. The Federal Food, Drug, and Cosmetic Act is a Federal law that regulates the manufacture, use, or sale of drugs.

52. *Id.* (“No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation.”).

53. *Medtronic*, 496 U.S. at 665.

54. *Id.* at 668-69. The statute reads “a Federal law which regulates the manufacture, use or sale of drugs.” 35 U.S.C. § 271(e)(1).

55. *Medtronic*, 496 U.S. at 669.

56. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997); *Chartex Int’l v. M.D. Personal Products Corp.*, 5 F.3d 1505 (Fed. Cir. 1993) (unpublished table decision).

57. *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997); *Chartex*, 5 F.3d at 1505 (unpublished table decision).

sonably related” to obtaining FDA approval for an implantable cardiac defibrillator even though premarket approval had not been obtained.⁵⁸ Thus, the exempted use no longer needed to be directly related to FDA approval. The latest expansion of the statutory exemption occurred in *Merck*. While the Federal Circuit declined to expand § 271(e)(1) in *Integra LifeSciences I, Ltd. v. Merck KGaA*,⁵⁹ the Supreme Court overturned the decision and applied § 271(e)(1) far upstream of any FDA approval process.⁶⁰

II. *MERCK KGAA V. INTEGRA LIFESCIENCES I, LTD.*

The *Merck* case provided the Federal Circuit and the Supreme Court an opportunity to clarify the boundaries of the statutory exemption. However, the ten-year saga of the *Merck* litigation left researchers, pharmaceutical companies, and research tool companies with more questions than answers.

A. Factual Background

Integra LifeSciences I, Ltd. (“Integra”) accused Merck KGaA (“Merck”) of infringing five of its patents covering short amino-acid sequences, known as peptides, which include the three amino-acid sequence “RGD,” and methods of using the peptides to regulate cellular adhesion.⁶¹ Although Integra’s predecessor, Telios, believed that the peptides’ ability to regulate cellular adhesion could be used therapeutically to stimulate wound healing, it was never able to develop the patented technology into a drug candidate suitable for clinical trials.⁶²

In 1988, Merck began funding the research of Dr. David Cheresh at the Scripps Research Institute (“Scripps”).⁶³ Dr. Cheresh had previously discovered that inhibition of cellular adhesion can suppress angiogenesis, the process of generating new blood vessels.⁶⁴ Scientists believed that inhibition of angiogenesis has applications in cancer therapy because re-

58. *Intermedics, Inc. v. Ventrics Co.*, 991 F.2d 808 (Fed. Cir. 1993) (unpublished table opinion), *cert denied*, 513 U.S. 876 (1994).

59. 331 F.3d 860 (Fed. Cir. 2003) [hereinafter *Integra*].

60. *Merck*, 125 S. Ct. at 2380-83.

61. “RGD” refers to a three amino-acid peptide having the sequence arginine-glycine-aspartic acid. The patents are U.S. Patent Nos. 4,789,734; 4,879,237; 4,988,621; 5,695,997; and 4,792,525. *Integra*, 331 F.3d at 862.

62. *Id.* at 873.

63. *Merck*, 125 S. Ct. at 2377.

64. *Integra*, 331 F.3d at 863.

stricted blood supply inhibits tumor growth.⁶⁵ From 1995 to 1998, Dr. Cheresh tested a library of RGD peptides that Merck provided as potential drug candidates for inhibiting angiogenesis.⁶⁶ These tests measured the efficacy, specificity, and toxicity of the particular peptides as angiogenesis inhibitors and evaluated their mechanism and pharmacokinetics in animals.⁶⁷ From this research, Scripps decided in 1997 that the peptide, EMD 121974, was the most promising candidate for testing in humans and filed an investigational new drug application (IND) in 1998.⁶⁸

In 1996, Integra filed a patent infringement suit against Merck.⁶⁹ Integra alleged that Merck willfully infringed and induced others to infringe its patents by supplying the RGD peptide to Scripps.⁷⁰ In its answer, Merck responded that its actions did not infringe Integra's RGD peptide patents and that they were protected both by the common-law research exemption and the safe harbor provision of 35 U.S.C. § 271(e)(1).⁷¹ The jury found that Merck infringed several of Integra's patents, and the district court concluded that the § 271(e)(1) did not cover the work performed for Merck at Scripps.⁷² The jury awarded Integra a reasonable royalty of \$15 million.⁷³

B. The Federal Circuit's Analysis

Merck appealed to the Federal Circuit where a divided panel of the Court of Appeals upheld the District Court's decision that § 271(e)(1) did not apply to the work Scripps performed for Merck.⁷⁴

1. *The Majority Opinion*

According to the court, the exemption was not applicable because "the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds."⁷⁵ The court focused on the text of the statute, particularly the phrase "solely for uses reasonably related to the

65. See George Fox, *Integra v. Merck: Limiting the Scope of the § 271(e)(1) Exception to Patent Infringement*, 19 BERKELEY TECH. L.J. 193, 200-02 (2004).

66. *Merck*, 125 S. Ct. at 2378.

67. *Id.*

68. *Id.* at 2379.

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.* at 2380.

73. *Id.*

74. *Integra*, 331 F.3d at 868.

75. *Id.* at 866.

development and submission of information' to the FDA."⁷⁶ It found that uses, such as Merck's, which merely identify a compound as a good candidate for clinical trials fall outside the scope of § 271(e)(1).⁷⁷

In exploring the legislative history of § 271(e)(1), the court determined that the express objective of § 271(e)(1) was to allow for the immediate entry of generic drugs into the market when the pioneer drug patent expired and that it was narrowly tailored to have only a de minimis impact on the patentee's right to exclude.⁷⁸ The court held that extending the safe harbor to include Merck's activities would not confine the exemption to a de minimis impact on the patentee's rights.⁷⁹ Additionally, the court noted that extending the exemption would effectively abolish biotechnology research tool patents,⁸⁰ and this was not the intent of § 271(e)(1).⁸¹ The Federal Circuit did not address the common law experimental use exception.⁸² Although Merck raised the common law experimental use defense at the district court level, it did not pursue the defense at the Federal Circuit, relying only on the statutory exemption of § 271(e)(1).⁸³

2. Judge Newman's Dissent

Judge Newman's dissent expressed concern that the majority decision effectively eliminated the common law research exemption.⁸⁴ In her view, either the common law research exemption or the § 271(e)(1) statutory experimental use defense covered Merck's activities.⁸⁵

Regarding the common law experimental use exemption, Judge Newman pointed out that the "subject matter of patents may be studied 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."⁸⁶ Thus, prohibiting research upon a patent

76. *Id.*

77. *Id.* at 867.

78. *Id.*

79. *Id.*

80. *Id.* at 872 n.4. According to the National Institutes of Health (NIH), research tools are defined to be "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinational chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." *Id.* (citing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts, 64 Fed. Reg. 72090, 72092 n.1 (Dec. 23, 1999)).

81. *Id.* at 867.

82. *Id.* at 864 n.2.

83. *Id.*

84. *Id.* at 872-73 (Newman, J., dissenting).

85. *Id.* at 874.

86. *Id.* at 875.

would impede technological advancement and would run counter to the framework of patent law.⁸⁷ Additionally, patent law implicitly allows for experimental use, because there would be little value in requiring public disclosure of an invention if the invention could not be experimented upon until the patent expired.⁸⁸ Judge Newman acknowledged that there is a limit on the common law exemption and proposed that the boundary may lie in the distinction between “research” and “development.”⁸⁹ She proposed that courts apply the exemption to research conducted to understand, improve upon, or modify the patented subject matter, even if the ultimate goal is profit.⁹⁰ She also agreed with the majority that the § 271(e)(1) exemption does not “reach back down the chain of experimentation to embrace development and identification of new drugs” but asserted that it simply picks up where the experimental use defense leaves off.⁹¹

In addressing the issue of research tools, Judge Newman determined that a common law research exemption would not eliminate research tool patents because the “[u]se of an existing tool in one’s research is quite different from study of the tool itself.”⁹² Thus, the court must distinguish between *research on* patented things, which has always been permitted, versus *research using* patented things, which has never been permitted.⁹³

C. The Supreme Court’s Decision

The Supreme Court reversed the decision of the Federal Circuit and delivered a unanimous opinion holding that: (1) the exemption set forth by § 271(e)(1) includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process; (2) the exemption is not limited only to preclinical data pertaining to safety of drugs in humans; and (3) the exemption does not categorically exclude either experimentation on drugs that are not ultimately the subject of an FDA submission or the use of patented compounds in experiments that are not ultimately submitted to the FDA.⁹⁴

The Court vacated and remanded the decision of the Federal Circuit with instructions that the evidence presented at trial was to be reviewed

87. *Id.*

88. *Id.*

89. *Id.* at 876.

90. *Id.*

91. *Id.* at 877 (citing the majority opinion at 845-55).

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

93. *Id.* at 878 & n.10.

94. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2380-83 (2005).

under the standards set forth in the jury instruction, which the Court believed to be consistent with the construction of § 271(e)(1) that the Court adopted.⁹⁵

In the opinion written by Justice Scalia, the Supreme Court broadened the § 271(e)(1) experimental use exemption and proclaimed that the statutory text “provides a wide berth” for using patented drugs in activities related to the federal regulatory process.⁹⁶ The Court framed the issue as “whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the [FDA], are exempted from infringement by 35 U.S.C. § 271(e)(1).”⁹⁷ In resolving the matter, the Court did not consider the legislative intent behind the statute. Instead, the Court scrutinized the statutory text and then evaluated the reality of the drug development process.

First, the Court found that “§ 271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Federal Food, Drug and Cosmetic Act].”⁹⁸ The court determined that this exemption includes the following activities:

Clinical and preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process;
Preclinical studies of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals;
Preclinical studies that provide information to the FDA so that the investigator can make a “risk-benefit assessment of the appropriateness of the proposed [clinical] trial”; and

95. *Id.* at 2384. The district court gave the following jury instruction regarding the § 271(e)(1) safe harbor exemption: “To prevail on this defense, [Merck] must prove by a preponderance of the evidence that it would be objectively reasonable for a party in [Merck’s] and Scripps’[s] situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question. Each of the accused activities must be evaluated separately to determine whether the exemption applies. [Merck] does not need to show that the information gathered from a particular activity was actually submitted to the FDA.” *Id.* at 2379.

96. *Merck*, 125 S. Ct. at 2380.

97. *Id.* at 2376.

98. *Id.* at 2380 (emphasis added).

Safety-related experiments even when not conducted under good laboratory practices and not suitable for submission to the FDA in an investigational new drug application.⁹⁹

Next, the Court considered the unpredictability of the trial-and-error process of drug development. Because there is no way to predict which drugs will make it to the FDA process, the Court concluded that Congress could not have intended to limit § 271(e)(1)'s safe harbor to information developed for submission to the FDA.¹⁰⁰ In its broader reading of § 271(e)(1), the Court determined that if a drug manufacturer has a "reasonable basis" for believing that a patented compound may work to produce a particular effect, and it uses the compound in research that would be appropriate to submit to the FDA, then § 271(e)(1) protects the use.¹⁰¹ Additionally, the Court determined on similar grounds that the use of a patented compound in experiments that are not themselves included in a submission of information to the FDA does not make the use infringing.¹⁰²

The Court did not address two important issues: the common law experimental use exception and the impact of § 271(e)(1) on "research tools." In fact, the Court explicitly stated in a footnote that it was not expressing an opinion as to whether § 271(e)(1) exempts "research tools" from infringement in the development of information for the regulatory process.¹⁰³

III. ANALYSIS

This Note calls for a congressional enactment of a new limited, but balanced, experimental use exemption in patent law. It is necessary not only in the field of biotechnology, but across all areas of industry. Section A analyzes the Supreme Court's decision in *Merck*. Section B recommends a broad statutory experimental use exemption, analogizes such an exemption to those found in many of the world's leading patent systems and the fair use doctrine in copyright law, and addresses the concerns of research tool companies.

99. *Id.* at 2380-82.

100. *Id.* at 2383.

101. *Id.*

102. *Id.*

103. *Id.* at 2382 n.7.

A. The Supreme Court was Correct in Drawing a Far Upstream Boundary for § 271(e)(1) Because of the Uncertainty that Exists in Pharmaceutical Development

The Court's interpretation of § 271(e)(1) in *Merck* is appropriate because it leaves adequate space for experimentation and failure on the road to regulatory approval. The Court reasoned that this broad exemption was necessary because "even at late stages in the development of a new drug, scientific testing is a process of trial and error,"¹⁰⁴ and "Congress did not limit § 271(e)(1)'s safe harbor to the development of information for inclusion in a submission to the FDA."¹⁰⁵ The Court emphasized the reach of the upstream boundary and explained that:

[I]t does not follow . . . that § 271(e)(1)'s exemption from infringement categorically excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations.¹⁰⁶

Thus, the drug manufacturer must simply have a "reasonable basis" for believing that a patented compound may produce a particular effect and conduct research on the compound that could be submitted to the FDA.¹⁰⁷ However, the Court cautioned that it also agreed with the Federal Circuit in that the safe harbor "does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process."¹⁰⁸

According to Judge Newman, the statutory exemption should apply where the common law exemption stops.¹⁰⁹ However, the common law exemption is on shaky ground after *Madey* and *Embrex*, and some wonder if it even still exists.¹¹⁰ With the uncertain footing of the common law experimental use exemption, allowing the statute to reach back as far as its text permits gives pharmaceutical companies some certainty in how to proceed.

104. *Id.* at 2382-83.

105. *Id.* at 2383.

106. *Id.* at 2382.

107. *Id.* at 2383 (quoting 35 U.S.C. § 271(e)(1) (2000)).

108. *Id.* at 2382 (quoting *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003)).

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

110. *See supra* notes 23-33 and accompanying text.

Merck appeared to be an ideal case for the common law experimental use exemption. *Integra*, the first patentee, owned patent rights to a genus of "RGD peptide."¹¹¹ *Merck*, the second patentee, created specific RGD peptides, that while novel and unobvious with regards to the peptides specifically disclosed in the *Integra* patent, infringed because they were within the genus the first patent covered.¹¹² Additionally, the utility of *Integra*'s patents was to promote wound healing whereas the utility of *Merck*'s patent was to provide a cancer treatment.¹¹³ *Merck* had no intention of selling the drug commercially until *Integra*'s patents expired.¹¹⁴ Thus, "Merck had a seemingly perfect case under the experimental use defense as its tests of the RGD peptides were to *study* and develop new RGD peptides and test their efficacy and otherwise determine which candidate RGD should be selected for clinical trials."¹¹⁵ However, perhaps in light of the dicta in *Embrex* and *Madey*, *Merck*'s new counsel for the Federal Circuit case expressly abandoned the experimental use defense and relied entirely on the statutory safe harbor of § 271(e)(1).¹¹⁶

Unfortunately, *Merck* does not provide adequate guidance on the boundaries of the experimental use defense for pharmaceutical companies or research tool companies, nor does it provide protection for experimental use outside of the areas of biotechnology and medical devices. Given the inability of the courts to clearly define an experimental use exemption, and their attempt to stretch the current statutory exemption for generic drugs far beyond its intended purpose, it is time for Congress to enact a broad experimental use defense.

B. Congress Should Enact a Well-Defined Experimental Use Exemption

Several commentators advocate a more robust experimental use doctrine.¹¹⁷ Additionally, in *Madey*, the Solicitor General submitted an amicus

111. Harold C. Wegner, *Post-Merck Experimental Use and the "Safe Harbor"*, 15 FED. CIR. B.J. 1, 19 (citing *Merck*, 125 S. Ct. at 2377).

112. *Id.* (citing *Merck*, 125 S. Ct. at 2378).

113. *Id.* (citing *Integra*, 331 F.3d at 862-63).

114. *Integra*, 331 F.3d at 863.

115. Wegner, *supra* note 111, at 21.

116. *Id.* (citing *Integra*, 331 F.3d at 860).

117. See Mueller, *supra* note 13, at 919 (calling for the congressional enactment of a limited but balanced experimental use exemption in patent law); 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

curiae brief arguing that the policy concerns were more suited to legislative rather than judicial consideration because the courts are not suited to engage in the kind of nuanced policy balancing necessary to craft a meaningful experimental use defense.¹¹⁸ Given the inability of the courts to articulate a well-defined experimental use exemption, a legislative solution is in order.

A broad experimental use doctrine is in harmony with the goals of the patent system. According to Thomas Jefferson, the primary purpose of granting patent monopolies is to benefit the public, not to reward labor.¹¹⁹ The Court has traditionally upheld this vision, holding that “[t]he primary objective of [intellectual property] is not to reward the labor . . . but [t]o promote the Progress of Science and the useful Arts.”¹²⁰ The patent system benefits the public by encouraging inventors to disclose their inventions, not by ensuring a profitable monopoly for the inventor. A limited but meaningful experimental use exemption would further the constitutionally mandated goal of the patent system by permitting the dissemination of information.¹²¹ Because innovation builds upon what came before, use of earlier innovations for experimental purposes enhances the process of creating new and improved inventions.¹²² The publication of issued patents is of little use to society if no one can experiment on the subject matter of the patent for the patent term.¹²³ Of course, an experimental use exemption must be carefully defined and judiciously applied so that it does not compromise incentives for innovation.¹²⁴

The right to experiment on a patented invention to create new inventions and to design around the patented invention is well established.¹²⁵

licensing scheme in which compulsory licenses would be available only after a limited period of patentee exclusivity).

118. Brief for the United States as Amicus Curiae at 15-16, *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>.

119. *Graham v. Deere Co. of Kansas City*, 383 U.S. 1, 9 (1966).

120. *Feist Publ'ns Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 349 (1991) (quoting U.S. CONST. art. I, § 8, cl. 8); accord *Graham*, 383 U.S. at 7-8; *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974); *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984).

121. See Mueller, *supra* note 13, at 921.

122. *Id.*

123. *Id.*

124. *Id.* at 922.

125. 3 MARTIN J. ADELMAN ET AL., PATENT LAW PERSPECTIVES § 3.6[2], at 3-78(2)-(3); accord *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d 735 (Fed. Cir. 1993); *Slimfold Mfg. Co. v. Kinkead Indust., Inc.*, 932 F.2d 1453, 1457 (Fed. Cir. 1991).

This Note considers three scenarios in this context.¹²⁶ The first is the use of a patented product to try to find new uses for the product.¹²⁷ Second, this Note considers the situation in which a patent covers a genus and experimentation is done to find the best species.¹²⁸ A third scenario this Note considers is where a patent product is used in order to design around the existing patent such that the new product does not infringe the patent.¹²⁹ Infringement occurs when the line is crossed from using the patented invention to satisfy idle curiosity to using the patented invention for commercial gain.¹³⁰

1. A Broad Common Law Experimental Use Exemption Finds Precedent in European and Japanese Patent Law As Well As in the Fair Use Doctrine in Copyright

While there is concern that a broad experimental use exemption will decrease the rate of innovation, most of the world's leading patent systems have codified a general experimental use exemption to patent infringement.¹³¹ Germany, which has the most progressive courts in Europe in regards to experimental use, has an experimental use exemption in its patent law that states that "[t]he rights conferred by the Patent shall not extend to the acts done for experimental purposes relating to the subject matter of the patented invention."¹³² Additionally, the German Supreme Court expanded this exemption to include the right to test inventions regardless of whether or not commercial purposes motivated the testing.¹³³ Similarly, the United Kingdom's 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

126. 3 ADELMAN ET AL., *supra* note 125, § 3.6[2], at 3-78(2) (describing the three scenarios).

127. *Id.*

128. *Id.*

129. *Id.* at 3-78(2), (3).

130. Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 458 (2004) ("[T]o early jurists, a clear distinction could be made between using patented material to learn about the patented invention and using patented material for business or for commerce—between using the patent to satisfy curiosity or using it to turn a profit.").

131. Mueller, *supra* note 13, at 969-70 & n.243 (noting that rather than following the United States on the experimental use issue, many nations "seem to be going the other direction").

132. Wegner, *supra* note 111, at 28 (citation omitted).

133. *Id.* at 28-29.

the subject matter of the invention.”¹³⁴ The Japanese have a clear-cut statutory experimental use exemption that states: “The effects of the patent right shall not extend to the working of the patent right for the purpose of experimentation or research.”¹³⁵

The experimental use exemption can also be analogized to the fair use doctrine in copyright, which allows unlicensed use of a copyrighted work provided the use meets a multi-factored standard.¹³⁶ The fair use doctrine, added to the copyright statute in 1976, finds its roots in the nineteenth century decisions of Justice Story.¹³⁷ While Justice Story also suggested a similar principal in patent law, an experimental use exemption in patent law has not yet taken hold.¹³⁸ According to Professor Janice Mueller, most scholars believe that the fair use doctrine affords a useful and important safety valve against over-inclusive application of copyright rights.¹³⁹ Maureen O’Rourke suggests that a similar system should be introduced in patent law to curb overly-broad patent rights.¹⁴⁰ Such a system should safeguard incentives to invent while providing an important safety valve to insure that innovation is not impeded.¹⁴¹

2. *A Legislative Proposal for a Broad Statutory Experimental Use Exemption*

Arguments for legislation of an experimental use exemption in patent law lie in its comparison with the fair use exemption in copyright, the judicial expansion of the narrow § 271(e)(1) exemption, and similar statutory enactments in the world’s leading patent systems. A broad experimental use defense must not be too narrow as to stifle research and restrict the ability to validate and build upon new knowledge. On the other hand, too broad a defense could cause companies to hesitate to invest in biotechnology research or rely on secrecy in lieu of patent protection.¹⁴² The strongest case for the experimental use defense is in designing around, or

134. Patents Act, 1977, c. 37, § 60(5) (Eng.), available at http://www.wipo.int/clea/docs_new/en/gb/gb001en.html.

135. Wegner, *supra* note 111, at 30 (citation omitted).

136. 17 U.S.C. § 107 (2000).

137. Mueller, *supra* note 13, at 926-27.

138. *Id.* at 927 (citation omitted).

139. *Id.* at 926 (citation omitted).

140. See generally Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

141. *Id.*

142. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 224 (1987).

developing alternatives to, a patented invention.¹⁴³ In this instance, the interests of the researcher are in line with the interest of the public.¹⁴⁴ The weakest case for the experimental use defense is when the researcher is using a patented invention in unrelated research effort, as is the case with research tools.¹⁴⁵

The House of Representatives proposed a highly plausible solution for the dilemma of what the experimental use exemption should be in the Patent Competitiveness and Technological Innovation Act of 1990.¹⁴⁶ The Act stipulates that the exemption should cover all patented inventions, provided that the use of the patented invention or process is done for the purpose of experimentation or research.¹⁴⁷ The House Report provides that:

the making or using of a patented invention solely for research or experimentation shall not be an act of patent infringement unless the patented invention has a primary purpose of research or experimentation. The exemption does not apply once a decision is made to commercialize the fruits of the research or experimentation. If the patented invention has a primary purpose of research or experimentation . . . it shall not be an act of infringement to manufacture or use one of these inventions to study, evaluate, or characterize it or to create a product outside the scope of the patent covering the particular invention.¹⁴⁸

The House Report justifies the Act on the grounds of public policy, the initial intent of patent law, and the realities of scientific research. In addressing the public policy concern and the intent behind patent rights, the Act states that:

It is a central tenet of American patent law that there is a right to use scientific information to create new and better inventions in competition with the patented invention . . . The framers of the Constitution clearly could not have envisioned shutting the door to further research for the long period of the patent grant.¹⁴⁹

The Act also takes research tools into consideration and ensures that they would not be swallowed up by the experimental use exemption. The Act

143. *Id.*

144. *Id.* at 225.

145. *Id.*

146. H.R. REP. NO. 101-960, pt. 1 (1990).

147. *Id.* at 2.

148. *Id.* at 41.

149. *Id.* (citations omitted).

carves out research tools by distinguishing between *experimentation on* a patented invention and *experimentation using* a patented invention as Judge Newman proposed in her dissent in *Integra*, and which has been widely accepted by commentators as an important factor in assessing experimental use.¹⁵⁰ Further, the Act excludes specific activities that would be exempted from patent infringement. According to the House Report:

The easiest method of limiting and describing the “experimental use of research exception” is to differentiate between *experimentation on* a patented invention and *experimentation using* a patented invention in order to accomplish another purpose, the former type of experimentation constituting the scope of the exception. Under this approach the following acts would not constitute patent infringement:

- (1) testing an invention to determine its sufficiency or to compare it to prior art;
- (2) tests to determine how the patented invention works;
- (3) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
- (4) experimentation for the purpose of “designing around” a patented invention;
- (5) testing to determine whether the invention meets the tester’s purposes in anticipation of requesting a license; and
- (6) academic instructional experimentation with the invention.

Business testing is clearly not an experimental use, and would not be authorized by Title IV.¹⁵¹

Had the court applied the *experimenting on* versus *with* distinction to the facts of *Merck*, the experimental use exemption would have resulted in the same outcome that the Supreme Court reached, and Judge Newman advocated.¹⁵² In *Merck*, Dr. Cheresch was *experimenting on* the patented RGD peptides in order to discover a new use for the peptides.¹⁵³ By contrast, in *Madey*, Duke researchers were *experimenting with* the patented lasers to conduct physics research; they were not trying to find a new use for the laser, or attempting to modify, improve or design around the laser.¹⁵⁴ Thus, the use in *Madey* was infringing while the use in *Integra* was not.¹⁵⁵

150. Mueller, *supra* note 13, at 956-57 (citations omitted).

151. H.R. REP. NO. 101-960, pt. 1, at 44-45 (1990).

152. Mueller, *supra* note 13, at 956-57 (citations omitted).

153. *Id.*

154. *Id.*

155. *Id.* at 957-58.

3. *Concerns of Research Tool Companies*

The most commonly stated objection to a broad experimental use doctrine is the possibility that it would reduce incentives for invention of new research tools.¹⁵⁶ Although an expanded experimental use exemption may result in some reduction of the development of research tools, it is just as likely that the lessening of the probability of royalty stacking problems will promote development of new products.¹⁵⁷ While the *experimenting on* versus *with* distinction carves out research tools, it may be difficult to apply at the margin. For example, a difficult problem may lie in the case of antibodies where the product is both a tool and a drug. In these cases, an inquiry will have to determine how the product was used. However, under an appropriately constructed *experimenting on* versus *experimenting with* distinction, research tools may effectively be carved out and protected.

IV. CONCLUSION

Given the uncertainty in the experimental use exemption, and the court's inability to craft an appropriately nuanced standard through judicial decision, it is time for Congress to enact a limited, but balanced, experimental use exemption similar to exemptions that exist in other patent systems and the fair use provision in copyright. While many companies will still choose to seek licenses *ex ante* in order to avoid the risk of an *ex post* hold up,¹⁵⁸ such an exemption would add certainty to the experimental use defense when issues arise. It is for the legislature, not the judiciary, to form the nuanced policy that must encompass a broad experimental use exemption. Given the diverse interests in Congress, it may be difficult to reach consensus, but the result is preferable to allowing the judiciary to incrementally expand the narrow foothold granted under § 271(e)(1) while at the same time dismissing the common law experimental use exemption.

156. Mueller, *supra* note 16, at 41 (citations omitted).

157. *Id.*

158. PETER S. MENELL & SUZANNE SCOTCHMER, *Intellectual Property*, in *HANDBOOK OF LAW & ECONOMICS* (forthcoming 2006) (manuscript at 31, on file with authors).