
The Experimental Use Exception: Looking Towards a Legislative Alternative

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Cite as: 6 J. High Tech L. 93

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Introduction

Under the patent statute, one who uses a patented invention without authorization from the patent holder is liable for patent infringement.¹ However, an accused infringer can escape a finding of infringement by invoking the common-law experimental use exception,² which permits a *de minimis* use of a patented invention where the use was motivated by an experimental purpose.³ Recent decisions from the Federal Circuit addressing experimental use have demonstrated that the exception is extremely narrow and unavailable in most practical circumstances. In this article we explore some of the problems posed by the present state of the exception and propose a policy-driven alternative. Part I summarizes the major cases discussing the experimental use exception, describing the current state of the exception. Part II discusses the interaction between the experimental use exception and the infringement “safe harbor” of the Hatch-Waxman Act, which exempts certain uses of a patented invention from liability for patent infringement. In Part III, we explore the policy arguments in favor of and against an experimental use exception, and advocate for replacing the judicially created exception with a legislative exemption that carefully balances the competing policies behind the patent system.

1. 35 U.S.C. § 271(a) (2000).

2. The exception originated from an 1813 case, in which Justice Story remarked in dicta that “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.” *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

3. Although courts sometimes refer to the experimental use exception and the *de minimis* exception as distinct doctrines, they are generally recognized as the same defense. See 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03[1] (2004) (“Some decisions suggest that the experimental purpose doctrine ‘is nothing more than an expression of the maxim *de minimis non curat lex*.’” (quoting *Douglas v. United States*, 181 U.S.P.Q. (BNA) 170, 177 (Ct. Cl. 1974) (subsequent history removed))).

I. The Contours of the Experimental Use Exception⁴

A. The *Embrex* decision: Commercial Use is Not Experimental Use

In *Embrex v. Service Engineering Corp.* the Federal Circuit narrowly construed the experimental use exception.⁵ Plaintiff Embrex was the exclusive licensee of a patent directed to methods primarily used to vaccinate birds from disease while still in the egg.⁶ Embrex designed machinery that implemented the claimed vaccination method in industrial chicken farms.⁷ In attempts to design around the patent, defendant Service Engineering Corp. (“SEC”) hired a professor to develop a prototype that would inject vaccine into the chorioallantoic sac (“CAS”), a part of the egg that was outside the scope of the method specified in the patent.⁸ SEC offered its prototype for sale while it was being tested.⁹ Although SEC’s design-around attempts ultimately failed, some of the test vaccinations were inadvertently injected into areas covered by the patent during testing due to the difficulty of injecting into the CAS.¹⁰ Embrex sued for patent infringement and SEC claimed that it was entitled to the benefit of the experimental use exception.¹¹

Despite language in the patent statute suggesting that “any and all uses of a patented invention” constitute infringement, the *Embrex* court recognized early precedent that carved out a narrow defense “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”¹² However, because SEC’s tests were conducted in furtherance of its business venture, SEC was not protected by the experimental use exception even though its use of the patented method was for testing and was accidental.¹³ The commercial

4. Some courts refer to the doctrine as the experimental use exception, others refer to it as an exemption, while still others label it as a defense. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1361 (Fed. Cir. 2002) (remarking that “we have referred to the defense in a variety of ways”). This article will refer to the doctrine of experimental use as an exception.

5. 216 F.3d 1343, 1349 (Fed. Cir. 2000).

6. *Id.* at 1346.

7. *Id.*

8. *Id.* at 1346-47.

9. *Id.* at 1347.

10. *Id.*

11. *Id.* at 1347, 1349.

12. *Id.* at 1349 (quoting *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984)) (internal quotations omitted).

13. See *id.* (affirming “district court’s denial of [judgment as a matter of law] on

character of the use rendered the experimental use exception inapplicable, irrespective of whether SEC realized a profit.¹⁴ Thus, after *Embrex*, it was clear that the experimental use exception was only available to non-commercial uses of a patented invention.

B. The *Madey* Decision: Use at an Academic Institution is Not Experimental When Related to Legitimate Business Interests

In 2002, two years after the *Embrex* decision, the Federal Circuit decided *Madey v. Duke University*.¹⁵ *Madey*, a research professor at Stanford University, conducted a research program through which he operated a free electron laser ("FEL") research laboratory.¹⁶ He was the exclusive owner of patents directed to two FEL devices, both of which were used in his laboratory.¹⁷ *Madey* later took a position at Duke University and brought his patented equipment with him to establish an FEL laboratory at Duke.¹⁸ After *Madey* resigned, Duke continued to use the equipment in the FEL laboratory, prompting *Madey* to bring an action for patent infringement.¹⁹ Duke moved for summary judgment of non-infringement, arguing that use of the FEL equipment was protected by the experimental use exception.²⁰ The district court granted the motion, concluding that Duke was entitled to the experimental use exception based on Duke's "evidence that all of its uses of the devices covered by [*Madey's* patents] have been in furtherance of its educational purpose or for experimentation only."²¹

On appeal to the Federal Circuit, *Madey* argued that the court should abrogate the common-law experimental use exception. *Madey* reasoned that under Supreme Court precedent, intent was irrelevant in an infringement analysis, while "the experimental use defense necessarily incorporates an intent inquiry."²² While the Federal Circuit declined to do away with the exception entirely, it reiterated the exception's narrow scope as expressed in

infringement").

14. *See id.* ("Just because SEC was unsuccessful in selling its machines does not confer infringement immunity upon SEC for its infringing acts.").

15. 307 F.3d 1351 (Fed. Cir. 2002).

16. *Id.* at 1352.

17. *Id.* at 1352; *Madey v. Duke Univ.*, 336 F. Supp. 2d 583, 585 (M.D.N.C. 2004).

18. *Madey*, 307 F.3d at 1352.

19. *Id.* at 1353.

20. *Id.* at 1355.

21. *Madey v. Duke Univ.*, 266 F. Supp. 2d 420, 427. (M.D.N.C. 2001)

22. *Madey*, 307 F.3d at 1360-61.

Embrex.²³ Although *Embrex* had framed the experimental use inquiry around a distinction between commercial and non-commercial use, the *Madey* court refocused the inquiry on whether the accused use is “in furtherance of the alleged infringer’s legitimate business.”²⁴ If it is, it cannot qualify as experimental use for purposes of the exception.²⁵ Since Duke was a major academic institution in the business of research and education, the Federal Circuit concluded, Duke’s use of the equipment in the FEL laboratory for educational purposes could be outside the bounds of the experimental use defense.²⁶ On these grounds, the court reversed the district court’s grant of summary judgment of non-infringement and remanded for the district court to assess whether Duke’s use fell within the clarified scope of the exception.²⁷

After remand, Duke again moved for partial summary judgment of non-infringement, again invoking the experimental use exception.²⁸ The district court denied Duke’s motion, noting that because Duke’s use of the patented invention was for educational purposes, it was, at least in part, in furtherance of a legitimate business purpose. Duke therefore did not qualify for the experimental use exception under the Federal Circuit’s formulation.²⁹

C. Experimental Use after *Embrex* and *Madey*: A Narrow Exception

While the experimental use exception has not been abrogated, it has lost any practical application following the decisions in *Embrex* and *Madey*. *Embrex* and *Madey* render almost any use of a patented invention for testing or designing around infringing, unless the use is in no way related to a legitimate business purpose.³⁰ Even if *Embrex*

23. *Id.*

24. *Id.* at 1362.

25. *Id.* (declaring that “the profit or non-profit status of the user is not determinative”).

26. *See id.* at 1363 n.7.

27. *See id.* at 1364. The *Madey* court also clarified that the burden of proving the experimental nature of the use rests on the defendant. *Id.* at 1361.

28. *Madey v. Duke Univ.*, 336 F. Supp. 2d 583, 589 (M.D.N.C. 2004).

29. *Id.* at 591-92.

30. *See Madey*, 307 F.3d at 1360-63; *Embrex v. Serv. Eng’g Corp.*, 216 F.3d at 1349; *see also Moore U.S.A., Inc. v. The Standard Register Co.*, 144 F. Supp. 2d 188, 196-99 (W.D.N.Y. 2001) (denying summary judgment of non-infringement because defendant’s assembly and subsequent tests of a machine were done in pursuit of defendant’s business goal to create a machine similar to the patented invention).

had left open an avenue for research institutions to rely upon the experimental use exception for scientific use, *Madey* closed it. Prior to *Madey*, it was assumed that use of patented inventions by research institutions in pursuit of science, knowledge, and education qualified as experimental use.³¹ *Madey*'s recognition that academic research institutions have business interests in addition to educational interests, many of which are furthered by using patented inventions, undermined that assumption. Instead, *Madey* fundamentally questioned the nature of academic research, considering the financial and commercial benefits that academic institutions receive through their scientific studies and advances.³² As a result, research universities can not rely on the exception when they use patented inventions.³³

Although some commentators argue that *Madey*'s holding will stifle research,³⁴ *Madey* merely recognizes that research at universities is often conducted in pursuit of commercial goals or in conjunction with commercial entities.³⁵ It follows that when a university benefits financially from its use of a patented idea, it should pay royalties to the patent holder or be liable for infringement. This is especially true when the university derives considerable revenue from licensing its own patents, many of which presumably result from research conducted at the institution.³⁶ *Madey* only

31. See Melanie K. Kitzan Haindfield, *Is the Experimental Use Exemption for Patent Infringement Still Needed?*, 3 J. Marshall Rev. Intell. Prop. L. 103, 104-106 (2003).

32. See *Madey*, 307 F.3d at 1362 (observing that research projects "increase the status of the institution and lure lucrative research grants, students and faculty").

33. See *id.*; JOHN R. THOMAS, CRS REPORT FOR CONGRESS: SCIENTIFIC RESEARCH AND THE EXPERIMENTAL USE PRIVILEGE IN PATENT LAW 8-9, (2004), <http://www.fas.org/sgp/crs/RL32651.pdf>.

34. See, e.g., Jennifer Miller, Sealing the Coffin on the Experimental Use Exception, 2003 DUKE L. & TECH. REV. 12 (May 7, 2003); David G. Sewell, Note, *Rescuing Science from the Courts: An Appeal for Amending the Patent Code to Protect Academic Research in the Wake of Madey v. Duke University*, 93 GEO. L.J. 759, 771 (2005).

35. See Ruth E. Freeburg, Comment, *No Safe Harbor and No Experimental Use: Is it Time for Compulsory Licensing of Biotech Tools?*, 53 BUFF. L. REV. 351, 404-05 (2005); THOMAS, *supra* note 33, at 10 ("Because academic institutions are increasingly benefited from the patent system . . . they should also be held accountable when they infringe the patents of others.").

36. See *Madey*, 307 F.3d at 1362-63, 1363 n.7. Many universities derive enormous revenue from licensing patents on inventions developed in university research programs. For example, data published by the Association of University Technology Managers demonstrates that at least twenty universities reaped more than \$10,000,000 in licensing revenue in the year 2003 alone. ASS'N OF UNIV. TECH. MANAGERS, INC., LICENSING SURVEY (1994), http://www.ir.ufl.edu/nat_rankings/research/royalty_old.pdf. Total license

updates the experimental use exception to make it consistent with the present realities of the research world.

The narrow scope of the post-*Madey* experimental use exception raises the question of when, if at all, the defense may be successful. *Embrex* suggested that use associated with testing or designing around a patent was not experimental. *Madey* held that use at research institutions in pursuit of scientific knowledge would not be excepted if it is too closely tied to the institution's business interests. Thus, the only remaining experimental use is that by an individual on his or her own time out of general interest in the invention without any intent to profit.³⁷ Since the exception ultimately remains only for small-scale tinkering with inventions, there is little practical application of the doctrine, especially with respect to sophisticated biotechnology research tools and scientific machinery that are generally inaccessible to the casual tinkerer.³⁸ The exception is unlikely to be litigated in such cases, however; neither the value of an injunction against such *de minimis* use nor any royalty for such use would be worth the cost of litigation.³⁹ Moreover, for the few who have access to patented inventions useful in scientific research, such access is likely gained through employment in a commercial or academic institution conducting research related to the patented invention – an environment in which the use of a patented invention is likely infringing under *Madey*.

II. The Experimental Use Exception and §271(e)(1)

The Federal Circuit first addressed the doctrine of experimental use in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*⁴⁰ *Roche* represents the Federal Circuit's first formulation of the exception as a narrow defense that does not protect uses related to the user's business interests.⁴¹ Specifically, it held that use of a patented invention to collect information for compliance with the Food and

revenues that year for the twenty listed universities exceeded \$530 million. *See id.*

37. That only the casual experimenter is protected by the experimental use exception was appreciated by the Federal Circuit in its *Roche* decision, which noted that the exception shelters uses of patented inventions "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

38. *See* Haindfield, *supra* note 31, at 117 ("Both academic and industrial scientists admit access to patented inventions does not usually come easy.").

39. *See* THOMAS, *supra* note 33, at 12.

40. 733 F.2d 858 (Fed. Cir. 1984), *superseded by*, 35 U.S.C. § 271(e)(1).

41. *Id.* at 863.

Drug Administration (“FDA”) approval process for generic drugs was not covered by the exception.⁴² In reaction to the *Roche* decision, Congress passed an amendment to the patent statute exempting certain uses, including the use at issue in *Roche*, from infringement.⁴³ Although §271(e)(1) supersedes *Roche*, an examination of the *Roche* decision, recent judicial opinions on §271(e)(1), and the interaction between §271(e)(1) and the experimental use exception provides insight into the purpose and viability of the exception.

A. The *Roche* decision and the Safe Harbor Provision of §271(e)(1)

At issue in *Roche* was defendant Bolar’s use of plaintiff Roche’s patented drug compound to generate data for submission to the FDA for approval to market a generic version of the drug.⁴⁴ The district court ruled that Bolar’s use of the patent compound was *de minimis* and therefore non-infringing, and Roche appealed.⁴⁵

The Federal Circuit first addressed and rejected Bolar’s argument that its studies fell within the experimental use exception.⁴⁶ Since Bolar’s use of the patented compound served Bolar’s business interest in marketing a generic drug, the Federal Circuit ruled, the experimental use exception did not apply.⁴⁷ The court feared that a broader construction of the exception might “allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”⁴⁸ The Federal Circuit concluded that tests conducted in furtherance of a business agenda constitute infringement, and identified experiments conducted in pursuit of FDA approval as use with an inherent commercial purpose.⁴⁹

Next, the Federal Circuit addressed Bolar’s argument that, as a matter of public policy, its use of a patented compound in seeking approval for a generic drug should not constitute infringement.⁵⁰

42. *Id.* at 860-63.

43. Pub. L. No. 98-417, Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 301, 355, 360cc (2003); 28 U.S.C. § 2201 (1993); 35 U.S.C. §§ 156, 271, 282 (2003)).

44. *Roche*, 733 F.2d at 860.

45. *Id.* at 861-67.

46. *Id.* at 862-63.

47. *Id.* at 863.

48. *Id.*

49. *See id.*

50. *Id.*

Bolar noted that changes in the Food, Drug, and Cosmetic Act (“FDCA”) increased the difficulty of obtaining a New Drug Application (“NDA”), required for approval to market a new drug, by requiring tests proving both safety and efficacy of the drug at issue.⁵¹ As a result of the more rigorous application process, more time elapsed from when a company begins testing and when the company obtains an FDA approved product that is ready for market.⁵² Bolar argued that unless others could use the patented drug for clinical testing during the life of the patent, the changes in the FDCA, which were intended to benefit the public by insuring that drugs on the market are safe and effective, would effectively increase the length of the patent-holder’s monopoly.⁵³

The court rejected Bolar’s policy argument.⁵⁴ It observed that in amending the FDCA, Congress was presumably aware of any effect the amendments would have on patent term.⁵⁵ The court concluded that policy concerns arising from the interaction between statutory enactments are better addressed by Congress than the courts.⁵⁶

In response to *Roche*, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act.⁵⁷ In an amendment codified at 35 U.S.C. §271(e)(1), the Hatch-Waxman Act attempted to cure any effective extension of a patent-holder’s monopoly by exempting from infringement “uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”⁵⁸ Section 271(e)(1), sometimes referred to as the regulatory “safe harbor” provision, permits use of patented inventions during the life of a patent for testing intended to develop generic drugs for FDA approval so that generics can enter the market upon the expiration of patented drugs on which they are based.⁵⁹

51. *Id.* at 864.

52. *See id.*

53. *Id.*

54. *Id.* at 864-65.

55. *Id.* at 864.

56. *Id.* at 865.

57. *See supra* note 43; *see also* Glaxo Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997) (noting that *Roche* has been superseded by statute); Sewell, *supra* note 34, at 764-65.

58. 35 U.S.C. § 271(e)(1).

59. *See id.*; *see also* THOMAS, *supra* note 33, at 15.

B. The *Integra* decision: Experimental Use and §271(e)(1)

A further discussion of the experimental use exception arose in *Integra Lifesciences I, Ltd. v. Merck KGaA*,⁶⁰ in which the majority primarily discussed the §271(e)(1) exemption while the dissent focused on the experimental use exception and its interaction with §271(e)(1). Plaintiff Integra owned multiple patents relating to a short peptide segment.⁶¹ A researcher at Scripps used these peptides for testing in research related to another peptide, which he hoped to develop sufficiently for clinical trials under FDA guidelines.⁶² Specifically, the Scripps scientist used the patented peptide in pre-clinical research in order to “[identify] the best drug candidate to subject to future clinical testing under the FDA processes.”⁶³ Integra subsequently sued the researcher, Scripps, and Merck, which was funding the research, for patent infringement.⁶⁴ The district court found that certain uses of the patented peptide in drug discovery research did not fall within the boundaries of the §271(e)(1) statutory exemption.⁶⁵

On appeal, the Federal Circuit affirmed the district court’s finding that the disputed uses of the peptide were too removed from the FDA process to qualify for the statutory exemption.⁶⁶ Ultimately the Supreme Court reversed the Federal Circuit, holding that the research could fit within the §271(e)(1) exemption provided it was “reasonably related” to the pursuit of information that would be used in FDA applications, even if that particular research was ultimately not submitted to the FDA.⁶⁷

The Federal Circuit majority in *Integra* rested solely on §271(e)(1) and declined to address the experimental use exception, noting that neither party had briefed the matter.⁶⁸ In dissent, however, Judge Newman expounded upon the experimental use exception and its

60. 331 F.3d 860 (Fed. Cir. 2003), *vacated and remanded by*, Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005).

61. *Id.* at 862-63.

62. *Id.* at 863.

63. *Id.* at 865.

64. *Id.* at 863.

65. *Id.* at 862.

66. *Id.* at 867.

67. See Merck KGaA v. Integra Lifesciences, Ltd., 125 S. Ct. 2372, 2383-84 (2005).

68. *Integra*, 331 F.3d at 863 n.2 (criticizing the dissent for its discussion of the experimental use doctrine). Although the *Integra* majority did not address the experimental use exception with respect to the research in issue on appeal, the district court found that other research performed by the Scripps researcher qualified for the experimental use exception. *Merck*, 125 S. Ct. at 2379.

relationship to §271(e)(1).⁶⁹ Judge Newman described the experimental use exception as a doctrine that permits others to use a patented invention in an effort to “understand it, or improve upon it, or to find a new use for it, or to modify or ‘design around’ it.”⁷⁰ She noted that in addition to providing incentives to innovate, the patent system is intended to further scientific knowledge by publicizing novel ideas that others can use to advance science.⁷¹ Judge Newman’s broad conception of the experimental use doctrine is based on this purpose of the patent system and the concern that a narrow exception would impede technological progress.⁷²

In Judge Newman’s view, preliminary research should be protected by the experimental use exception, and §271(e)(1) should “[take] up where the research exemption left off.”⁷³ Thus Judge Newman conceives of the experimental use exception and the statutory exemption together as a continuum on which an accused infringer is sheltered from liability for a wide range of research and development activity.⁷⁴ While her view is grounded in sound policy arguments, her formulation of the experimental use exception is nevertheless at odds with the *Embrex* and *Madey* decisions, which foreclose the availability of the exception for many uses that Judge Newman would protect.⁷⁵

C. The Interaction between Experimental Use and §271(e)(1): Can They Fit Together?

More recent application of the experimental use exception suggests that Judge Newman’s dissent overstates the exception’s scope, particularly its relation to §271(e)(1).⁷⁶ In *Third Wave Technologies, Inc., v. Stratagene Corp.*, plaintiff Third Wave Technologies owned

69. See *Integra*, 331 F.3d at 872 (Newman, J. concurring in part, dissenting in part).

70. *Id.* at 875.

71. *Id.* at 873.

72. See *id.* at 875-76. In a footnote in her dissent, Judge Newman expressed her opinion that the experimental use exception was not at issue in *Madey*. *Id.* at 878 n.10. *Madey*, she noted, was a case in which research tools were being used for their intended purpose, and not with the intent to understand, improve or design around the patented equipment. *Id.*

73. *Id.* at 878.

74. See *id.*

75. See discussion *supra* Part I.C.

76. See *Third Wave Techs., Inc., v. Stratagene Corp.*, 381 F. Supp. 2d 891, 894-909 (W.D. Wisc. 2005).

two patents claiming specific “methods for detecting the presence of a target nucleic acid molecule by forming nucleic acid cleavage structures and cleaving them in a site-specific manner so as to release distinct detectable non-target cleavage products.”⁷⁷ In the course of its research and development, defendant studied the efficacy of its own commercial products for identifying biological compounds.⁷⁸ Third Wave sued for patent infringement, alleging that defendant’s products practiced its patented method.⁷⁹

In response to plaintiff’s motion for summary judgment of infringement, the defendant argued that its activities were protected by both the experimental use exception and the §271(e)(1) statutory exemption, as its testing was related to FDA submissions.⁸⁰ The court observed that although defendant’s testing “might seem to fall under the experimental use exception,” the *Madey* decision and previous precedent made clear that the exception was extremely narrow.⁸¹ Thus, the court rejected defendant’s experimental use argument, noting that *because* defendant’s studies were to seek marketing approval, the studies were for business purposes and therefore not experimental use.⁸² On this formulation, the experimental use exception and the §271(e)(1) exemption are mutually exclusive, since any use reasonably related to FDA approval is necessarily also related to business interests.⁸³

Federal Circuit precedent, too, demonstrates that the experimental use exception is at odds with §271(e)(1), rather than coexistent on a continuum as Judge Newman argued. In its explanation of the experimental use exception in *Embrex* and *Madey*, the Federal Circuit relied on its reasoning in *Roche*.⁸⁴ While the result in *Roche* would be different today due to the enactment of §271(e)(1), the Federal Circuit’s reliance on *Roche*’s rationale shows that the court’s original conception of the experimental use exception is still compelling.⁸⁵ Since the *Roche* court equated use of a patented drug

77. *Id.* at 896-97.

78. *Id.* at 911-13.

79. *Id.* at 894.

80. *Id.* at 911-13.

81. *Id.* at 912.

82. *Id.*

83. *See id.* The court commented that the defendant lacked evidence indicating that testing its products were related to FDA submissions of any sort and suggested that the defendant “[show] a far more concrete relationship between its past testing and its future intent to seek FDA approval if it intends to revive its argument under § 271(e)(1) at trial.” *Id.* at 913.

84. *See Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (noting that “[i]n *Embrex* we followed the teachings of *Roche* ...”).

85. Indeed, in a footnote in *Madey*, the Federal Circuit remarked that “[a]fter the

in research to develop generics with use motivated by commercial intent, it follows that use of a patented compound in the earlier stages of drug development, in which many compounds are studied in the hope that they might yield promising drug candidates, is also commercial in nature and therefore excluded from the experimental use exception.⁸⁶

III. The Future of the Experimental Use Exception

The Hatch-Waxman Act exemplifies Congressional action to exempt certain uses of patented inventions from infringement after the *Roche* result demonstrated that the patent statute failed to properly balance the countervailing forces behind the patent system.⁸⁷ The appropriate balance of these forces is best determined by an empirical investigation into both the realities of research and the economics underlying the value of patents.⁸⁸ As the *Roche* Court pointed out, such policy concerns are better left to Congress and not the courts.⁸⁹ A legislative experimental use exception would provide the protection for certain desirable experimental uses that the exception articulated in *Madey* lacks. In this section we propose abandoning the judicially-created exception in favor of a statutory exception grounded in the policies at the foundation of the patent system.

Roche decision ... Congress changed the law, overruling *Roche* in part, but without impacting the experimental use doctrine.” *Id.* at 1355 n.3.

86. See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2382-83 (2005). In *Merck*, the Supreme Court noted that drug discovery is related to development as drug discovery research is conducted because “[i]n the vast majority of cases, neither the drugmaker nor its scientists have any way of knowing whether an initially promising candidate will prove successful over a battery of experiments.” *Id.* In holding that drug discovery research can fall under the scope of § 271(e)(1) the Court recognized that drug discovery is often a prerequisite for development of drugs for FDA submission and approval and ultimately for market. See *id.* Under *Roche*’s logic then, drug discovery research is still illustrative of commercial intent.

87. See discussion *supra*, Part II.A, II.B.

88. For an assessment of the economics that play into patent protection see Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

89. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 865 (Fed. Cir. 1984), superseded by, 35 U.S.C. § 271(e)(1).

A. The Legislative Alternative: A Policy-Driven Solution

At least one judge on the Federal Circuit is of the view that the experimental use defense should be abandoned altogether. In a concurring opinion in *Embrex*, Judge Rader noted that since a finding of direct infringement does not require an inquiry into intent, whether the intent of an accused infringer is experimental or commercial should be irrelevant.⁹⁰ Similarly, in Judge Rader's view, inquiry into whether an infringing use is *de minimis* or substantial should be considered only when calculating damages, not when assessing infringement.⁹¹

Moreover, the limited applicability of the judicially-created experimental use exception suggests that it has outlived its usefulness and should be abandoned. As noted above, *Embrex* and *Madey* have left the exception with little practical application.⁹² In its current formulation, therefore, the exception is superfluous; given the "insufficient economic justification to commence litigation against individuals who are not making commercially important uses of patented inventions," the defense as it now stands will rarely, if ever, arise in litigation.⁹³

Despite these weaknesses in the doctrine as it presently stands, there are nevertheless compelling considerations in favor of some protections for certain experimental uses. As Judge Newman pointed out in her *Integra* dissent, the patent system is founded on two countervailing policies.⁹⁴ On the one hand, it requires that patentees provide complete public disclosure of their inventions, to foster the further development of scientific knowledge.⁹⁵ In exchange, it

90. See *Embrex v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J. concurring). *Madey* later reiterated this argument in his case against Duke. *Madey v. Duke Univ.*, 307 F.3d 1351, 1360-61 (Fed. Cir. 2002). The argument is grounded in Supreme Court precedent holding that intent is irrelevant with respect to infringement. *Embrex*, 216 F.3d at 1352 (Rader, J. concurring) ("[T]he Supreme Court and this court have recently reiterated that intent is irrelevant to infringement." (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 34 (1997))).

91. *Embrex*, 216 F.3d at 1352 (Rader, J. concurring).

92. See discussion *supra* Part I.C.

93. See THOMAS, *supra* note 33, at 12. In an article written before *Madey* even further narrowed the scope of the exception, Professor Rebecca Eisenberg noted that "the defense has almost never succeeded in practice." Eisenberg, *supra* note 88, at 1023. After *Embrex* and *Madey* exception is even more likely to be a losing argument.

94. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J. concurring in part dissenting in part), *vacated and remanded by* *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).

95. See *id.*

provides inventors with incentives to innovate by granting them a limited monopoly over those inventions.⁹⁶ As the scope of that monopoly decreases, however, so does the incentive for inventors to publicize their inventions through the patent system. An experimental use exception that permits researchers to use a patented invention to design around the patent or for scientific exploration promotes the progress of science. At the same time, such an exception reduces the value of the monopoly that rewards the inventor's full public disclosure. Thus, the appropriate scope of exceptions to infringement, such as an experimental use exception, depends on what is perceived as the ideal balance between the two purposes.

Professor Rebecca Eisenberg has studied how the patent system's underlying economics and its effects on scientific research inform the experimental use exception.⁹⁷ Eisenberg observed that the tension between the dual purposes of the patent system is in sharpest focus when considering use of a patented invention to design around the patent.⁹⁸ This is so because a successful design-around represents scientific advancement.⁹⁹ But it also produces a new invention that competes with the patented invention in the marketplace.¹⁰⁰ This competition devalues the patent monopoly, which in turn decreases the incentives to invent.¹⁰¹ The preservation of such incentives suggests that use of patented invention for design-around should constitute infringement.¹⁰² Exempting design-around uses from infringement, however, would lower the cost of research, which would increase research and development.¹⁰³

Eisenberg argues for striking the balance between these countervailing forces with a compulsory license for design-around uses of patented invention. She concludes that although "[a] patent holder should not be entitled to enjoin" such use, "it might be appropriate in some cases to award a reasonable royalty after the fact to be sure that the patent holder receives an adequate return on the initial investment in developing the patented invention."¹⁰⁴

96. *See id.*

97. *See* Eisenberg, *supra* note 88.

98. *Id.* at 1075.

99. *Id.* at 1075-76.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.* at 1078.

Eisenberg acknowledges that an experimental use exception should not protect “use of a patented invention with a primary or significant market among research users” since such use would significantly decrease the value of a patent and thus the incentives to invent.¹⁰⁵ Nevertheless, it should protect “use of a patented invention to check the adequacy of the specification and the validity of the patent holder’s claims,” as such use has minimal impact on the value of the patent and adds considerable value to the public by helping interested and capable parties to monitor patent validity.¹⁰⁶

Thus, to scrap the experimental use altogether, as Judge Rader advocates, would deny protection for certain uses of patented inventions that a properly-functioning patent system should permit. The result would improperly strike the balance between the patent system’s countervailing properties, giving too much value to the patent monopoly and not enough freedom for studies that improve upon and challenge existing patents. The legislative solution we discuss in the next section addresses these considerations.

B. Legislation: A New Approach to Experimental Use

Although there are compelling policy arguments supporting an infringement exception for at least some experimental uses, these policies are better implemented via legislation than through judicially-created exceptions.¹⁰⁷ The American Intellectual Property Law Association (“AIPLA”) recently supported a proposal recommending that Congress amend the patent statute to permit experimental uses of patented inventions in limited circumstances.¹⁰⁸ AIPLA suggests that a statutory experimental use exception would serve public policy by fostering scientific development while at the same time clarifying when legitimate experimental use of a patented

105. *Id.*

106. *Id.* at 1074-78.

107. See Freeburg, *supra* note 35, at 403-04 (quoting from an amicus brief filed in *Madey* in which the Solicitor General concluded that “the policy issues ‘may be better suited for legislative rather than judicial consideration’”). Any legislative proposal should take into consideration the possible interaction with the Agreement on Trade-Related Aspects of Intellectual Property Rights, known as TRIPS to insure that it is in accordance with the international agreement. See THOMAS, *supra* note 33, at 19 (noting that TRIPS limits the ability of its signatories to grant compulsory licenses).

108. See AM. INTELLECTUAL PROP. LAW ASS’N, AIPLA RESPONSE TO THE NATIONAL ACADEMIES REPORT ENTITLED “A PATENT SYSTEM FOR THE 21ST CENTURY,” 23-27, available at, http://www.aipla.org/Content/ContentGroups/Issues_and_Advocacy/Comments2/Patent_and_Trademark_Office/2004/NAS092304.pdf (last accessed Oct. 25, 2005).

invention is proper.¹⁰⁹ In particular, AIPLA supported the codification of an exemption when a patented invention is used for:

(1) evaluating the validity of the patent and the scope of protection afforded under the patent; (2) understanding features, properties, inherent characteristics or advantages of the patented subject matter; (3) finding other methods of making or using the patented subject matter; and (4) finding alternatives to the patented subject matter, improvements thereto or substitutes therefor.¹¹⁰

The proposed legislation would allow for use of a patented invention to test the validity of the patent claims and to design around the patent via new methods, models, or substitutes.¹¹¹ It balances the competing purposes of the patent system by permitting narrow uses of a patented invention that advance technology without too much imposition on the patent-holder's rights. Recent articles and notes addressing the experimental use exception echo AIPLA's point of view, and recommend legislation in response to the fading common-law experimental use exception, whether in the form of compulsory licensing or carved out exceptions to infringement.¹¹² Some note that the fair use exception in the Copyright Act, which was derived from the common law fair use exception in copyright law, can serve as an example in which a statutory exception limiting intellectual property rights has been successful.¹¹³

The costs and benefits of an experimental use exception, including

109. See *id.* at 2 (noting that a statutory exception "would remove the uncertainty that now exists over the manner in which a patented invention can be used to better understand and/or extend what is patented"). AIPLA noted that a Congressional response is particularly important in light of the "varying views at the Federal Circuit," since Judge Rader's concurrence in *Embrex*, Judge Newman's dissent in *Integra*, and the current state of the law each suggest conflicting perceptions of the experimental use exception. *Id.* at 24 n.2.

110. *Id.* at 25.

111. *Id.*

112. See, e.g., Freeburg, *supra* note 35, at 403-04 (commenting that compulsory licensing is preferable to a statutory exemption to allow for reasonable use of biotech tools); Sewell, *supra* note 34 at 779-82 (concluding that *Madey* threatens scientific progress and that Congress should overrule *Madey* with an amendment to the patent statute that provides an exception for academic and non-profit institutions); Haindfield, *supra* note 31, Part III (recommending that courts retain the narrow conception of the experimental use exception and that Congress implement a compulsory licensing scheme for research tools); THOMAS, *supra* note 33, at 18 (suggesting multiple avenues for Congressional action depending on how Congress views the experimental use exception).

113. See Mark D. Janis, *Experimental Use and the Shape of Patent Rights for Plant Innovation*, Part III, available at, <http://www.card.iastate.edu/research/stp/papers/Janis-seminar-Fall-03.pdf> (last accessed Oct. 18, 2005); Freeburg, *supra* note 35, at 406.

“[w]hether such an [exception] is... desirable in the interest of promoting and continuing scientific progress[,] is... an empirical question.”¹¹⁴ Thus, Congress, given its resources for fact-finding, should define the contours of a statutory experimental use exception as it did with the Hatch-Waxman Act and other acts permitting specific uses of patented inventions.¹¹⁵ Ideally, those seeking to use patented inventions for uses that might be excepted as experimental would find better guidance in clearly established statutory rules as opposed to a judicially created defense.

In her *Integra* dissent, Judge Newman stated that she would not “undertake to define the boundaries of the research exemption for all purposes and all activities, other than to observe that there is 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.”¹¹⁶ Even though policy arguments support her call for broader protection of experimental use, Judge Newman’s hesitancy to define the boundaries of the exception suggests that a judicial reformulation of the exception would require considerable litigation on the issue before the doctrine develops clear guidelines.¹¹⁷ Alternatively, legislation provides a framework for individuals or

114. Eisenberg, *supra* note 88, at 1074.

115. See Sewell, *supra* note 34, at 774 (noting that “[b]etween 1970 and 1990, Congress exempted from infringement liability academic and noncommercial research related to: plant genetics, semiconductors, generic drugs, and copyrighted works”).

116. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 876 (Fed. Cir. 2003) (Newman, J. concurring in part, dissenting in part), *vacated and remanded by*, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005). Although Judge Newman sees a clear division between research and development, the Supreme Court in *Merck* noted that in reality, research and development are often intertwined. *Merck*, 125 S. Ct. at 2382-83 (recognizing that “even at late stages in the development of a new drug, scientific testing is a process of trial and error”).

117. At least one district court has already struggled with the application of the post-*Madey* experimental use formulation to jury instructions and the presentation of evidence at trial. See *Applera Corp. v. MJ Research, Inc.*, 311 F. Supp. 2d 293 (D. Conn. 2004). In *Applera*, the District Court for the District of Connecticut granted plaintiff’s motion in limine to “preclude defendants from presenting evidence or arguing at trial that certain classes of [the allegedly infringing product] and certain uses of [the allegedly infringing product] . . . are exempt from liability.” *Id.* at 295. The court based its decision on its concern that excessive focus on the profit or non-profit status of the defendant’s customers would confuse the jury “with legally irrelevant evidence and argument” in light of *Madey*. *Id.* at 297. This result seems misguided, as the character and financial implications of the research conducted by defendant’s customers could be legitimately persuasive as to whether the use was related to a business interest. Nevertheless, the case illustrates that courts are still attempting to ascertain when the experimental use exception is available and how proof of experimental use functions at trial.

institutions seeking to use a patented invention for what might seem like experimental purposes to look to in attempt to comply with the law prior to any potentially infringing use.

Conclusion

Following *Embrex* and *Madey*, it is clear that under most practical circumstances neither industrial nor academic researchers can successfully invoke the experimental use exception to charges of patent infringement. Instead, the exception remains unavailable for uses of patented inventions in pursuit of any business interests, including both design-around attempts and at least some uses in a university research setting. Policy considerations weigh in favor of limiting the patent monopoly to permit use of the patented invention to develop ideas and expand scientific and technological knowledge. However, the appropriate limits on any permissible use are best addressed by detailed legislation, rather than by continued judicial reformulation of the experimental use exception.