

**NOTE: HOW MUCH DO WE VALUE RESEARCH AND
DEVELOPMENT?: BROADENING THE EXPERIMENTAL
USE EXEMPTION TO PATENT INFRINGEMENT IN
LIGHT OF *INTEGRA LIFESCIENCES I, LTD. v. MERCK
KGAA*, 331 F.3D 860 (FED. CIR. 2003)**

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I. INTRODUCTION

Since the early 1800s, courts have recognized but seldom used a common-law exemption to patent infringement now known as the research or experimental use exemption.¹ This exemption to infringement allows one party to use another party’s patented invention “merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the [invention] to

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1. See 5 Donald S. Chisum, CHISUM ON PATENTS § 16.03[1][a]-[b] (2002).

produce its described effects.”²

In 1984, following the Federal Circuit’s decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,³ Congress enacted 35 U.S.C. § 271(e)(1), the Food and Drug Administration (FDA) approval safe harbor provision to patent infringement.⁴ Section 271(e)(1) allows a generic drug manufacturer to make or import and then use another company’s patented drug during the patent term—activities that would otherwise infringe the patent—to conduct the clinical studies required for the manufacturer to gain FDA approval for its generic form of the patented drug.⁵ This safe harbor enables a generic drug manufacturer to begin selling its version of a drug immediately after the patent expires because FDA approval will already have been obtained.⁶ Without it, the patent holder would receive a virtual extension on its patent term of several months or even years while the generic companies attempted to gain FDA approval on their generic forms of the drug.⁷

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

3. 733 F.2d 858 (Fed. Cir. 1984), *superseded by* 35 U.S.C. § 271(e)(1) (1984).

4. CHISUM, *supra* note 1, § 16.03[1][d]. In addition to the FDA approval safe harbor, the 1984 enactment, known as the “Hatch-Waxman Act” also included the extension of patent terms and filing of “abbreviate new drug applications” among other provisions. *See infra* Part II.B.

5. 35 U.S.C. § 271(e)(1) (2003). The language of § 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 or veterinary biological products.

Id.

The FDA approval safe harbor has been extended to include implantable medical devices, food additives, color additives, and human biological products, as those products also require FDA approval. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 674 (1990). The exception has also been applied to activities that the courts have deemed to be “reasonably related” to seeking FDA approval, such as business development and promotional activity that may be necessary to begin the FDA approval process and is necessary to be able to effectively market the product immediately after the patent term ends. *See Intermedics, Inc. v. Ventritex, Inc.* 775 F. Supp. 1269, 1278 (N.D. Cal. 1991) (stating for the typical products requiring FDA approval “that are extremely sophisticated, that will carry a large price tag . . . and that are very expensive to develop, potential competitors foreseeably must engage in considerable ‘business’ development and promotion activity just to meet the FDA’s requirements, let alone to be in a position to market their products meaningfully when [the patent term ends]”).

6. *See* CHISUM, *supra* note 1, § 16.03[1][d].

7. *See Roche Prods.*, 733 F.2d at 864 (noting “[a] recent study indicated that it

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EXPERIMENTAL USE EXEMPTION

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In its recent *Integra Lifesciences I, Ltd. v. Merck KGaA* decision,⁸ the Federal Circuit Court of Appeals decided that neither the experimental use exemption nor the FDA approval safe harbor provision allowed Merck to use Integra's patented drug to conduct research and develop a completely different and more useful drug.⁹ The Federal Circuit has severely limited the usefulness of either exception to the disappointment of the dissenting Judge Newman.¹⁰

This note argues *Integra Lifesciences I, Ltd. v. Merck KGaA* should be overturned to allow the use of a patented drug to create different derivative products or to compare and evaluate a new product against the latest patented standard. Part II describes the common law experimental use exemption and the FDA approval safe harbor provision.¹¹ Part III reviews the facts, holding, and dissent in *Integra*.¹² Part IV analyzes *Integra* in light of the experimental use exemption and FDA approval safe harbor provision.¹³ Finally, this note concludes by proposing that the experimental use exemption to patent infringement should be broadened to allow all scientific research on patented subject matter to comport with the patent specification's full disclosure requirement and further the patent law principles of promoting innovation and rapid technological development.¹⁴

II. BACKGROUND

A. *The Experimental Use Exemption*

The common-law experimental use exemption excuses a potential patent infringer who uses a patented invention only for intellectual, non-commercial research.¹⁵ The exemption has been mentioned regularly in case law but seldom applied to exempt a

now can take on average from 7 to 10 years for a pharmaceutical company to [gain FDA approval]").

8. 331 F.3d 860 (Fed. Cir. 2003).

9. *Id.* at 864 n.2, 867-68.

10. *Id.* at 872-78 (Newman, J., dissenting).

11. *See infra* Part II.

12. *See infra* Part III.

13. *See infra* Part IV.

14. *See infra* Part V.

15. Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 17 (2001).

defendant from patent infringement.¹⁶ In recent years, there has been a fair amount of scholarly debate about the experimental use exemption and whether it should be broadened.¹⁷ Congress has even proposed legislation, albeit unsuccessfully, to create a statutory experimental use exemption.¹⁸ In modern case law, the common-law experimental use exemption is well established, but it remains weak and underutilized.¹⁹

1. *Origin of the Experimental Use Exemption*

The experimental use exemption can be traced to 1813 when Justice Story handed down the famous *Whittemore v. Cutter* decision.²⁰ Justice Story reasoned that “it could never have been the intention of the legislature to punish a man, who constructed [another’s patented invention] merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of [the patented invention] to produce its described effects.”²¹ The term “philosophical experiments” in Justice Story’s opinion has

16. *Id.*

17. See, e.g., Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) [*hereinafter* Eisenberg, *Patents*]; Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12; Mueller, *supra* note 15; Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Gregory N. Pate, *Analysis of the Experimental Use Exception*, 3 N.C. J.L. & TECH. 253 (2002); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999); John A. Tessensohn, *Reversal of Fortune—Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT’L LEGAL STUD. 1 (1998); Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 NW. U. L. REV. 667 (1997); Jennifer A. Johnson, Comment, *The Experimental Use Exception in Japan: A Model for U.S. Patent Law?*, 12 PAC. RIM L. & POL’Y J. 499 (2003); Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991).

18. H.R. REP. NO. 101-960, pt. I (1990). The “Patent Competitiveness and Technological Innovation Act of 1990” proposed a broad experimental use exemption and was supported by the House Judiciary committee, but was not enacted by Congress. *Id.* See also Johnson, *supra* note 17, at 528-29. A 1988 bill on patenting transgenic animals also originally included an experimental use exemption, but the exemption was later removed from the bill. *Id.* Upon removing the exemption, the House Report suggested instead that sometime in the future, Congress should enact an experimental use exemption that applies to all inventions. *Id.*; H.R. REP. No. 100-888, at 51 (1988).

19. CHISUM, *supra* note 1, § 16.03[1].

20. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); See also CHISUM, *supra* note 1, § 16.03[1][a].

21. *Whittemore*, 29 F. Cas. at 1121.

come to mean “scientific experiments” in modern usage.²² Justice Story used identical reasoning in the case of *Sawin v. Guild*,²³ which was decided in the same year as *Whittemore*. The *Whittemore* and *Sawin* decisions are credited with creating the experimental use exemption.²⁴ However, since 1813, the experimental use exemption has been only infrequently applied as a true exception to patent infringement.²⁵

In the earlier first half of the twentieth century, a few courts recognized the doctrine. A 1935 Colorado district court in *Ruth v. Stearns-Roger Manufacturing Co.*²⁶ excused the defendant’s manufacture and sale of parts for a patented machine to the Colorado School of Mines because the school used the machines only for experimental purposes.²⁷ The court held that the “making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement.”²⁸ Two years later in *Akro Agate Co. v. Master Marble Co.*,²⁹ a West Virginia district court held that use of a patented feature of a competitor’s marble-making machine for “experimental testing by defendants . . . for a brief period before going into commercial production, . . . [with a different machine] . . . was not in law an act of infringement as marbles were not commercially sold.”³⁰

Subsequently, courts applied the exemption and established it as a defense to patent infringement. In 1944, the Southern District Court of New York held in *Dugan v. Lear Avia*³¹ that the experimental use exemption applied to one of the defendant’s accused devices because “it affirmatively appeared, without contradiction by plaintiff, that defendant built that device only

22. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875 n.8 (Fed. Cir. 2003) (Newman, J., dissenting) (explaining the modern translation of the term “philosophical experiments” as scientific experiments).

23. 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (stating “the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification”).

24. *See* CHISUM, *supra* note 1, § 16.03[1][a].

25. *See id.*

26. 13 F. Supp. 697 (D. Colo. 1935), *rev’d*, 87 F.2d 35 (10th Cir. 1936).

27. *Id.* at 703.

28. *Id.* at 713.

29. 18 F. Supp. 305 (N.D. W. Va. 1937).

30. *Id.* at 333.

31. 55 F. Supp. 223 (S.D.N.Y. 1944), *aff’d*, 156 F.2d 29 (2d Cir. 1946).

experimentally and that it has neither manufactured it for sale nor sold any.”³² In 1958, the Court of Claims held in *Chesterfield v. United States*³³ that the United States was not liable for infringement of Chesterfield’s patented metal alloy.³⁴ The court held that “the evidence shows that the portion of the [patented] alloy procured by the defendant was used only for testing and for experimental purposes, and there is no evidence that the remainder was used other than experimentally.”³⁵

2. *Restrictions on the Experimental Use Exemption*

Courts have limited the experimental use exemption doctrine when the infringer’s experimental use was coupled with commercial exploitation or is linked to the infringer’s business interests. Although several cases have applied the experimental use exemption, many more have decided that it was inapplicable due to the commercial nature of the defendant’s use.³⁶ In one case, the defendant’s claim that its use of a patent was “experimental only, incidental to their search for a new [method for extracting pearl essence] which they claim to have discovered” was rejected because the defendant sold the pearl essence resulting from the experiments.³⁷ In another case, a defendant used a patented method for freezing fish while on a commercial fishing expedition.³⁸ The defendant claimed that its use was “only for the purpose of experimentation as to the desirability of using this method” and that defendant “reached the conclusion that it was not necessary to use the patented method in order to get satisfactory freezing.”³⁹ The Ninth Circuit held the experimental

32. *Id.* at 229 (citing *Bonsack Mach. Co. v. Underwood*, 73 F. 206, 211 (C.C.E.D.N.C. 1896)).

33. 159 F. Supp. 371 (Ct. Cl. 1958).

34. *Id.* at 375.

35. *Id.* The court found that claims of the two patents at issue relating to the metal alloys were anticipated by prior art and were invalid, but even if they were valid, were not infringed due to the experimental use exemption. *Id.* The court clearly notes that “[e]xperimental use does not infringe.” *Id.*

36. See CHISUM, *supra* note 1, § 16.03[1][b] (citing at least twelve cases where research or experimental use exemption is noted but still holding defendant liable for infringement due to the commercial nature of the use).

37. *Pairpearl Prods., Inc. v. Joseph H. Meyer Bros.*, 58 F.2d 802, 804-05 (D. Me. 1932).

38. *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*, 322 F.2d 34, 35 (9th Cir. 1963).

39. *Id.* at 36 (noting the patented method was used only on one or two

use exemption did not exempt an experimental use that was coupled with commercial exploitation.⁴⁰

The trial court decisions of *Douglas v. United States*⁴¹ and *Pitcairn v. United States*⁴² further exemplify limitations of the common-law doctrine. The *Douglas* court held that the experimental use exemption had not “been permitted where there was a pattern of systematic exploitation . . . of the accused devices for the purpose of furthering the legitimate interests of the user.”⁴³ In *Pitcairn*, the government purchased helicopters that infringed the plaintiff’s patents.⁴⁴ Based on the experimental use exemption, the government argued that any aircraft used for testing, evaluation, demonstrational, or experimental purposes should be excluded from the plaintiff’s compensation.⁴⁵ The court agreed that testing new aircraft was necessary to ensure they worked properly, but because such tests were intended to further the legitimate business interests of the user they were not excluded from infringement.⁴⁶ Both *Douglas* and *Pitcairn* limited the usefulness of the experimental use exemption if the infringing research is to promote a legitimate business interest of the infringer.

In *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*,⁴⁷ the Federal Circuit refused to apply the experimental use doctrine when a

voyages).

40. *Id.* at 36-37. The defendant cited *Chesterfield v. United States*, 159 F. Supp. 371 (Ct. Cl. 1958) and *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223 (S.D.N.Y. 1944) for the proposition that its use was an experimental use exempt from infringement. *Id.* at 36. The court disagreed and noted that neither *Chesterfield* nor *Dugan* involved an “experimental use coupled with a commercial use.” *Id.*

41. 181 U.S.P.Q. (BNA) 170 (Ct. Cl. Trial Div. 1974) *aff’d on other grounds at* 510 F.2d 364 (Ct. Cl. 1975). The Court of Claims affirmed on the grounds that the patent was invalid and did not reach the issue of experimental use. *See* 510 F.2d 364 (Ct. Cl. 1975).

42. 188 U.S.P.Q. (BNA) 35 (Ct. Cl. Trial Div. 1975) (affirming and adopting the trial court’s decision regarding the experimental use issue).

43. 181 U.S.P.Q. (BNA) at 177 (“At no time were the accused devices used for amusement, to satisfy idle curiosity, or for philosophical inquiry; to the contrary, each use was in keeping with the legitimate business of the using agency and served a valuable governmental and public purpose”).

44. 188 U.S.P.Q. at 47. The government purchased seven models of helicopters that infringed fifty-nine claims in eleven of the plaintiff’s patents. *Id.* at 35, 47.

45. *Id.* at 47. The government claimed that ninety-three of 2237 aircraft involved in the litigation were used for experimental purposes and thus should be excluded from plaintiff’s compensation. *Id.* at 46.

46. *Id.* at 47.

47. 733 F.2d 858 (Fed. Cir. 1984).

generic drug manufacturer made and used a patented drug to perform experimental tests to gain FDA approval before the patent term ended.⁴⁸ Although Bolar argued its tests were “true scientific inquiries,” the court stated “[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”⁴⁹ The *Roche* court severely weakened the experimental use exemption by construing it as “truly narrow.”⁵⁰ Although the specific rule as applied to the case’s facts has been overruled by 35 U.S.C. § 271(e)(1),⁵¹ the court’s very narrow interpretation of the experimental use exemption has lived on.

More recent cases also have narrowed the scope of the experimental use exemption, refusing to apply it in cases where the infringer has a commercial or profitable intention. For example, in *Embrex, Inc. v. Service Engineering Corp.*,⁵² Service Engineering used Embrex’s patented methods to test their prototype machine and to solicit orders for their machine.⁵³ Both the district court and the Federal Circuit agreed that, although its uses were experimental in nature, Service Engineering’s ultimate goal was commercialization. The Federal Circuit held that uses for research or experimental purposes coupled with intent to profit or commercialize would not be deemed experimental only.⁵⁴

48. See *id.* at 863; see also *infra* Part II.B (explaining how the decision of *Roche Prods., Inc.* prompted the congressional enactment of the FDA approval safe harbor, 35 U.S.C. § 271(e)(1), among other provisions).

49. *Roche Prods., Inc.* 733 F.2d at 863. The court refused to allow “exploitation of a patented invention for the purpose of furthering the legitimate business interests of the infringer” under an experimental use exemption. *Id.*

50. *Id.*

51. See *infra* Part II.B.

52. 216 F.3d 1343 (Fed. Cir. 2000).

53. *Id.* at 1346-47.

54. *Id.* at 1349 (stating the experimental use exemption does not apply when a “particular use ‘in the guise of ‘scientific inquiry’ ” had ‘definite, cognizable, and not insubstantial commercial purposes.’”) (quoting *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984)). In a concurring opinion, Judge Rader went further, stating that: “the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement When infringement is proven either minimal or wholly non-commercial, the damage computation process provides full flexibility for courts to preclude large (or perhaps any) awards for minimal infringements.” *Embrex, Inc.*, 216 F.3d at 1352. See also *Infigen, Inc. v. Advanced Cell Tech., Inc.*, 65 F. Supp. 2d 967, 981 (W.D. Wis. 1999) (holding research with the remote prospect of future commercial success cannot be an exempt experimental use).

In *Madey v. Duke University*,⁵⁵ the Federal Circuit reiterated that an experimental use that is “in any way commercial in nature” would not be exempted from infringement by the experimental use exemption.⁵⁶ Duke University’s use appeared to be only for research and education,⁵⁷ which seemingly fits within the oft-noted “philosophical experiments” category from the very first experimental use case.⁵⁸ The Federal Circuit held, however, that because Duke’s business is education, Duke’s use of the patented invention to educate students had a commercial purpose and was not exempt under the experimental use exemption.⁵⁹ Even though education may be what Justice Story had in mind when he mentioned “philosophical experiments” on the patented invention as being exempt from infringement in 1813,⁶⁰ today’s courts have decided that even educational research does not fall within the experimental use exemption.

The experimental use exemption is a nearly 200-year-old defense to a patent infringement action. Traditionally, courts narrowly construed and infrequently allowed it. Recently, however, cases have interpreted the experimental use exemption so narrowly as to nearly eliminate it.

55. 307 F.3d 1351 (Fed. Cir. 2002).

56. *Id.* at 1362.

57. *Madey v. Duke Univ.*, 266 F. Supp. 2d 420, 423 (M.D.N.C. 2001) (“Plaintiff concedes that the overwhelming majority of Defendant’s uses of the patented devices were for academic or experimental purposes . . .”).

58. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (creating the experimental use rule and defining the rule as applying to uses “merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the [invention] to produce its described effects”).

59. *Madey*, 307 F.3d at 1362-63. The court stated:

[O]ur precedent does not immunize any conduct that is in keeping with the alleged infringer’s legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty [T]he district court attached too great a weight to the non-profit, educational status of Duke, effectively suppressing the fact that Duke’s acts appear to be in accordance with any reasonable interpretation of Duke’s legitimate business objectives.

Id.

60. *See supra* Part II.A.1.

B. *FDA Approval Safe Harbor Provision—35 U.S.C. § 271(e)(1)*

1. *The Roche Decision*

In its 1984 *Roche Products, Inc. v. Bolar Pharmaceutical Co.*⁶¹ decision, the Federal Circuit held that a generic drug manufacturer's infringing use of a patented drug for clinical trials to gain FDA approval did not fall within the experimental use exemption.⁶² Bolar wanted to begin marketing its generic version of Roche's patented sleep aid, Dalmane, as soon as possible.⁶³ Bolar refused to wait until Roche's patent expired on January 17, 1984 to begin clinical trials because speed to market was vital to the success of the generic drug and the FDA approval process could take upwards of two years.⁶⁴ Bolar purchased a quantity of Dalmine from a foreign manufacturer in mid-1983 and began the necessary testing for FDA approval.⁶⁵ Roche filed an infringement suit against Bolar.⁶⁶ The district court held in favor of the defendant Bolar, reasoning that the experimental use exemption applied to Bolar's infringing use.⁶⁷ The Federal Circuit reversed, holding "the experimental use exception to be truly narrow," and refused to expand it to include Bolar's activities, holding that Bolar's "use is solely for business reasons."⁶⁸

61. 733 F.2d 858 (Fed. Cir. 1984).

62. *Id.* See also *supra* Part II.A. for a discussion of the common-law experimental use exemption to patent infringement.

63. *Id.* at 860.

64. *Id.*

65. *Id.*

66. *Id.*

67. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 572 F. Supp. 255, 258 (E.D.N.Y. 1983). The district court reasoned:

[This] court cannot find a basis for holding that Bolar's limited experimental use . . . constitute[s] infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law. This court will not act to protect a right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best *de minimis* and will not support an action for infringement.

Id.

68. *Roche Prods., Inc.*, 733 F.2d at 863.

The court recognized that the lengthy FDA approval process granted a virtual extension of the patent term to holders of a drug patent.⁶⁹ However, the court declined to “engage in legislative activity proper only for the Congress.”⁷⁰

2. *Congressional Reaction to Roche*

In response to *Roche*, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the “Hatch-Waxman Act.”⁷¹ The Hatch-Waxman Act overturned the ruling in *Roche* by enacting the FDA approval safe harbor provision, codified at 35 U.S.C. § 271(e)(1), among many other provisions.⁷² Section 271(e)(1) allows a generic drug manufacturer to make and use a patented drug during the patent term in order to seek FDA approval for its generic form of the drug.⁷³

69. *Id.* at 863-64. The term of the drug patent is skewed at both the beginning and the end. *Id.* at 864. The FDA approval process can take, in some instances, seven to ten years. *Id.* At the beginning of the term, the patent generally issues before FDA approval is received, so that the patentee must conduct significant amounts of testing for the FDA before the drug can be marketed, eating up a portion of the patent term. *Id.* At the end of the patent term, if generic manufacturers are restricted from starting the FDA approval process until after the patent term ends, then the patentee gains an effective extension of the patent term past the expiration date of the patent while the generic manufacturers complete the FDA approval process. *Id.* However, these two distortions are rarely equivalent and the patent owner either loses part of its patent monopoly or gains additional monopoly time. *Id.*

70. *Id.* at 863-64.

71. Pub. L. No. 98-417, Title II, 98 Stat. 1585 (Sept. 24, 1984).

72. In addition to 35 U.S.C. § 271(e)(1), the Hatch-Waxman Act included provisions for: 1) extension of drug patent terms, under 35 U.S.C. § 156, for the amount of time it takes the patent owner to gain FDA approval; 2) authorization for the filing of “Abbreviated New Drug Applications” (ANDAs) under 21 U.S.C. § 355(j); and 3) a special patent infringement remedy for a patent owner when a generic manufacturer files an ANDA seeking FDA approval before the patent covering the product has expired. See Ann K. Wooster, Annotation, *Construction and Application of Hatch-Waxman Act*, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Codified as Amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994)), 180 A.L.R. FED. 487 (2002). The ANDA simplifies the FDA approval process for generic manufacturers by allowing them to piggyback on the information already submitted by the patent owner and approved by the FDA regarding clinical trials on humans and labeling requirements. *Id.* Thus the FDA approval process for generic manufacturers is made faster, easier, and cheaper. *Id.*

73. 35 U.S.C. § 271(e)(1) (2003). The relevant text of § 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

Public policy strongly favors allowing generic manufacturers to receive FDA approval as early as possible so that the cheaper generic form of a drug will be available to consumers immediately after the patent term ends.⁷⁴ The Hatch-Waxman Act filled in where the Federal Circuit in *Roche* had refused to concede to Bolar's public policy argument and "engage in legislative activity."⁷⁵ However, the Hatch-Waxman Act also provided to the patentee a corresponding extension of the patent term for the length of time the patentee takes to gain FDA approval by also enacting 35 U.S.C. § 156.⁷⁶ This provision ensures that the patentee is not penalized by the FDA approval process and still receives a full twenty years of patent protection.⁷⁷

3. *Effects of 35 U.S.C. § 271(e)(1) and 35 U.S.C. § 156*

The FDA approval safe harbor provision under 35 U.S.C. § 271(e)(1) and the patent term extension for the patent owner under 35 U.S.C. § 156 eliminate the "distortion" at the beginning and end of the patent term due to the FDA approval process.⁷⁸ At the beginning of the patent term, the patentee must seek FDA approval.⁷⁹ During this time, the patentee is unable to sell its product commercially, so the patent term is effectively shortened

manufacture, use, or sale of drugs or veterinary biological products.

Id.

Note that § 271(e)(2) qualifies the language of § 271(e)(1) by stating: "It shall be an act of infringement . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a [patented] drug . . . before the expiration of the patent." 35 U.S.C. § 271(e)(2) (2003).

74. See, e.g., *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990) (finding that "if [generic drug manufacturers] had to wait to begin testing until after a patent expired, [that would give] an effective extension of the patent term, which was contrary to the interests of the public in obtaining lower cost drugs as soon as possible").

75. See *supra* notes 47-51, 61-70 and accompanying text.

76. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, Title II, 98 Stat. 1585 (Sept. 24, 1984). See also 35 U.S.C. § 156 (2003).

77. See 35 U.S.C. § 156 (2003). Section 156 provides a patent term extension for "drug products" as well as "any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug and Cosmetic Act." *Id.* at (f). The extension is based upon the "regulatory review period before [the product's] commercial marketing or use." *Id.* at (a)(4).

78. *Eli Lilly & Co.*, 496 U.S. at 670 (1990).

79. *Id.* at 669.

by the amount of time it takes the patentee to gain FDA approval.⁸⁰ Section 156 allows the patent term to be extended by the amount of time it takes the patentee to gain FDA approval.⁸¹

At the end of the patent term, the generic manufacturer must gain FDA approval for its generic equivalent.⁸² If the generic manufacturer must wait until the patent expires before starting FDA approval, then the patentee can continue to sell its product without any competition past the end of the patent term while the generic manufacturers work through the FDA approval process.⁸³ Section 271(e)(1) allows the generic competitor to make the otherwise infringing generic equivalent during the patent term to gain FDA approval before the patent expires.⁸⁴ Thus, the combination of § 156 and § 271(e)(1) ensure not only that generic drugs are available immediately after the patent expires, but also ensure that the patentee receives a uniform twenty years on its patent term.⁸⁵

4. *Judicial Interpretation of 35 U.S.C. § 271(e)(1)*

The awkward wording of 35 U.S.C. § 271(e)(1)—“*solely* for uses *reasonably related* to the development and submission of information . . .”⁸⁶—has caused interpretive problems for the courts. The strict term “solely” seems to contradict the more lax phrase, “reasonably related” and this contradiction has led to conflicting results in early cases interpreting the statute, although the conflict seems to be resolved.⁸⁷

Not long after the statute’s enactment, the U.S. District Court for the Northern District of California, in *Scripps Clinic & Research*

80. *Id.* at 669-70.

81. 35 U.S.C. § 156 (2003).

82. *Eli Lilly & Co.*, 496 U.S. at 670.

83. *Id.*

84. 35 U.S.C. § 271(e)(1) (2003).

85. *See Eli Lilly & Co.*, 496 U.S. at 669-71 (discussing in detail how the Drug Price Competition and Patent Term Restoration Act of 1984 eliminates the “distortion” at the beginning and end of the patent term for products requiring FDA approval). Note that under 35 U.S.C. § 154(a) the current patent term is twenty years, whereas at the time of the *Eli Lilly* decision the term was seventeen years. *Id.* As of June 8, 1995, the patent term changed from seventeen years from the date of patent issuance to twenty years from the date of filing the patent application in order to correspond with other countries’ patent laws. *Merck & Co., v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996).

86. 35 U.S.C. § 271(e)(1) (emphasis added).

87. *See* CHISUM, *supra* note 1, § 16.03[1][d][iii].

Foundation v. Genentech, Inc.,⁸⁸ strictly construed the language of § 271(e)(1). The court held that any use of a patented drug not *solely* related to FDA approval would not be exempt from infringement.⁸⁹ Genentech's use of Scripps' patented drug was probably reasonably related to FDA approval, but it was also related to preparation of a European patent application and development of a process for manufacturing the drug on a commercial scale, and thus the use was not "solely" related to FDA approval. Therefore, Genentech's use of the § 271(e)(1) safe harbor was denied.⁹⁰

However, in 1989, the U.S. District Court of Delaware in *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*⁹¹ analyzed the same patent on similar facts, but came to a different conclusion.⁹² Baxter had submitted clinical data that it had gathered not only to the FDA, but also to foreign regulatory agencies.⁹³ Scripps moved to strike Baxter's § 271(e)(1) defense on the basis that Baxter's use was not solely for submission of data to the FDA.⁹⁴ Although the court denied the motion because it felt that the case needed a more developed record, it also stated that "[t]he question of law . . . is whether any foreign activities can be 'reasonably related' to FDA drug approval."⁹⁵ The court focused on the "reasonably related" language of § 271(e)(1), whereas *Scripps v.*

88. 666 F. Supp. 1379 (N.D. Cal. 1987), *modified on other grounds*, 678 F. Supp. 1429 (N.D. Cal. 1988) and 707 F. Supp. 1547 (N.D. Cal. 1989), *aff'd in part, rev'd in part, vacated in part, and remanded on other grounds*, 927 F.2d 1565 (Fed. Cir. 1991).

89. *Id.* at 1396.

90. *Id.* The court states, "Even if the uses . . . were reasonably related to meeting FDA requirements, they certainly were not solely related to that purpose [Genentech's] sales and uses of [the patented drug], serving multiple purposes unrelated to meeting FDA requirements, clearly lie beyond the protection of § 271(e)(1)."

91. 7 U.S.P.Q.2d (BNA) 1562 (D. Del. 1989).

92. *Id.* at 1565.

93. *Id.* at 1564-65.

94. *Id.* Scripps put forth multiple arguments against Baxter's FDA approval safe harbor defense, including that 1) Baxter had made a motion on the defense earlier and withdrew the motion, thus eliminating the defense; 2) Baxter had distinguished the defense from "the merits" of the case, thus eliminating the defense; 3) a similar defense was dismissed by the District Court for the Northern District of California in an unrelated case; and 4) Baxter had filed for regulatory approval in foreign countries, and thus the uses were not solely for FDA approval. The court summarily dismissed all of Scripps's arguments except for the foreign use argument. *Id.*

95. *Id.* at 1565.

Genentech had focused on “solely” just two years before.⁹⁶ As will be seen, subsequent decisions also seem to agree with the District Court of Delaware’s focus on the “reasonably related” language.

5. *Expanding the Safe Harbor Provision of 35 U.S.C. § 271(e)(1)*

Many of the subsequent cases applying § 271(e)(1) involve determining just how far the safe harbor should extend. In 1990, the scope of § 271(e)(1) was greatly expanded when the Supreme Court held in *Eli Lilly & Co. v. Medtronic, Inc.*⁹⁷ that the exemption should also apply to medical devices that require FDA approval.⁹⁸ The Court held in a 6-2 decision⁹⁹ that “[t]he phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone.”¹⁰⁰ The court also held that not only does the Hatch-Waxman Act apply to drugs and medical devices, but rationally to any product requiring regulatory approval under the Federal Food, Drug, and Cosmetic Act (FDCA), which also includes food additives and color additives.¹⁰¹ The Supreme Court reasoned that Congress would have logically intended the safe harbor provision to include other products requiring FDA approval, as those other products would encounter the same distortions at the beginning and end of the patent term due to the FDA approval process.¹⁰²

In 1991, the Northern District of California broadly construed § 271(e)(1) when it held in *Intermedics, Inc. v. Ventritex, Inc.*¹⁰³ that

96. *See id.* The court noted the *Scripps v. Genentech* decision and its focus on the term “solely” but was disinclined to follow that rule, stating:

Judge Schwarzer of the Northern District of California dismissed a similar defense raised by Genentech, Inc., based on similar facts, in another patent infringement suit brought by Scripps Clinic. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379, 1395-97 (N.D. Cal. 1987). It argues that this proves that Baxter’s defense [§ 271(e)(1)] is insufficient. That case, however, is not controlling in this Court . . . Judge Schwarzer was faced with this issue, but he interpreted the statute to only cover activities that were “solely related” to FDA approval and did not consider what acts are “reasonably related” to it.

Id. at 1564-65.

97. 496 U.S. 661 (1990).

98. *Id.* at 673-74.

99. Justice O’Connor took no part in the case. *Id.* at 661.

100. *Id.* at 665.

101. *Id.* at 671-72.

102. *Id.* at 668-69.

103. 775 F. Supp. 1269 (N.D. Cal. 1991), *aff’d*, 991 F.2d 808 (Fed. Cir. 1993)

activities by the non-patentee Ventritex were “reasonably related” to gaining FDA approval.¹⁰⁴ Ventritex’s activities included: demonstrating the device at medical/scientific conferences or trade shows to solicit clinical investigators, relying on descriptions of the device to raise capital, publishing articles about the device, and using data gathered from clinical trials to gain import approval from foreign governments.¹⁰⁵ The court held that although these activities did not directly create data for gaining FDA approval, the activities were necessary to promote Ventritex’s business in its quest for FDA approval and thus were *reasonably related* to gaining FDA approval.¹⁰⁶

Many of Ventritex’s activities did not involve making, using, or selling the patented device, so they were not technically infringing acts.¹⁰⁷ Furthermore, the court held that these non-infringing activities, although commercial in nature and not related to FDA approval, did not eliminate the safe harbor provision for Ventritex’s other *infringing* activities that *were* reasonably related to

(non-precedential).

104. *Id.* at 1289.

105. *Id.* at 1281.

106. *Id.* The district court also noted that Congress, in enacting § 271(e)(1), not only wanted generic manufacturers to gain FDA approval before the patent expired, but also likely intended the companies to “engage in a range of business activities (like raising capital, establishing mechanisms for product distribution, etc.)” so they could “enter the commercial market in a significant way immediately after a patent expired” *Id.* at 1278.

107. *Id.* at 1281. The court states that:

[O]ur inquiry should be confined to “uses” that would be infringing but for the exemption, these collateral, non-infringing, activities are not relevant [T]he use of clinical *data*, in a prospectus or otherwise, is not an infringing act . . . Moreover, the fact that this non-infringing activity reveals a commercial “purpose” unrelated to obtaining FDA approval cannot provide a basis for denial of the exemption [T]hese activities are important means for Ventritex to position itself to enter the marketplace if the Cadence ever receives FDA approval.

Id. (emphasis added).

The court also states: “the exemption . . . is not lost simply as a result of a showing that the defendant has engaged in *non-infringing* acts whose ‘uses’ fall outside those permitted by the statute.” *Id.* at 1278 (emphasis in original). *See also* Teletronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520, 1523-24 (Fed. Cir. 1992) (stating that demonstrations of a patented medical device at medical conferences for purposes of soliciting clinical trial candidates are exempt under § 271(e)(1) and also stating that incidental non-infringing activities such as reporting clinical trial progress to doctors, investors, analysts, journalists, and other non-FDA officials are not relevant to a determination of exemption under the safe harbor of § 271(e)(1)).

seeking FDA approval.¹⁰⁸

The *Intermedics* court also distinguished between objective “uses” of a patented product and subjective “purposes” behind the use in interpreting § 271(e)(1).¹⁰⁹ The court needed to determine when a defendant’s use was “reasonably related” to seeking FDA approval. The patent owner contended that the court must analyze the *purpose* of the infringer’s activities.¹¹⁰ But the court held that Congress intended an objective test for § 271(e)(1).¹¹¹ The court then created an objective test to determine what acts are “reasonably related” to seeking FDA approval, and ignored the defendant’s subjective intent.¹¹²

The *Intermedics* court found that sales of otherwise-infringing devices to hospitals for use in clinical trials were exempt under § 271(e)(1) because the hospitals were using the devices to collect data for the FDA.¹¹³ The court also held that when Ventritex continued to sell devices to hospitals even after the application had already been submitted to the FDA, these sales were still exempt because Ventritex reasonably believed the FDA might withhold approval, in which case additional data from continued sales would be necessary.¹¹⁴ Thus, continued clinical trials were objectively

108. See *Intermedics, Inc.*, 775 F. Supp. at 1277-78.

109. *Id.* at 1278.

110. *Id.* The patentee argued that although the use by the defendant might be reasonably related to seeking FDA approval, the true purpose or intent behind the defendant’s activities was to engage in conduct “beyond generating and presenting data to the FDA,” and therefore the conduct infringed the patents. *Id.*

111. *Id.* at 1278-80 (basing its holding on statutory language, probable congressional intent, the trend away from subjective tests, the difficulty of applying a subjective test, and the irrationality of applying a subjective test). The court states it should focus on:

[T]hose acts by Ventritex which would be deemed “infringing” but for § 271(e)(1) and in which Ventritex actually has engaged (as opposed to the acts in which the company might engage in the future). With respect to those actual acts, we do not ask what underlying motives might have inspired them or what indirect, ripple effects . . . they might bring.

Id. at 1280.

112. See *id.* at 1278-79. The court formulated its test by stating: “[W]e should ask: would it have been reasonable, objectively, for a party in defendant’s situation to believe that there was a decent prospect that the ‘use’ in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant [for FDA approval].” *Id.* at 1280.

113. *Id.* at 1282. The devices must be sold at cost to the persons performing the clinical trials. *Id.*

114. *Id.* (“[E]ven after being accepted for filing, a substantial number of applications for pre-market approval are provisionally rejected because the FDA

“reasonably related” to seeking FDA approval.¹¹⁵

The *Intermedics* decision broadened the safe harbor of § 271(e)(1) by allowing commercial, non-infringing uses even though unrelated to FDA approval while also defining “solely for uses reasonably related” to FDA approval as an objective analysis of the activity rather than the subjective purpose behind the use.¹¹⁶ Other courts have followed the *Intermedics* two-part test or inquiry to apply § 271(e)(1).¹¹⁷ The court first determines whether the activity at issue is an infringing one under § 271(a); and if so, whether the § 271(e)(1) exemption applies to that activity.¹¹⁸ The Federal Circuit adopted the *Intermedics* test in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*¹¹⁹ The *Telectronics* court held that demonstration of a medical device to physicians and non-physicians was necessary to obtain clinical investigators.¹²⁰ It further held that non-infringing activities that fell outside the statutory exemption were irrelevant, such as using the data collected to do fundraising and other activities to prepare to enter the market.¹²¹

Even the making and stockpiling of drugs by a non-patent owner has been found to be exempt from infringement as long as reasonably related to FDA approval.¹²² In *NeoRX v. Immunomedics, Inc.*, the court held that production of large, commercial-scale batches of a drug by a non-patentee were exempt from

concludes that [more information is needed].” The court concludes, “it is reasonable to continue to generate clinical data after submitting an initial [FDA approval] application”). *Id.*

115. *Id.*

116. *Id.* at 1280-81.

117. *See, e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 107 (D. Mass. 1998) (“First, § 271 applies generally only to activities that might constitute infringement Second, the potentially infringing activity must be ‘solely for uses’ related to FDA approval.”); *NeoRX Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 206 (D. N.J. 1994).

118. *See, e.g., Amgen, Inc.*, 3 F. Supp. 2d at 107; *NeoRX, Corp.*, 877 F. Supp. at 206.

119. 982 F.2d 1520, 1525 n.5 (Fed. Cir. 1992); *see also Amgen, Inc.*, 3 F. Supp. 2d at 108; *Abtox, Inc. v. Exitron Corp.*, 888 F. Supp. 6, 8 (D. Mass. 1995), *aff’d*, 122 F.3d 1019 (Fed. Cir. 1997); *NeoRX, Corp.*, 877 F. Supp. at 205.

120. 982 F.2d at 1525.

121. *Id.* The court added: “To adopt [the patentee’s] interpretation we would have to read into [§ 271(e)(1)] an unspoken requirement that the disclosure of information obtained during clinical trials to persons other than FDA officials, although not itself an act of infringement, somehow “repeals” the exemption. We do not find that requirement in the words of the statute.” *Id.* at 1524.

122. *See NeoRX, Corp.*, 877 F. Supp. at 206-07 (finding that other activities by Immunomedics were infringing and not exempt).

infringement regardless of the need for them because the FDA required proof that the manufacturer could make commercial quantities.¹²³ However, in *Biogen, Inc. v. Schering AG*,¹²⁴ Biogen's excessive stockpiling was found to be in preparation of future sales rather than to satisfy an FDA requirement.¹²⁵ Even though the FDA had not yet approved Biogen's generic version, the court held that the stockpiling was not reasonably related to FDA approval and thus not exempt.¹²⁶ Courts appear willing to extend § 271(e)(1) to the limits of seeking FDA approval but not to activities that are clearly infringing and wholly unnecessary for FDA approval.

In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*,¹²⁷ the court held that use of a patented drug as a reference standard for multiple experimental manufacturing processes was reasonably related to seeking FDA approval.¹²⁸ Hoechst was seeking FDA approval on a first manufacturing process for erythropoietin (EPO), a drug patented by Amgen.¹²⁹ Hoechst used EPO, made using its first process, as a reference standard for a second experimental manufacturing process for which Hoechst had not yet begun seeking FDA approval.¹³⁰ Amgen sued Hoechst, claiming that Hoechst's use of EPO as a reference standard for the second manufacturing process was infringement because it had not yet begun to seek FDA approval for that process.¹³¹ The court held that Hoechst's use of the reference standard was exempt from infringement because Hoechst would seek FDA approval on the second process in the future.¹³² Thus, the court interpreted §

123. *Id.*

124. 954 F. Supp. 391 (D. Mass. 1996).

125. *Id.* at 396-97. "Biogen had done far more than merely do clinical trials for submission to the FDA, it had spent \$24 million to stockpile and prepare to market Avonex immediately upon the anticipated, imminent FDA approval These actions took Biogen out of the 'safe harbor' . . ." *Id.*

126. *Id.*

127. 3 F. Supp. 2d 104 (D. Mass. 1998).

128. *Id.* at 109.

129. *See id.* at 108-09.

130. *Id.* at 109.

131. *Id.* The EPO used by Hoechst was manufactured in New Hampshire by an independent contractor. One batch of this EPO was sent to Japan to use as a reference standard where a Japanese affiliate was working on an alternative manufacturing process. The EPO sent to Japan would presumably be used to compare to the output of the new process to ensure that the new process worked properly. *Id.*

132. *Id.* The court further stated:

There is no question but that an alternative manufacturing process would require separate FDA approval. Moreover, the FDA guidelines

271(e)(1) as allowing otherwise infringing activities in anticipation of future requests for FDA approval.

In general, courts interpret § 271(e)(1) broadly. Various courts have held that nearly any product requiring FDA approval is exempt from infringement so that other manufacturers can seek FDA approval before the patent term expires.¹³³ Courts also have decided that the infringer's subjective intent should *not* be analyzed, but rather, if the otherwise-infringing activities can be objectively related to seeking FDA approval, they are exempt.¹³⁴ Furthermore, courts have broadly interpreted the term "reasonably related" to include many activities that will benefit the manufacturer once the patent term expires, such as marketing activities or producing commercial-sized batches of drugs, as long as the activities can be reasonably related back to seeking FDA approval.¹³⁵ Non-infringing activities that have a commercial purpose such as fundraising, soliciting investors, and other activities necessary to enter the market effectively, are held to be irrelevant and to not affect the FDA approval safe harbor.¹³⁶ Courts have generally relied on § 271(e)(1)'s strong public policy of providing cheaper generic drugs as soon as possible after the patent expires.¹³⁷ However, *Integra Lifesciences I, Ltd. v. Merck KGaA*¹³⁸ shows that the Federal Circuit is unwilling to overextend either the FDA approval safe harbor provision or the experimental use exemption in the name of public good.

contemplate the use of a reference standard sample from one manufacturing process to evaluate the effects of alterations in that process. The Defendants' efforts to evaluate that process were therefore within the class of activities protected by the statute, regardless of whether they had sought FDA approval at the time.

Id. (citations omitted).

133. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 668-69, 672 (1990).

134. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1278-80 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993) (non-precedential).

135. *See, e.g., id.* at 1278; *NeoRX Corp.*, 877 F. Supp. at 206-07 (D. N.J. 1994).

136. *See Intermedics, Inc.*, 775 F. Supp. at 1280; *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1524-25 (Fed. Cir. 1992).

137. *See, e.g., Intermedics, Inc.*, 775 F. Supp. at 1276-77.

138. 331 F.3d 860 (Fed. Cir. 2003).

III. INTEGRA LIFESCIENCES I, LTD. V. MERCK KGAA¹³⁹A. *Background*

Integra Lifesciences I, Ltd. (Integra) owns several patents related to the RGD peptide.¹⁴⁰ RGD is a short segment of a protein having the amino acid sequence Arginine-Glycine-Aspartic Acid (“Arg-Gly-Asp” or “RGD”).¹⁴¹ The RGD peptide was found to promote cell adhesion to substrates, as well as blood vessel growth.¹⁴² In theory, the RGD peptide can be used to encourage wound healing as well as improve biocompatibility of prosthetic devices.¹⁴³ The RGD peptide works by attaching to $\alpha_3\beta_1$ receptors on cell surface proteins called integrins.¹⁴⁴

Dr. David Cheresh, a scientist and professor at The Scripps Research Institute (Scripps), discovered that blocking the $\alpha_3\beta_1$ receptors inhibits the formation of new blood vessels.¹⁴⁵ Inhibiting new blood vessel growth appeared promising as a means of halting tumor growth, and was, therefore, a possible candidate for treatment of cancer.¹⁴⁶ Dr. Cheresh believed that Integra’s RGD-peptide might be useful in this respect.¹⁴⁷ Dr. Cheresh’s work involved the use of cyclic RGD-containing peptides, rather than Integra’s linear peptides.¹⁴⁸ Merck also realized the importance of

139. *Id.*

140. *Id.* at 862. The patents owned by Integra relating to the RGD peptide are U.S. Patent Nos. 4,792,525 (the ’525 patent), 4,988,621 (the ’621 patent), 4,789,734 (the ’734 patent), 4,879,237 (the ’237 patent), and 5,695,997 (the ’997 patent). *Id.* The RGD peptides were originally invented and patented by Integra’s co-plaintiff Telios Pharmaceuticals, Inc. *Id.* at 873. Telios failed to develop a commercially viable product and later sold its patents to Integra. *Id.*

141. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 50 U.S.P.Q.2d (BNA) 1846, 1847 (S.D. Cal. 1999).

142. *Integra Lifesciences I, Ltd.*, 331 F.3d at 863, 873.

143. *Id.* at 863.

144. *Id.* at 862.

145. *Id.* at 863. The process of forming new blood vessels is known scientifically as angiogenesis. *Id.*

146. *Id.* at 863, 874. New blood vessel formation is essential to feed the growth of a tumor, so stopping blood vessel formation could inhibit further tumor growth. *Id.* In addition to anti-tumor potential, the anti-angiogenic therapies could theoretically also treat diabetic retinopathy, rheumatoid arthritis, psoriasis, macular degeneration, and inflammatory bowel disease, among other medical maladies. *Id.*

147. *Id.* at 863.

148. *Id.* at 873-74 (stating that “the cyclic peptide structure [used by Cheresh] solved certain problems that had been experienced with the Telios linear RGD

Dr. Cheresch's work and in 1988 offered to fund further research by Dr. Cheresch and Scripps.¹⁴⁹ In return for the funding, Scripps granted Merck an option to license any future inventions derived from the work.¹⁵⁰ The Merck-Scripps research effort continued through the late 1990s.¹⁵¹ In 1997, Dr. Cheresch's research team chose the best new drug candidate to begin developing data for submission to the FDA.¹⁵²

Integra found out about the Scripps-Merck research and, "[b]elieving the angiogenesis research was a commercial project that infringed its RGD-related patents," Integra offered Merck a license to use the RGD technology.¹⁵³ Merck declined to take a license from Integra, and Integra filed a patent infringement suit against Merck, Scripps, and Dr. Cheresch.¹⁵⁴

B. Holding

1. Majority Opinion

At the trial in the U.S. District Court for the Southern District of California, the jury found that Merck infringed Integra's patents and awarded Integra \$15 million as a reasonable royalty.¹⁵⁵ Although the district court found that one of Integra's patents, Patent No. 4,988,621, was invalid due to prior art,¹⁵⁶ the jury held

peptides . . .").

149. *Id.*; see also *Integra Lifesciences I, Ltd.*, 50 U.S.P.Q.2d (BNA) at 1847.

150. *Integra Lifesciences I, Ltd.*, 50 U.S.P.Q.2d (BNA) at 1847.

151. *Integra Lifesciences I, Ltd.*, 331 F.3d at 873.

152. *Id.* at 863. The drug candidate chosen by the Scripps research team was a cyclic RGD peptide identified as EMD 121974. *Id.* The researchers had three possible drug candidates—EMD 66203, EMD 85189, and EMD 121974—and performed several different *in vivo* and *in vitro* tests on each one to determine the "histopathology, toxicology, circulation, diffusion, and half-life of the peptides in the bloodstream. These tests also examined the proper mode of administering the peptides for optimum therapeutic effect." *Id.*

153. *Id.*

154. *Id.*

155. *Id.* at 862.

156. *Integra Lifesciences I, Ltd.*, 50 U.S.P.Q.2d (BNA) at 1848. Defendant Merck moved for summary judgment of invalidity of Claim 2 of the '621 patent. The judge found in favor of Merck on the motion and held that plaintiff's own article, entitled *Cell Attachment Activity of Fibronectin can be Duplicated by Small Synthetic Fragments of the Molecule*, 309 NATURE 30, 30-33 (May 3, 1984), was prior art with respect to Claim 2 of Integra's '621 patent under 35 U.S.C. § 102(b). Section 102 states that the inventor "shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication . . . more than one year prior to

that Integra's four other patents were valid and infringed.¹⁵⁷ The district court held that Merck's infringing activities did not fall within the safe harbor provision of § 271(e)(1).¹⁵⁸

On appeal, the Federal Circuit in a panel consisting of Circuit Judges Rader, Prost, and Newman affirmed that Merck infringed Integra's patents.¹⁵⁹ In a 2-1 decision, Judges Rader and Prost held that neither the common-law experimental use exemption nor the statutory safe harbor provision of § 271(e)(1) applied to Merck's activities.¹⁶⁰ The majority held that even though Merck's activities might eventually lead to a product that requires FDA approval, the research activities leading up to that point are not within the safe harbor.¹⁶¹ The court stated:

[T]he 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. The FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval.¹⁶²

The court focused on the purpose of the FDA approval safe harbor provision, noting that "the express objective of the 1984 [Drug Price Competition and Patent Term Restoration] Act was to facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent."¹⁶³

Although the language of § 271(e)(1) broadly permits activities "reasonably related" to FDA approval,¹⁶⁴ the majority clearly refused to "expand the phrase 'reasonably related' to embrace the development of new drugs [simply] because those

the date of the application for patent . . ." 35 U.S.C. § 102(b) (2003). The *Nature* article was published one year and three weeks before the effective filing date of the patent application. 50 U.S.P.Q.2d at 1848-49.

157. *Integra Lifesciences I, Ltd.*, 331 F.3d at 863 (finding "Merck liable for infringing the '525, '997, '237, and '734 patents").

158. *Id.* at 862.

159. *Id.* While upholding the district court's finding of infringement, it remanded the reasonable royalty award because the award of \$15 million was not supported by substantial evidence in the record. *Id.* at 870-71.

160. *Id.* at 872.

161. *Id.* at 865-66.

162. *Id.* at 866.

163. *Id.* at 866-67. The court stated "[t]he focus of the entire exemption is the provision of information to the FDA. Activities that do not directly produce information for the FDA are already straining the relationship to the central purpose of the safe harbor." *Id.* at 866.

164. *See supra* Part II.B.

new products will also need FDA approval.”¹⁶⁵ The court believed such an expansion would “exonerate infringing uses only potentially related to information for FDA approval” and “would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents.”¹⁶⁶

2. Judge Newman’s Dissenting Opinion

Judge Newman dissented in part from the majority in this case because she felt that the common-law experimental use exemption should apply to Merck’s research activities and use of the RGD peptide.¹⁶⁷ The majority refused to consider the common-law experimental use exemption, stating that the experimental use exemption was not an issue presented to the jury and consequently could not be properly considered on appeal.¹⁶⁸ The majority further stated in dictum that even if the experimental use exemption were before the court on appeal, the exemption

165. 331 F.3d at 867 (stating § 271(e)(1) “simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process”).

166. *Id.* In stating that expanding the FDA approval would effectively eliminate biotechnology tool patents, the court is referring to inventions that can be used as research tools. The court’s fear is that expanding the § 271(e)(1) safe harbor would allow drug researchers to use another’s patented research tool to perform experiments without recourse as long as the use of the research tool relates to a product requiring FDA approval. The National Institutes of Health (NIH) defines research tools to be “tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PRC), methods, laboratory equipment and machines.” *Id.* at 87-721 n.4 (quoting Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999)).

167. *Id.* at 872 (Newman, J., dissenting).

168. *Id.* at 864 n.2. The majority opinion states in footnote 2 that:

[T]he common law experimental use exception is not before the court in the instant case. The issue before the jury was whether the infringing pre-clinical experiments are immunized from liability via the “FDA exemption,” i.e., 35 U.S.C. 271(e)(1). The district court did not instruct the jury on the common law [experimental use] exemption with respect to the Merck’s infringing activities.

Id.

The court’s footnote goes on to explain that on appeal, Merck did not attempt to argue that the experimental use exemption applies to its activities. Counsel for Merck expressly stated during oral arguments that the common law experimental use exemption was irrelevant. The majority chastises Judge Newman’s dissent and the fact that Judge Newman believes that the common law experimental use exemption should apply to Merck’s activities. *Id.*

probably would not apply, as the majority believed that the doctrine was better suited to cases of *de minimis* infringement and minimal damages.¹⁶⁹ However, Judge Newman's dissent noted that the district court did in fact apply the common law doctrine to one Scripps experiment conducted in 1994, but did not apply the exemption to any of the other experiments.¹⁷⁰ Judge Newman argued that the issue was accordingly before the district court and could be properly considered on appeal.¹⁷¹

Judge Newman believed the common-law experimental use exemption should apply to the type of research performed by Merck/Scripps for a number of reasons.¹⁷² First, the requirement that the patent fully discloses the invention has the very purpose of allowing others to study, improve upon, and reverse-engineer the patented invention.¹⁷³ Full disclosure would serve no purpose whatsoever if the information cannot be used during the term of the patent.¹⁷⁴

Second, the routine and rapid appearance of improvements on patented subject matter, without a corresponding infringement suit by the patent owner, is proof that the patent system allows the use of the information contained in the patent to conduct research and develop new products.¹⁷⁵ Judge Newman argued that the current rate of technological advancement is due in large part to the knowledge gleaned from patented inventions; if the patentee were allowed to prohibit such research, then the advancement of technology in the patentee's field would stop.¹⁷⁶

Third, Judge Newman disagreed with the majority's characterization of Integra's patent as a "research tool."¹⁷⁷ The

169. *Id.*

170. *Id.* at 878. Judge Newman also noted that on appeal Merck's counsel "explained at oral argument that they were not pressing this argument 'in part because of a very recent case.'" *Id.*

171. *See id.*

172. *Id.* at 875.

173. *Id.* *See* 35 U.S.C. § 112 (2003).

174. *Integra Lifesciences I, Ltd.*, 331 F.3d at 875. Judge Newman noted that the requirement of disclosing "details of enabling experiments and technical drawings and best modes and preferred embodiments . . . would be idle and purposeless if this information cannot be used [by others] for 17-20 years." *Id.*

175. *Id.*

176. *Id.* Judge Newman broadly argued that "the first patentee in the field could bar not only patent-protected competition, but all research that might lead to such competition, as well as barring improvement or challenge or avoidance of patented technology." *Id.*

177. *Id.* at 877-78. *See also id.* at 871-72 (majority opinion).

majority's argument that allowing the experimental use exemption to apply to the use of a research tool patent to conduct other research would effectively eliminate the usefulness of the patent is correct.¹⁷⁸ However, Judge Newman characterized the RGD peptides not as research tools, but "simply new compositions having certain biological properties."¹⁷⁹

Finally, Judge Newman believed that even if the researcher's ultimate goal is to commercialize a product, the experimental use exemption should still apply to pre-commercialization research.¹⁸⁰ She reasoned that patent law barred development and commercialization, but not the research itself that led to commercialization.¹⁸¹ However, Judge Newman did not define the crossover point between research and development.¹⁸²

Even though Judge Newman did not define where research ends and development and commercialization begin, she rationalized that for a product requiring FDA approval the development and commercialization aspects were covered by the FDA approval safe harbor provision of § 271(e)(1) because the development and commercialization would necessarily involve gathering and submitting data to the FDA.¹⁸³ Any period of use not

178. *See id.* at 867 (stating that "expansion of § 271(e)(1) to include the Scripps/Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents . . . exaggerating § 271(e)(1) would [eliminate all patent protection] for some categories of biotechnological inventions").

179. *Id.* at 878.

180. *Id.* at 876 (stating that "an ultimate goal or hope of profit from successful research should not eliminate the exemption. The better rule is to recognize the exemption for research conducted in order to understand or improve upon or modify the patented subject matter, whatever the ultimate goal").

181. *Id.* Judge Newman stated: "That is how the patent system has always worked: the patent is infringed by and bars activity associated with development and commercialization of infringing subject matter, but the research itself is not prohibited, nor is comparison of the patented subject matter with improved technology or with designs whose purpose is to avoid the patent." *Id.*

182. *See id.* at 876-77.

183. *See id.* Judge Newman stated:

[T]he territory that the Scripps/Merck research traversed, from laboratory experimentation to development of data for submission to the FDA, was either exempt exploratory research, or was immunized by § 271(e)(1). It would be strange to create an intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed and the activity can be prohibited [T]he law does not favor such an illogical outcome.

Id. at 877.

Thus rather than defining a point where the experimental use exemption ends,

exempt from infringement by the research exception would be covered by the FDA approval safe harbor.¹⁸⁴ Hence, the entire Scripps/Merck pursuit would be exempt from infringement—the first portions under the experimental use exemption, and the latter under the FDA approval safe harbor.¹⁸⁵ However, once the FDA approval was gained and the safe harbor provision is no longer applicable, then the full force of any valid patent would be in effect to prevent sales of the infringing products.¹⁸⁶

Judge Newman further disagreed with the majority's analysis of the reasonable royalty calculation.¹⁸⁷ She believed the standard to be looser than the majority made it out to be, and the exact date of the hypothetical negotiation was not as important as the majority held.¹⁸⁸

IV. ANALYSIS

A. *The FDA Approval Safe Harbor Provision—35 U.S.C. § 271(e)(1)*

The *Integra* court correctly construed § 271(e)(1) and correctly applied it to Merck's research activities.¹⁸⁹ Merck's research activities do not fall within the purpose of the statute. The court could have concluded that since Merck's research eventually would lead to a product requiring FDA approval, the research must be "reasonably related" to FDA approval. The court properly uses the original purpose behind the statute to reject this overly broad interpretation.

When Congress enacted § 271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984, the intent was clearly to allow a generic drug manufacturer the latitude to

Judge Newman stated that where the experimental use exemption ends, the FDA approval safe harbor begins and no further analysis is necessary. *See id.*

184. *See id.* at 876-77.

185. *See id.*

186. *See id.* at 877.

187. *Id.*

188. *Id.* Judge Newman's dissent stated that "[t]he 'hypothetical negotiation' is no more than a convenience in estimating value, not a compulsory economic standard, and surely not one that requires appellate speculation as to when the parties might have hypothetically negotiated." *Id.* Judge Newman believed that, in the case that Merck has been found to be an infringer, the jury's award was "well supported" by "extensive" evidence on damages. *Id.*

189. *See id.* at 867-68; 35 U.S.C. § 271(e)(1) (2000).

gain pre-approval on a similar generic form of a patented drug.¹⁹⁰ The purpose of the statute was to make generic forms of a patented drug available to the public as soon as a patent expired.¹⁹¹ Merck's research activities do not fall within this purpose. Merck was attempting to create an entirely new product using Integra's patented RGD peptide as only a starting point, rather than gaining FDA approval on a generic version of Integra's product for sale upon expiration of the patent.¹⁹²

Even if the Federal Circuit had applied the broad *Intermedics* test, the court still should not have held Merck's activities to fall within the FDA approval safe harbor provision. The *Intermedics* test asks, "would it have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the 'use' in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant [to FDA approval]?"¹⁹³ Although this rule uses broad language such as "reasonable," "decent prospect," and "kinds of information . . . likely to be relevant," Merck's uses still fall outside it. Merck's uses cannot be said to have contributed *relatively directly* to the generation of information relevant to FDA approval. Merck's activities were not meant to create data for FDA approval on an existing Integra product, but rather were intended to discover a different product worthy of submitting to the FDA. Merck's activity is so far beyond the clear purpose set forth by Congress that interpreting its actions as falling within the safe harbor provision would defeat Congress' intent.

Even Judge Newman's dissent in *Integra* admits "that 'the § 271(e)(1) safe harbor [does not] reach back down the chain of experimentation to embrace development and identification of new drugs.'"¹⁹⁴ Judge Newman agreed that the initial research and development should not be exempted from infringement by the FDA approval safe harbor.¹⁹⁵ However, Judge Newman did believe

190. See *supra* Part II.B.

191. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990). The Supreme Court stated, "[s]ince [FDA approval] could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's *de facto* monopoly would continue for an often substantial period . . . The 1984 Act sought to eliminate this distortion . . ." *Id.*

192. *Integra Lifesciences I, Ltd.*, 331 F.3d at 862-63.

193. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991).

194. See 331 F.3d at 877 (quoting the majority opinion at 865-66).

195. *Id.*

that once Merck had chosen a drug to submit to the FDA, then those activities thereafter would be exempt under the FDA approval safe harbor. But more importantly, Judge Newman thought that Merck's initial research should have been exempted under the common-law experimental use exemption, whereas the majority refused such a finding.¹⁹⁶

B. Common-Law Experimental Use Exemption

The *Integra* majority properly applied the common-law experimental use exemption as developed by previous case law. However, the experimental use exemption as it now stands is too narrow and should be broadened to apply to research activities such as Merck's. Thus, the majority's decision in *Integra* is erroneous when considered from the perspective of a broader experimental use exemption. Judge Newman's dissent correctly broadens the experimental use exemption and applies it to Merck's research.

The majority and dissent in the *Integra* case are diametrically opposed as to the application of the common-law experimental use exemption. It should be noted again that the majority did not analyze or apply the experimental use exemption. They concluded that the trial court did not hear the issue, the jury did not decide the issue, and thus the issue was not ripe for appeal.¹⁹⁷ However, even if they had considered the experimental use exemption issue, they would not have allowed it as a defense for Merck's activities.¹⁹⁸ In dicta, the court stated, "the Patent Act does not include the word 'experimental,' let alone an experimental use exemption from infringement."¹⁹⁹ The majority, or at least Judge Rader, believed the experimental use exemption is not necessary and should be eliminated. Judge Rader has expressly stated so at least once before in his concurring opinion in *Embrex, Inc. v. Service Engineering Corp.*²⁰⁰ Judge Rader is correct that the Patent Act does not explicitly call for an experimental use exemption. However,

196. *Id.* at 874-76; *see supra* Part II.B.; *infra* Part IV.B.

197. *Integra Lifesciences I, Ltd.*, 331 F.3d at 864 n.2.

198. *See id.*

199. *Id.* The court also stated in dicta that "the judge-made [experimental use] doctrine is rooted in the notions of *de minimis* infringement better addressed by limited damages." *Id.*

200. 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring) (stating "the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement").

the lack of statutory language on the subject does not inescapably mean that a common-law experimental use exemption serves no purpose or is unnecessary.

As Judge Newman noted in her dissent, the requirement of full disclosure of the invention in the patent seems to presuppose the right of the public to use this information. In addition, patents provide a monopoly that is intended to spur innovation by giving the patentee a reward. The patent monopoly need only be extended far enough to continue to spur innovation, and need not monopolize the right to do research on as well as commercialize a patented invention.

1. *Full Disclosure Argument in Favor of an Experimental Use Exemption*

a. *The Full Disclosure Rule*

A fundamental exchange of rights occurs in the patent system. The inventor agrees to give the public a full disclosure of the invention in exchange for a government-sanctioned monopoly for twenty years.²⁰¹ As Judge Newman noted in her *Integra* dissent, “[t]he patent statute requires full disclosure of the invention, including details of enabling experiments and technical drawings and best modes and preferred embodiments, even commercial sources of special components.”²⁰² The patent system also requires that the documents be accessible to the public.²⁰³ The Patent Act

201. See 35 U.S.C. § 112 (2003) (requiring the patent contain a specification describing the patented invention in “full, clear, concise, and exact terms”); 35 U.S.C. § 154 (2003) (granting patent rights for twenty years from the filing date of the patent application).

202. 331 F.3d at 875. See also 35 U.S.C. § 112 (2003). Section 112 states that the patent specification must include:

[A] written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Id.

203. See United States Patent and Trademark Office Editorial Standards, available at <http://www.uspto.gov/main/ccpubguide.htm> (last visited March 24, 2004). The USPTO web site states:

Patents are published into the public domain as part of the terms of granting the patent to the inventor. As such, they are not subject to copyright restrictions. The inventors’ right to exclude others from making, using, offering for sale, or selling the invention . . . is not

even allows for patent applications to become publicly available eighteen months after the filing date, consequently facilitating full public disclosure of the invention, even before a patent has issued.²⁰⁴ The patent application and patent itself must contain a description of the patented invention, as well as how to make and use it, in “full, clear, concise and exact” details such that “any person skilled in the art” could make and use it.²⁰⁵ The patent must also include what the inventor considers to be the “best mode” of the invention.²⁰⁶ Thus, the patentee gives up the right to secrecy and makes a full disclosure of the invention to the public in order to gain the right to exclude others from making, using, or selling the invention.²⁰⁷

Judge Newman believed that prohibiting all research on patented subject matter is both “impractical” and “incorrect” as patents are a major source of scientific knowledge.²⁰⁸ While discussing the full disclosure rule, Judge Newman stated, “such details would be idle and purposeless if this information cannot be used for 17-20 years.”²⁰⁹ This argument makes sense. What

compromised by the publication of the description of the invention. In other words, the fact that a patent’s description is in the public domain does not give you permission to manufacture or use the invention without permission from the inventor during the active life of the patent.

Id.; see also 35 U.S.C. § 2(a)(2) (2003) (stating that the USPTO “shall be responsible for disseminating to the public information with respect to patents and trademarks”). See generally 35 U.S.C. §§ 9, 10, 12 (2003) (allowing for different methods of making patents available to the public).

204. See 35 U.S.C. § 122(b)(1) (2003) (stating that, with a few exceptions under § 122(b)(2), “each application for a patent shall be published . . . promptly after the expiration of a period of 18 months from the earliest filing date . . .”). The exceptions include when the application is: 1) no longer pending; 2) subject to a secrecy order under § 181; 3) a provisional application filed under § 111(b); 4) an application for a design patent; or 5) the invention has not and will not be the subject of a patent application in a foreign country and the applicant requests that the application not be published).

205. 35 U.S.C. § 112 (2003).

206. *Id.*

207. See, e.g., *Amgen, Inc. v. Genetics Inst., Inc.*, 877 F. Supp. 45, 52 (D. Mass. 1995) (“From the early days of the republic, our patent law has required that in exchange for a government-sanctioned monopoly on the rights to an invention or discovery, the inventor must teach the world the secret behind the method or device”); see also 35 U.S.C. § 271(a) (2003) (stating “whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent” thus giving the patent holder the right to sue the infringers for damages, an injunction, or both).

208. 331 F.3d at 875.

209. *Id.*

purpose does the full disclosure rule have if the public cannot build and improve upon this knowledge? If the patent system does not want the public to utilize the information until after the patent expires, then patents should not be published and made available, but instead be kept secret until expiration.²¹⁰ If the patentee is to have complete supremacy over the information in the patent, then it would be much easier for the patentee to secure and enforce those rights if the patent is not disclosed to the public. The patentee could more easily exclude others from making, using, selling, *and researching* the patented subject matter if the patent was not publicly disclosed.²¹¹

One could argue that a broader experimental use exemption would encourage an inventor to make an incomplete disclosure of the invention in the patent, revealing as little as possible to prevent researchers from effectively using the disclosure.²¹² However, an incomplete disclosure would violate 35 U.S.C. § 112, which requires, 1) a full description of the invention, 2) enablement, and 3) the best mode.²¹³ An inadequate disclosure will cause either the patent examiner to reject the patent application²¹⁴ or cause a court to invalidate the patent.²¹⁵ In addition, other practitioners in the

210. See Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 219 (1987) [*hereinafter* Eisenberg, *Proprietary Rights*].

If the public had absolutely no right to make, use, or sell the patented invention until the end of the patent term, it would be somewhat puzzling to require that the patentee give the public an enabling disclosure of the invention at the beginning of the patent term. The requirement of early disclosure suggests that certain uses of patented inventions during the patent term do not constitute patent infringement.

Id.

211. *Id.*

212. Some argue that this incomplete disclosure problem already occurs. See *Brenner v. Manson*, 383 U.S. 519, 533-34 (1966); Eisenberg, *Patents*, *supra* note 17, at 1029.

213. 35 U.S.C. § 112 (2003).

214. See MANUAL OF PATENT EXAMINING PROCEDURE § 608.01 (2003); 37 C.F.R. § 1.71 (a) (2003).

215. See, e.g., *Beidler v. United States*, 253 U.S. 447, 453 (1920) (stating that “it has been consistently held that a correct and adequate description or disclosure of a claimed discovery . . . is essential to the validity of a patent, for the reason that such a disclosure is necessary in order to give the public the benefit of the invention after the patent shall expire”) (emphasis added); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361 (Fed. Cir. 1997) (invalidating the plaintiff’s patent for lack of an enabling disclosure).

field can examine the disclosure and decide if it is enabling.²¹⁶ If it is not, then the practitioner can infringe the patent with the knowledge that lack of enablement is a sufficient defense to invalidate the patent.²¹⁷ Therefore, this incomplete disclosure problem should not dissuade the use of a broader experimental use exemption.

b. Allowed Uses of the Patent Disclosure

The patent system already seems to acquiesce to the public's use of patented information. Improvements on patented subject matter appear quickly and routinely regardless of whether the patentee has licensed the technology to others.²¹⁸ It is highly unlikely that all of these improvements come by way of independent research. Rather, ambitious inventors or researchers likely study the current state of the art including issued patents and then improve upon the art. The appearance of improvements to patented subject matter tends to prove that the public already uses the patent disclosure to conduct some amount of research and development.

c. Designing Around a Patented Invention

As further proof that the patent system allows the public to use the information in the patent, the Federal Circuit has stated on many occasions that the public is not only able, but *encouraged*, to "design around" a patented invention.²¹⁹ Designing around a

216. See Eisenberg, *Proprietary Rights*, *supra* note 210, at 219.

217. *Id.* Eisenberg states that practitioners in the field may be more able to discern defect in the patent specification than the patent examiner. *Id.* "Since an insufficient disclosure makes the patent invalid and unenforceable, those who have a use for the patented technology will be motivated to uncover defects in the specification in order to avoid liability to the patentee." *Id.*

218. See generally *Beidler*, 253 U.S. at 453.

219. See, e.g., *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235-36 (Fed. Cir. 1985) (stating that "keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace"); *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991) (stating "designing or inventing around patents to make new inventions is encouraged" when the party designs around by making a "substantial change" to the invention. However, "piracy" by making an "insubstantial change" is not allowed"); *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d

patented invention entails making changes to the invention so that the new design no longer fits within the scope of the patent's claims.²²⁰ The new design may be very similar to the patented invention and directly compete in the same marketplace against the invention; but because the new design does not contain all the elements of the patent claim, it is not an infringing product.²²¹ The Federal Circuit has stated that designing around a patented invention is encouraged because it promotes free competition, which benefits the public.²²² The full disclosure rule effectively enables competitors to more easily design around a patented invention.

However, in *Embrex, Inc. v. Service Engineering Corp.*,²²³ the Federal Circuit did not allow Service Engineering to infringe Embrex's patent while attempting to design around it.²²⁴ Service Engineering built several machines that were held to still infringe the patents.²²⁵ The Federal Circuit rejected Service Engineering's argument that the machines were for experimental use only to design around the patent.²²⁶ Even though Service Engineering never sold any of the machines built, the court held that the use had a commercial purpose and was not an exempt experimental use.²²⁷ Apparently, the Federal Circuit encourages designing around the patent only when an infringing design is not made. Service Engineering was unsuccessful in building a non-infringing device.²²⁸ One wonders if Service Engineering would have been

735, 745 (Fed. Cir. 1993) (quoting both *State Industries* and *London* with approval); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457 (Fed. Cir. 1991) (holding "[i]ntentional 'designing around' the claims of a patent is not by itself a wrong which must be compensated Designing around patents is, in fact, one of the ways in which the patent system works to the advantage of the public in promoting progress in the useful arts").

220. See *Slimfold Mfg. Co.*, 932 F.2d at 1457.

221. See *id.* The subtle test of whether the design around has been effective in avoiding the patent claims involves applying what is known as the "doctrine of equivalents" to determine whether a "substantial change" has been made to the product by the alleged infringer. *Id.*

222. See *State Indus., Inc.*, 751 F.2d at 1235 ("designing around a patented invention creates "new and possibly better or cheaper functional equivalents . . . and is supposed to benefit the consumer"); *Westvaco Corp.*, 991 F.2d at 745 (same). See also *Slimfold Mfg., Inc.*, 932 F.2d at 1457.

223. 216 F.3d 1343 (Fed. Cir. 2000).

224. *Id.* at 1346-47, 1349.

225. *Id.* at 1349.

226. See *id.*

227. *Id.*

228. *Id.* at 1346-47.

liable for infringement if it had successfully designed around the patent claims.

A patent system that encourages designing around a patented invention to promote competition seems to contradict a system that will not allow a competitor to use the patent disclosure to conduct independent research on a completely different derivative product. During the process of designing around a patented product, the competitor is likely to: 1) build the patented invention the competitor wants to design around as a first step,²²⁹ and 2) build multiple attempts to design around the patent that would still infringe. The process of designing around a patent seems to encourage infringement as long as the end product does not directly infringe.²³⁰ Using the patent disclosure to design around a patented invention is similar to conducting research based on the patent disclosure. The usual process of designing around a patent likely involves a great deal of research. The competitor conducting independent research based on a patent and the competitor designing around a patent both have the ultimate goal of producing a differentiable product that is based on the patented invention. Yet, the courts seem to encourage designing around while penalizing commercial research. Designing around the patented subject matter is clearly a “commercial purpose.” Consequently, exploratory research using the patented subject matter should not be deemed infringement simply because the research might be linked to a future commercial purpose to the researcher.

One major difference between designing around and exploratory research is that in designing around, the ultimate goal is to produce a product that does not infringe, whereas research does not necessarily lead to a non-infringing product. For example, Merck created a different and more useful product than *Integra*,²³¹ but the final product created by Merck still contained

229. This argument assumes that the patented invention is not available on the market. If the patented invention is available on the market, the competitor might simply purchase the product from the patentee as a first step, study the purchased product, and then attempt to design around it.

230. *But see Embrex, Inc.*, 216 F.3d 1343 (Fed. Cir. 2000) (not allowing the infringing defendant to use the experimental use exemption as a defense to patent infringement when the defendant made and used the plaintiff's patented machine for experiments in an attempt to design around the patent).

231. *See Integra Lifesciences I, Ltd.*, 331 F.3d at 863 (noting Merck's research created a new cyclic RGD peptide product potentially effective and safe enough to warrant clinical human testing).

the limitations of Integra's claims (the peptide sequence RGD) and therefore still infringed Integra's patent.²³² The patentee may claim an invention comprising the elements A-B-C, where the researcher's final product may contain the narrower group of components A-B-C-D. The researcher's final product is indeed different, but it still contains all the elements (A-B-C) of the patented invention. Consequently, the researcher could not commercialize his product without infringing the patent.²³³ However, as discussed more in depth later, this does not necessarily mean that the researcher should be barred from conducting his research on the patented invention in the first place.

The full disclosure rule, the encouragement of designing around a patented invention, and the rapid appearance of independent improvements to patented inventions all point to the conclusion that the patent system tolerates the public's use of the patent disclosure to improve upon the patented subject matter. Therefore, the Federal Circuit's recent decisions, including *Integra v. Merck*, construed the experimental use exemption too narrowly based on the existence of potential commercial purpose.

The full disclosure rule effectively supports free use of patented subject matter for research. But on a more fundamental level, the patent system should allow free use of patented subject matter for research purposes. The ultimate purpose of the patent system is to create an incentive to invent. Based on that incentive, the patent monopoly should not be construed to exclude research activities.

2. *The Patent Monopoly and Incentive to Invent Arguments*

a. *Purpose and Theory Behind Patent Law*

The Constitution of the United States authorized a patent system in order to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the

232. See *id.* at 868-69 (rejecting Merck's argument that its product was non-infringing due to the cyclic structure of Merck's RGD peptide).

233. For comparison's sake, the party designing around the patented invention would attempt to create a product such as A-B-E. Although A-B-E will be very similar to patentee's A-B-C and may directly compete with it, since A-B-E does not contain all of the elements of the patented invention, it is not infringing and can be commercialized.

exclusive Right to their respective Writings and Discoveries.”²³⁴ A patent gives its holder the right to exclude others from making, using, or selling²³⁵ the patented invention for a term of twenty years.²³⁶

A patent is an anomaly in our economic system.²³⁷ The United States economy favors capitalism and free competition over all other ideals. Our wide body of antitrust law²³⁸ provides ample evidence that our government favors free trade.²³⁹ One of the greatest impediments to free competition is a government-sanctioned monopoly, such as a patent. In addition, patents are contrary to the general scientific principle that discoveries should be disclosed for the benefit of all.²⁴⁰ Scientists are generally inclined to share their discoveries with fellow scientists, at least in the academic fields, to allow all to benefit from their discoveries.²⁴¹ Full disclosure allows other scientists to validate the findings and also prevents duplicative research. Thus a patent that allows the inventor to preclude the public from using the invention for research is counter to the traditional scientific norms as well as the

234. U.S. CONST. art. I, § 8, cl. 8. This clause of the Constitution also allows for copyrights to authors. *See id.*

235. *See* 35 U.S.C §§ 154(a)(1), 271(a) (2003) (granting the patentee “the right to exclude others from making, using, offering for sale, or selling the invention . . .”).

236. *See* 35 U.S.C § 154(a)(2) (2003) (allowing twenty-year patent term from the date of filing the patent application).

237. *See* *Graham v. John Deere Co.*, 383 U.S. 1, 8-9 (1966) (noting that Thomas Jefferson, when acting as a founder of the patent system, had aversions to the patent monopoly and monopolies in general and wanted the patent to be only as strong as necessary to promote invention).

238. BLACK’S LAW DICTIONARY 92 (7th ed. 1999) (defining “antitrust law” as “[t]he body of law designed to protect trade and commerce from restraints, monopolies, price-fixing, and price discrimination”). The federal antitrust laws are generally set forth in the Sherman Act (15 U.S.C. §§ 1-7) and the Clayton Act (15 U.S.C. §§ 12-27). *Id.*

239. *See* LAWRENCE A. SULLIVAN, HANDBOOK OF THE LAW OF ANTITRUST, § 5, at 20 (1977) (noting that “[a]s legislative history and case law both disclose, the general objective of the antitrust laws is the maintenance of competition. Competition per se thus becomes a goal of the legal order”).

240. *See* Eisenberg, *Patents*, *supra* note 17, at 1046-47. Enforcing patent rights against researchers “fundamentally conflicts with traditional scientific norms calling for free dedication of new knowledge to the scientific community.” *Id.* at 1046. The tradition among scientists, at the very least in the non-commercial sector, has always been to publish their results for the benefit of all. *Id.* at 1046-47. Allowing others to use a new discovery to their advantage prevents duplicative research, which wastes time, wastes resources, and benefits no one. *Id.* at 1028-47.

241. *See id.* at 1046-47.

capitalist ideal of free competition.

Multiple theories explain the purpose of awarding patents. Main theories include: 1) the patent system gives an inventor his natural right to be the only one to profit from his creation;²⁴² 2) the patent system encourages public disclosure of inventions that might otherwise be used as a trade secret and not publicly disclosed;²⁴³ and 3) the patent system spurs innovation and gives people an incentive to invent.²⁴⁴

The natural rights theory, that an inventor deserves a monopoly as his natural right for inventing, was expressly rejected by the Supreme Court in the case of *Graham v. John Deere Co.*²⁴⁵ The Court supported Thomas Jefferson's view that the patent is based on social and economic rationales, intended to be a reward to induce people to "bring forth new knowledge."²⁴⁶ The Court noted the "high level of patentability" and the strict requirements that must be met before obtaining a patent (novelty, utility, and non-obviousness).²⁴⁷ Another argument in support of the Court's

242. See *Graham*, 383 U.S. at 9 (discussing how the patent was not created to represent an inventor's natural right to his/her invention).

243. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 494 (1974) (Marshall, J., concurring) (finding "the existence of trade secret protection provides in some instances a substantial disincentive to entrance into the patent system, and thus deprives society of the benefits of public disclosure of the invention which it is the policy of the patent laws to encourage"); *Winston Research Corp. v. Minnesota Mining & Mfg. Co.*, 350 F.2d 134, 138 n.2 (9th Cir. 1965) ("The federal patent statutes require full disclosure of the invention as a condition to the grant of monopoly. . . . Thus, the federal patent statutes would seem to reflect a congressional determination that any individual or social interests which may be served by secrecy [or a trade secret law] are outweighed by those served by full disclosure.").

244. See Eisenberg, *Patents*, *supra* note 17, at 1024-30. Eisenberg notes two main theories behind the patent's purpose: the incentive to invent and the incentive to disclose. *Id.* She also notes a more abstract theory that the patent provides an "incentive to innovate" that is distinct from an incentive to invent. *Id.* at 1036-38.

245. 383 U.S. at 9 (noting commentary from the 1800s on the subject by Thomas Jefferson and stating that "[t]he patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather it was a reward, an inducement, to bring forth new knowledge.").

246. See *id.* (supporting Thomas Jefferson's belief that the patent "was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given."). Regarding Thomas Jefferson, the Court states, "[b]ecause of his active interest and influence in the early development of the patent system, Jefferson's views on the general nature of the limited patent monopoly under the Constitution, as well as his conclusions as to conditions for patentability under the statutory scheme, are worthy of note." *Id.* at 7.

247. See *id.* at 8-9. See also CHISUM, *supra* note 1, at chs. 1-5 (detailing the

reasoning in *Graham* is that if the patent were a natural right of the inventor, it should last forever rather than expiring after twenty years. In general, a natural right should not expire after a set period of time.

The other two theories, incentive to publicly disclose and incentive to invent, are the reasons most commonly advanced as the purpose of the patent system.²⁴⁸ The incentive-to-disclose argument has been favored by courts but has had less support from economists.²⁴⁹ In most cases, if patents did not exist, the public eventually would be able to gain disclosure of the invention by buying the product and reverse engineering it.²⁵⁰ Although reverse engineering probably is more difficult than reading the disclosure of a patent, this reason alone is not enough to justify the patent system. For the few inventions that cannot be reverse engineered and can be effectively used as a trade secret, it does not make sense for the inventor to seek a patent. A patent requires disclosure and the protection lasts for only twenty years, but a trade secret theoretically could be exploited perpetually as a monopoly.²⁵¹ The full disclosure rule alone is not an effective argument to justify patents.

The best argument in favor of a patent system is that the patent provides a reward that induces creative minds to invent.²⁵² In *Graham*, the Supreme Court stated that the patent monopoly was designed to be “a reward, an inducement, to bring forth new knowledge.”²⁵³ Without the reward of the patent monopoly, an inventor’s invention would be too easy for competitors to misappropriate and sell without the expense and effort of having to invent.²⁵⁴ Inventing may be expensive, as it consumes time, manpower, and large amounts of money. Copying, on the other hand, is always cheaper. Without patent protection, inventors

patentability criteria of eligible subject matter (ch. 1), originality (ch. 2), novelty (ch.3), utility (ch. 4), and nonobviousness (ch. 5)). Logically, a patent should not require passing so many hurdles if it were a natural, inherent right.

248. See *Kewanee Oil Co.*, 416 U.S. at 480-81 (noting that patents provide an incentive or reward to inventors to encourage inventing, as well as a method to ensure public disclosure of the invention for the benefit of the public’s use once the patent expires); Eisenberg, *Patents*, *supra* note 17, at 1024-29.

249. See Eisenberg, *Patents*, *supra* note 17, at 1028-29.

250. *Id.* at 1029.

251. *Id.*

252. See *id.* at 1024-26; *Graham*, 383 U.S. at 9.

253. 383 U.S. at 9.

254. Eisenberg, *Patents*, *supra* note 17, at 1024-28.

would be less likely to invent for fear of their ideas being stolen and potential financial rewards being obtained by competitors. If the inventor must face free competition, the market price of the invention may be driven down to the point where the inventor can no longer recoup the initial investment cost of creating the invention, which the free-loading competitors do not have to pay.²⁵⁵ The patent monopoly allows the inventor to stop infringers, increases profitability of the invention, and creates a stronger incentive to invent.

b. Application of the Incentive-to-Invent Theory

Because the incentive-to-invent argument seems to be the strongest underlying purpose of the patent system, the experimental use exemption should be analyzed in view of the incentive to invent. Would there still be an adequate incentive to invent and obtain patents if the experimental use exemption were broadened, allowing researchers to freely use inventions for research purposes? A broader experimental use exemption would promote free use of ideas, would encourage competitors to study and improve upon patented subject matter, and arguably would spur more innovation. However, a broader experimental use exemption also weakens the patent monopoly, possibly decreasing the incentive to invent in the first place.²⁵⁶ A balance must be struck between the two competing objectives.

The current judicial trend appears to be to weaken, if not eliminate, the experimental use exemption.²⁵⁷ The *Integra* decision leans toward the view that the power to exclude and monopolize should be all-encompassing.²⁵⁸ Judge Rader stated in dicta that the patent statute did not allow for an experimental use doctrine, and that the judge-made experimental use doctrine was better addressed by limited damages to the patentee when infringement was *de minimis*, rather than an outright exemption from infringement.²⁵⁹ Similarly, in *Madey v. Duke University*,²⁶⁰ the Federal

255. *Id.* at 1025.

256. *See* Karp, *supra* note 17, at 2169 (arguing that a broad experimental use exemption would decrease the incentive to innovate, would not result in a corresponding increase in research, and would, therefore, lead to a decline in the rate of invention).

257. *See supra* Part II.B.

258. *See* *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003).

259. *Id.* at 864 n.2.

Circuit held that if the researcher's use of the patented subject matter could be linked to the slightest commercial purpose or legitimate business interest, then the experimental use exemption should not apply.²⁶¹ These Federal Circuit decisions eliminate any useful facet of an experimental use exemption.

Congress has considered enacting a statutory experimental use exemption but has failed to do so.²⁶² A 1988 bill on patenting transgenic animals originally included an experimental use exemption, but the exemption was later removed from the bill.²⁶³ Upon removing the exemption, the House Report suggested instead that sometime in the future, Congress should enact an experimental use exemption that applied to all inventions.²⁶⁴ Shortly thereafter, the Patent Competitiveness and Technological Act of 1990 proposed a broad experimental use exemption supported by the House Judiciary Committee but not enacted by Congress.²⁶⁵ The Plant Variety Protection Act contains a fairly broad experimental use exemption, but it is limited to plant patents.²⁶⁶ Clearly, Congress has contemplated an experimental use exemption for patents but has failed, as of yet, to enact one.

Judge Newman's dissent in *Integra* favored a broader experimental use exemption—specifically, an exemption that would protect research activities, such as Merck's, that have a commercial undertone.²⁶⁷ Judge Newman framed her argument on the full disclosure aspect of patent law, as well as the generalization that research and improvement on patented subject matter historically have always been allowed.²⁶⁸ This note illustrates that the argument in favor of a broad experimental use exemption can

260. 307 F.3d 1351 (Fed. Cir. 2002).

261. *See id.* at 1362.

262. *See* Johnson, *supra* note 17, at 528-29.

263. *Id.* at 528.

264. *Id.*

265. *Id.* at 529. *See also* H.R. REP. NO. 101-960, pt. I (1990).

266. 7 U.S.C. § 2544 (2003). *See also* Peter J. Goss, Comment, *Guiding the Hand That Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 CAL. L. REV. 1395, 1408-10 (1996) (noting that the experimental use exemption was narrowed by Congress in 1994). "Congress attempted to limit the potential for abuse of the experimental use exemption by declaring that varieties 'essentially derived' from protected varieties are infringing" *Id.* at 1410 (quoting 7 U.S.C. § 2541(c)(1) (1994)).

267. *See Integra Lifesciences I, Ltd.*, 331 F.3d at 876 (Newman, J., dissenting). Judge Newman stated that "an ultimate goal or hope of profit from successful research should not eliminate the [experimental use] exemption." *Id.*

268. *See id.* at 876-77.

also be made on the basis of the incentive to invent.

A patent system with a broader experimental use exemption would continue to spur innovation by providing patentees with adequate protections from infringement. An inventor would still have the sole right to commercialize the invention. If the invention is a product, then the inventor would still have the sole right to sell the invention. If the invention is a process, then the inventor would still have the sole right to sell products made with the patented process. A patentee's commercialization should be the main source of revenue for a majority of inventions, rather than licenses to competitors conducting research. The patentee would still be able to gain back any money invested into creating the patented invention and also make a profit through commercial sales. This would be true regardless of whether the competitive researcher's purpose is purely "philosophical" or if the research is conducted with an eye toward future profits. Either way, a patent that allows others to research but not commercialize would provide the patentee with ample incentive to invent.

c. Harmonizing the United States with Foreign Patent Practices

Some commentators argue that weakening the patent monopoly will decrease the incentive to invent, leading to a decrease in the rate of invention.²⁶⁹ Compared to other countries, the United States has always had strong patent protection and has been, and is currently, one of the highest ranked producers of technological innovation.²⁷⁰ But it does not necessarily follow that a broader experimental use exemption will decrease the rate of innovation. Countries including Japan, Germany, France, Italy, Spain, Switzerland, Sweden, Canada, and the United Kingdom, have high "innovative capacity."²⁷¹ Many top innovators, such as

269. See Karp, *supra* note 17, at 2187-88 (arguing "[a]ny weakening of the patent monopoly will discourage inventors from utilizing patent protection" and proposing instead to use compulsory licensing from patentees to researchers for a "reasonable royalty" that is paid only when the research "resulted in a benefit to the experimenter").

270. See Michael E. Porter & Scott Stern, *The New Challenge to America's Prosperity: Findings from the Innovation Index* 34 (1999), available at <http://www.compete.org/pdf/innovation.pdf> (last visited March 24, 2004). A Washington, D.C., think tank known as the Council on Competitiveness conducted a study comparing the "innovative capacity" of the United States and other countries. *Id.* The study consistently ranked the United States as one of the top innovators in the world. *Id.*

271. *Id.*

Japan, Germany, the United Kingdom, France, Italy, Korea, and Canada, have broad experimental use exemptions in their patent law.²⁷² Yet, these countries continue to create many innovative products, and their citizens continue to seek patent protection from their respective patent systems.²⁷³ It cannot be said that a broad experimental use exemption necessarily will lead to a decrease in innovation.

The broad experimental use exemptions in other countries may place American inventors and researchers at a disadvantage. Today, many inventors seek patent protection in their own country as well as in other countries.²⁷⁴ Consider when a Japanese company receives a patent both in Japan and the United States. Other competitive researchers in Japan would be able to freely conduct research on the patentee's invention due to Japan's broad experimental use exemption. But in the United States, the Japanese patentee can prevent American researchers from commercially researching the patented subject matter under the current law.²⁷⁵ This problem occurs with respect to every country that has a broad experimental use exemption. Competitive researchers in foreign countries can and will receive patents on derivative subject matter, whereas the American competitive researchers do not even have a chance to conduct research on the foreign inventor's patented invention. A correspondingly broad experimental use doctrine in the United States would eliminate

272. See John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 718-19 (2002); Mueller, *supra* note 15, at 37-40; Eisenberg, *Patents, supra* note 17, at 1018 n.6; Johnson, *supra* note 17, at 527.

273. See John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2148 (2000). In the United States patent system, only about fifty-five percent of patents are from American inventors. *Id.* Japan, Germany, the United Kingdom, France, Italy, Korea, and Canada were all in the top ten foreign countries for most patents filed in the United States. *Id.* The author makes the assumption that the vast majority of inventors seek protection in their own countries, as well as seeking U.S. patent protection.

274. See UNITED STATES PATENT AND TRADEMARK OFFICE, *PERFORMANCE AND ACCOUNTABILITY REPORT FOR FISCAL YEAR 2001—WORKLOAD TABLES* 112-16 (2002), available at <http://www.uspto.gov/web/offices/com/annual/2001/01accompinfo.pdf> (last visited March 24, 2004) [hereinafter USPTO *Performance and Accountability*]. Of the 344,717 patent applications filed in the United States in 2001, forty-five percent were filed by residents of foreign countries. *Id.* Of the 187,822 patents issued in 2001 by the USPTO, forty-six percent went to residents of foreign countries. *Id.*

275. See, e.g., *Madey v. Duke Univ.*, 307 F.3d 1351, 1361-62 (Fed. Cir. 2002).

this problem.

d. Lost Profits and Patented Inventions That Are Only Useful for Research

A broader experimental use exemption might create unfairness to the patentee if the invention is not commercially successful but still has research potential. This was the unfortunate case for Integra. Integra knew its patented RGD peptide was useful, but could not seem to produce a product that was commercially viable.²⁷⁶ Dr. Cheresch saw potential value in the invention, and Merck funded his further study of the RGD peptides.²⁷⁷ In such a case, Integra's only revenue from the patents would be from licenses to outside researchers, such as Dr. Cheresch and Merck. To prove that such revenue can be substantial, one only needs to consider the \$15 million jury award of reasonable royalties to Integra.²⁷⁸

On the other hand, forcing researchers to seek licenses will hamper further research. Researchers may not have millions of dollars to pay royalties and would be especially reluctant to pay royalties unless research will surely lead to a valuable product. In more extreme cases, a patentee may refuse to grant a license if the patentee views a researcher as a hungry competitor out to design a competing product based on the patented invention, rather than a customer willing to pay royalties for it.²⁷⁹ A broader experimental use exemption would eliminate these restraints on research; but eliminating royalties to patentees also reduces the patentee's profits.

276. See *Integra Lifesciences I, Ltd.*, 331 F.3d at 873. The RGD peptide was actually discovered and patented by co-plaintiff Telios Pharmaceuticals in the mid-to late 1980s. Telios was unable to develop a commercially viable product and sold all of its patent rights to Integra in December of 1996. *Id.*

277. *Id.* at 863.

278. See *id.* at 862. Although the Federal Circuit reversed the jury's award of \$15 million for lack of substantial evidence, the figure gives a rough estimate of what research licenses can be worth. *Id.*

279. See Eisenberg, *Proprietary Rights*, *supra* note 210, at 224. The author postulates:

The patent holder . . . has an interest in prolonging the period in which the public is dependent on the patented technology. If the patentee sees the research user as a competitor rather than a customer, she may refuse to license the invention. Without an experimental use defense, it is possible that no one would be able to build on the inventor's discovery until the patent expired.

Id.

However, the patent system is not in place to guarantee maximum profits to the inventor, but instead to promote invention. The royalties from other researchers might add to an inventor's wealth, but the loss of such financial benefits can hardly take away all of scientists' incentive to invent.²⁸⁰ Very few inventors set out to invent a product that appeals only to other researchers. A majority of scientific research is aimed to create a product that will achieve eventual commercial success in the general consumer market. Therefore, scientists arguably would continue to innovate even if a broader experimental use exemption might eliminate potential royalties from other researchers.

On the other hand, a patentee could lose revenue from a broader experimental use exemption due to: 1) lost royalties from researcher licenses; 2) lost revenue when the outside researcher successfully designs around a patented invention and creates a directly competitive product; and 3) lost revenue when other researchers create a separately patentable derivative product that the patentee could have otherwise invented but failed to. However, none of these harms to the patentee should deter the implementation of a broader experimental use exemption.

First, very few inventions gain major revenue from license royalties.²⁸¹ Most revenue from a patent should come from the sale of products to consumers rather than research royalties. If most of the revenue comes from research royalties, should a patent on the invention be awarded at all? Such an invention does not benefit the public in a direct sense, since the public is not buying the product. The only public benefit occurs if a subsequent researcher, paying royalties, creates a publicly useful product. Perhaps the subsequent inventor of the derivative, public-benefiting product should be the only person rewarded with a patent. The patent system should encourage inventions with public

280. Most patented inventions never attain wide commercial success, and receiving a patent does not guarantee success in the marketplace. See Frank H. Easterbrook, *Cyberspace Versus Property Law?*, 4 TEX. REV. L. & POL. 103, 106 (1999) ("Most inventions receive no royalties; about ten percent earn significant returns, and a very few have huge payoffs"). Furthermore, a large number of inventions do not even receive patents due to a failure to meet the strict statutory requirements of novelty, utility, and non-obviousness. For example, from 1997 to 2001, the Patent Office granted patents to only seventy to seventy-two percent of the patent applications processed to completion during the year. See USPTO *Performance and Accountability*, *supra* note 274, at 106. Yet the patent system continues to stimulate the search for new products and processes in the hopes for commercial success.

281. See Easterbrook, *supra* note 280, at 106.

benefit more than inventions that require further research to be of public use. A broader experimental use exemption promotes creating publicly desired inventions because a patentee could derive profits only from public sales rather than licenses to other researchers. The one exception to this rule is for inventions termed “research tools,” which are described in more detail below.²⁸²

Second, a patentee loses revenue from competitive researchers who create a directly competing product. This should not stop a broader experimental use exemption. Patentees lose the most revenue when a competing product is invented that creates a better and/or cheaper solution to the same problem.²⁸³ As discussed earlier, this is known as “designing around” a patent.²⁸⁴ Allowing researchers to design around a patent clearly decreases the patentee’s incentive to invent. But, as noted above, the patent system already encourages designing around a patent because the American economy derives benefit from free competition.²⁸⁵ Patentees already face the possibility that a competitor will design around the patent. A broader experimental use exemption would only make designing around a patent less risky, as researchers would not have to worry about infringement charges.²⁸⁶ A broader experimental use exemption would further promote an already existing ideal.

Third, the fact that a competitor might create a separably patentable derivative invention will only spur more innovation. The risk of competition would lead a patentee to create and patent any derivative products even more quickly to avoid the potential loss of derivative patents to competitors. A broader experimental use exemption would bring about a more rapid development of improvements on patented subject matter and also derivative

282. See *infra* Part IV.B.2.e.

283. See Eisenberg, *Patents*, *supra* note 17, at 1035-36 (noting that when a researcher aims to develop a competing product, a broader experimental use exemption lowers the patentee’s profits, and thus also the incentive to invent, in two ways: first, by denying the patentee of royalties that would have otherwise been paid; and second, by threatening to “cut short the effective duration of the patent holder’s monopoly if the user succeeds in developing a competing technology”).

284. See *infra* Part IV.B.1.c.

285. See *supra* notes 229-30 and accompanying text.

286. See *Embrex Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000) (awarding patentee infringement damages against a competitor who made and used the patented invention for research in an attempt to design around the patent).

products. In this sense, revenue loss to the patentee due to a broader experimental use exemption is justified.

e. Special Rules for Research Tools

Products intended from the start to be valuable only to other researchers are usually termed as “research tools.” A research tool is “a product or method whose purpose is use in the conduct[ing] of research”²⁸⁷ One simple example of a research tool would be a chemist’s test tube. The inventor of a patented test tube intends to sell it, for the most part, to other researchers. The test tube itself is not being researched, but functions as a tool to conduct research. The majority and dissent in *Integra* disagreed about whether *Integra*’s RGD peptide was a research tool. The majority held that the RGD peptides were a research tool, but the dissent called them “simply new compositions having certain biological properties.”²⁸⁸ However, both the majority and dissent seem to agree that the experimental use exemption should not apply to unrelated research conducted using a patented “research tool.”²⁸⁹

Using the test tube example, if a chemist copies a patented test tube and uses it to perform other experiments, then neither the majority nor dissent in *Integra* would allow the chemist to claim an experimental use exemption if the test tube patentee sues. However, Judge Newman realized and noted that if a researcher was studying and trying to improve upon the research tool itself, then the experimental use exemption (if broadened) should apply.²⁹⁰ But, as a matter of common sense, if the value of an invention is to serve as a research tool, the use of such an invention to conduct other research cannot be exempted from infringement under the experimental use exemption. If such use is exempted, the patent on the research tool would lose all of its value.²⁹¹ In the

287. *Integra Lifesciences I, Ltd.*, 331 F.3d at 878 (Newman, J. dissenting).

288. *Id.* at 871-72, 878.

289. See also Eisenberg, *Patents*, *supra* note 17, at 1035 (noting that allowing researchers an exemption when using so-called research tools “would plainly undermine the interest of the patent holder” and “thereby reduce incentives to make and disclose such inventions in the future.”).

290. See 331 F.3d at 878 (“There is a fundamental distinction between research into the science and technology disclosed in patents, and the use in research of patented products or methods, the so-called ‘research tools’ . . . Use of an existing [research] tool in one’s research is quite different from study of the tool itself.”).

291. See Eisenberg, *Patents*, *supra* note 17, at 1035 (noting a broader

face of a broader common-law experimental use exemption, the courts would have to closely distinguish between research done to improve the research tool itself and unrelated, infringing use of a patented research tool. A further difficulty is to distinguish what constitutes a research tool and what does not—a point upon which the majority and dissent in *Integra* did not agree.²⁹² Other than carefully distinguishing between a research tool and non-research tool, a broader experimental use exemption comports with the purpose of the patent system: to encourage scientific invention and technological innovation.

A patent system with a broader experimental use exemption still rewards patentees with adequate protection, allowing them the sole right to commercialize their products and make a return on their investments. At the same time, a broader experimental use exemption could accelerate the rate of improvements on patented subject matter and the creation of derivative products by giving other researchers free use of the invention to conduct further research. This broader experimental use exemption should apply despite the researchers' intentions to commercialize their research at a later date.

3. *Limiting the Experimental Use Exemption*

This note advocates a broader experimental use exemption, one that would allow researchers to freely use patented subject matter in their research. The broader exemption should apply even if a researcher may have a commercial purpose in mind. Unless the exemption has some limitations, however, unrestrained research could quickly turn into usurpation of a patentee's rights when other researchers profit from the use of the patentee's technology.

The person researching a patented technology must not be allowed to commercialize or profit from the sale of the patentee's invention during the patent term. Allowing researchers to profit

experimental use exemption should not apply to the use of research tools because such patents would have no value, thus eliminating the patent's incentive and leading to a decline in the creation of research tools).

292. See 331 F.3d at 878. The majority seems to hold that the RGD peptide was a research tool because the defendant Merck used the RGD peptide in their research. *Id.* at 872 n.4. Dissenting Judge Newman viewed the RGD peptides instead as "simply new compositions having certain biological properties" and characterized Merck's activities as "syntheses and evaluations of new RGD peptides." *Id.* at 878.

from selling the patentee's claimed invention would strip away some, if not most, of the incentive of obtaining a patent. Once the competitor goes beyond research and begins to commercialize a product, the full force of the original patent must be in effect against the competitor. In addition, some other limitations might be prudent.

The range of possible limitations placed upon the research exemption includes: 1) exempting only non-commercial research, 2) exempting all research from infringement, 3) exempting only research that is not "essentially derived from" or relies heavily on the patented invention,²⁹³ or 4) exempting all research, but imposing a reasonable royalty for commercialization of any non-infringing derivative product.

First, an experimental use exemption that exempts only non-commercial research is the current state of the law²⁹⁴ and is too narrow. As noted by commentators, infringement by non-commercial researchers is rarely prosecuted.²⁹⁵ Thus, this rule has little if any usefulness.

Second, allowing all research on patented subject matter to be exempt, even if the research has a commercial purpose, may decrease the incentive to invent. Under such a rule, a researcher would be allowed to profit from his research if he creates a wholly non-infringing product. If the researcher's product derived from another's patent is considered infringing on the patent, then the researcher would have to wait until after the patent expires to sell the derivative product. The result is similar to designing around a patented invention, which is encouraged by courts.²⁹⁶ If the researcher's product successfully "designs around" the patented invention, then the researcher can commercialize the new product and the patentee loses some, possibly all, of the patent monopoly power. As argued above,²⁹⁷ such a rule might still provide ample incentive to invent and innovate, but it is the most severe and poses the greatest risk of decreasing the incentive to invent, as it gives researchers the strongest rights.²⁹⁸

293. This language is similar to and derived from the Plant Variety Patent Act, 7 U.S.C. §§ 2541, 2544 (2003).

294. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1361-63 (Fed. Cir. 2002).

295. See, e.g., Eisenberg, *Patents*, *supra* note 17, at 1019.

296. See *supra* notes 229-30 and accompanying text.

297. See *infra* Part IV.B.2.

298. See Eisenberg, *Patents*, *supra* note 17, at 1036 (hypothesizing that an exemption "[p]ermitting the unlicensed use of patented inventions for the

Third, exempting all research that is not “essentially derived from” or that relies heavily on a patented invention is similar to the rule created under the Plant Variety Protection Act.²⁹⁹ Such a rule would give the patentee more rights against researchers. Under this rule, a researcher that creates a technically non-infringing product by relying heavily on the patented subject matter would still infringe the patent. If the researcher, however, created a substantially different product than the patented one, he should not owe the patentee any royalties. This rule would be fraught with ambiguity, difficult to formulate, and difficult to enforce. Drawing the line between a product that relies heavily on the patent and one that does not would most likely be a hypertechnical application, resulting in difficulty for judges and juries. Courts exert enough effort construing the patent claims and determining whether an accused infringing product falls within the claim construction. Creating a rule where a product falls outside the scope of the respective patent’s claim construction but nevertheless infringes because it relied heavily on the patent during its development would be even more difficult to apply.

The final solution is a more moderate approach, as it suggests creating some type of compulsory license if a researcher wants to commercialize a derivative product, regardless whether the derivative product infringes the patent.³⁰⁰ If the researcher made

purpose of inventing around patents would appear to reduce the value of patents by shortening the term of effective commercial monopoly,” thus reducing the incentive to invent).

299. See 7 U.S.C. §§ 2541(c)(1), 2544 (2003) (providing a research exemption, but also providing that plants “essentially derived from” a protected variety will be considered infringing). See also *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l*, 534 U.S. 124, 139-40 (2001).

300. This rule already has at least some support in academia. See Eisenberg, *Patents*, *supra* note 17, at 1078. Eisenberg recommends an experimental use exemption such that:

A patent holder should not be entitled to enjoin the use of a patented invention in subsequent research in the field of the invention, which could potentially lead to improvements in the patented technology or to the development of alternative means of achieving the same purpose. However, 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.

Id.

See also Mueller, *supra* note 15, at 55-58 (supporting Eisenberg’s proposed rule and proposing a modified version for research tools); Karp, *supra* note 256, at 2187-88 (arguing for an experimental use exemption that forces an experimenter to pay a

or used the patented subject matter during the course of the research, then the researcher would be liable upon commercialization of the derivative product to pay a reasonable royalty. The royalty could be based on the extent of the use of the patented subject matter during research. Because this rule ensures an after-the-fact payment to patentees, it is almost certain to continue to spur innovation on the part of inventors seeking patents. The patentees could recoup some of their investment from the royalty paid for the use of the patented invention. In addition, this rule allows free research without the fear of infringement charges until the researcher creates a commercialized product. This suggested rule is fairly conservative because it gives patentees a financial reward in the form of royalties, yet promotes more research on already-patented subject matter.

C. Combining the Experimental Use Exemption and FDA Approval Safe Harbor Provision

When a competitor conducts research on a patented product that also requires FDA approval, as was the case in *Integra*, the court should combine a broadened experimental use exemption with the FDA approval safe harbor provision. In her dissenting opinion in *Integra*, Judge Newman states that any of Merck's allegedly infringing activities that were not considered "research," and thus not covered by the experimental use exemption, should be exempt from infringement under the FDA approval safe harbor provision.³⁰¹ She argued that in cases where the product required FDA approval, the experimental use exemption and FDA approval safe harbor provision should flow seamlessly into one another so as to avoid an awkward period where the researcher would be liable for infringement when the activities directly before and after that period are exempt from infringement.³⁰²

reasonable royalty to the patentee when the research "resulted in a benefit to the experimenter").

301. *Integra Lifesciences I, Ltd.*, 331 F.3d at 877.

302. *Id.* Judge Newman stated:

[T]he territory that the Scripps/Merck research traversed, from laboratory experimentation to development of data for submission to the FDA, was either exempt exploratory research, or was immunized by § 271(e)(1). It would be strange to create an intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed.

Id.

Judge Newman's argument is both logical and practical. When considering a product that requires FDA approval, it can be difficult to determine where the research ends and seeking FDA approval begins. Once a product is chosen for submission to the FDA, the applicant may no longer be conducting research, so the experimental use exemption no longer applies.³⁰³ But when conducting research and development, the research phase probably ends and the development phase begins somewhere before the product is ready to submit to the FDA.³⁰⁴ The development stage is most likely, in the language of § 271(e)(1), "reasonably related" to seeking FDA approval and exempt from infringement.³⁰⁵ Either way, it would be unreasonable to permit the competing researcher free use of the patented subject matter for initial research and later exempt him from infringement while seeking FDA approval, while also enforcing the patent infringement in the gray area in between those two stages.

The best rule, as Judge Newman stated, would allow all stages of research and development, from initial research to the final stages of FDA approval, to be exempt from infringement. Such a rule will ensure maximum improvements, development, and innovation in the drug and medical device markets by allowing drug companies to freely conduct research on their competitors' patents, even if the drug company fully intends to create a commercially viable product. This liberal rule would also ensure that products derived from patented subject matter can be sent through the FDA approval process during the patent term and commercially exploited as soon as the original patent expires, thus furthering the purpose of the Hatch-Waxman Act.³⁰⁶ Allowing the competitive researcher to seek FDA approval on his derivative product under the safe harbor provision will also enable the researcher to test if his derivative product is even worthy of FDA approval.

However, this rule could become difficult to apply if the experimental use exemption is coupled with a reasonable royalty for commercialization. The question then becomes, "where does

303. *See id.* at 876. Judge Newman drew the distinction between "research" and "development" and stated that the experimental use rule should apply to research, but submitting information to the FDA should be considered "development" and no longer exempt under the experimental use rule. *See id.*

304. *See id.* at 877.

305. *See infra* Part II.B.

306. *Id.*

the experimental use exemption end and the FDA approval safe harbor provision begin?” The difficulty lies in the fact that the proposed experimental use exemption period would require royalty payments, whereas the FDA approval safe harbor period is royalty-free. One possibility is that the researcher would owe royalties until clinical testing begins. In this case, the power of the FDA approval safe harbor would be somewhat lessened, but would be easier to administer. Furthermore, companies such as Merck that are testing new derivative drugs would have more protection under an experimental use exemption. Overall, allowing all stages of research and development to be exempt from patent infringement (including seeking FDA approval) produces more public benefit than public burden.

V. CONCLUSION

The Federal Circuit in *Integra Lifesciences I, Ltd. v. Merck KGaA* has followed its prior precedents and narrowly construed the experimental use exemption to patent infringement. However, this holding does not further patent law’s overriding goal of encouraging innovation. Permitting free use of patented subject matter for further research would lead to faster improvements on existing and derivative products from patented technology. But because the scope of the current experimental use exemption is fairly well established by the Federal Circuit, a legislative approach may be better suited to implement such a change.³⁰⁷

If Congress or the federal courts were to broaden the experimental use exemption, the tough issue would be how far to broaden it. A very broad exemption to infringement would allow researchers free use, but might reduce the incentive to invent, and thus, reduce the rate of invention. The current scope of the experimental use exemption allows almost no one to conduct research without a license from the patentee, inhibiting independent research on patented subject matter.³⁰⁸ Little evidence is available to point to the optimal level of patent

307. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997) (both stating that major changes to well-settled doctrines in patent law should be handled by Congress rather than the courts).

308. See, e.g., *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (2002) (holding that even universities conducting educational research cannot invoke the experimental use exemption).

protection.³⁰⁹

One thing is clear: research leads to new inventions, new discoveries, faster improvements, and more innovation. Forcing researchers to seek licenses and to pay the patentee royalties to conduct research is counterproductive in a system that is meant to promote innovation. Free research means more people will be financially able to conduct research, and more funds will be devoted to improvements rather than paying the patentee for known technology.

A patent system that wants maximum innovation, requires full disclosure, and encourages designing around a patented invention should be more enthusiastic about a broader experimental use exemption. Furthermore, an economy that favors free competition and is skeptical of monopolies should not be so quick to give patentees the utmost protection from competition without having concrete reasons for doing so.

For now, a fairly conservative experimental use exemption would allow free use of patented subject matter for experimental use and would require researchers to pay a reasonable royalty only upon commercialization of derivative products. In the future, an even stronger experimental use exemption without any royalties, similar to those in place in countries such as Japan or Germany, would likely still promote sufficient original innovation while strongly promoting follow-up inventions, designing around, and improvements to patented subject matter.

309. Eisenberg, *Patents*, *supra* note 17, at 1030. *See also* Eisenberg, *Proprietary Rights*, *supra* note 210, at 224. The author states:

The optimal extent of the experimental use defense cannot be determined without attention to its likely effects on the scientific community. Too narrow a defense could stifle basic research and impair the community's mechanisms for validating and building upon new knowledge. Too broad a defense could cause industrial sponsors to lose interest in biotechnology research or to rely on secrecy in lieu of patent protection. There may be no way to avoid both of these potential problems completely.

Id.