

**ROUGH WATERS AHEAD:
THE STATUS OF THE SAFE HARBOR
PROVISION AFTER *PROVERIS SCIENTIFIC
CORP. V. INNOVASYSTEMS, INC.***

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INTRODUCTION

The right to protect an idea or an invention is one that is rooted in the United States Constitution and has been codified by Congress in the form of patent protection.¹ In return for disclosure of a new technology, the inventor can exclude others from making, selling, or using the

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1. U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 101 (2010).

invention in the United States for a limited time.² These exclusive rights help to incentivize new innovation and reward inventors for their innovative ideas. However, a balance exists between the benefits to innovation gained by granting exclusive rights to the patent holder and the cost of denying competition in the marketplace.³ This is especially true for biotechnology inventions such as pharmaceuticals and medical devices. Generic versions of these inventions decrease the price and make them more affordable for health care providers and the public.⁴ However, the large costs and lengthy periods of research associated with successfully developing biotechnology places a high importance on patentability and patent protection in this area.⁵ Such a delicate balancing act in the biotechnology sector has warranted careful attention from both the legislature and the courts.

One issue Congress has specifically addressed in the biotechnology sector is the *de facto* patent term extension granted to some patent holders as a result of requiring competitors to first receive the required FDA (or other regulatory agency) approval before putting a competing product on the market.⁶ Any testing done by competitors to receive regulatory approval before the patent term expiration would be considered “use” of the patented technology, and therefore the testing would infringe on the patent holders rights. The patent holder could consequently prevent any competitor from performing the required tests until after the patent expired, and since regulatory approval can take years, the patent holder received a *de facto* patent term extension. To

2. 35 U.S.C. § 154(a)(1) (2009).

3. Patent rights allow the patent holder to avoid competition in the market and may lead to a limited time monopoly. The limited patent term is evidence of the attempt to balance the importance of encouraging innovation while avoiding strong monopolies that can “stifle” innovation. FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

4. A generic drug is one that is “bioequivalent” to the brand-name drug listed in a New Drug Application (NDA). The FDA states that “[a] generic drug is identical—or bioequivalent—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts for the branded price.” FDA, What are generic drugs?, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm> (last visited Mar. 1, 2010); *See also* Media Advisory, Comm. on Energy & Commerce, Bipartisan Group of Members Introduces “Promoting Innovation and Access to Life-Saving Medicines Act” (Mar. 11, 2009), *available at* http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1528&Itemid=1.

5. John V. Duca & Mine K. Yucel, *Exploring the Economics of Biotechnology: An Overview*, in SCIENCE & CENTS: EXPLORING THE ECON. OF BIOTECHNOLOGY 6 (John V. Duca & Mine K. Yucel eds., 2002), *available at* <http://www.dallasfed.org/research/pubs/science/science.pdf>.

6. *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008).

prevent this, Congress enacted 35 U.S.C. § 271(e)(1), often referred to as the safe harbor provision, to allow an exception to infringement if the research was “reasonably related to the development and submission of information” to the FDA.⁷

Although the intent of the legislation was to have a minimal impact on patent holders while allowing competing generic version to enter the market upon patent expiration, the courts began to construe the protection granted by the safe harbor statute very broadly.⁸ And while some of this broadening was needed to clarify which types of activities qualified for the infringement exception, the Supreme Court may have gone too far when it decided *Merck KGaA v. Integra Lifesciences*.⁹ In the wake of this broad (and slightly ambiguous) decision, the Court of Appeals for the Federal Circuit scrambled to clarify the scope of the exception. However, even after the decision in *Proveris Scientific Corp. v. Innovasystems, Inc*, there are still many lingering questions to be answered about how far the safe harbor statute will extend, and the concern that an overly broad interpretation of the type of activities that qualify for the exception is not in line with legislative intent and has diminished the value of biotech patents.

This paper discusses the need for Congressional clarification on the safe harbor provision and the consequences of an overly broad judicial interpretation of this statute. Section I of this paper discusses the history of both the common law research exception, and statutory safe harbor provision, and evaluates how the two are related. Section II summarizes the case history involved with the judicial expansion of section 271(e)(1). Section III discusses the issues remaining after the decision in *Merck* and analyzes if the decision in *Proveris* clarifies any of the outstanding issues. Then, several decisions decided post-*Merck* are analyzed, and finally, the implications of an overly broad research exemption and suggested congressional reformations to the statute are discussed.

I. BACKGROUND

A. Common Law Research Exception

Article I, Section 8 of the Constitution of the United States empowers Congress “[t]o promote the Progress of Science and useful

7. 35 U.S.C. § 271(e)(1) (2009).

8. Christopher M. Jackson, *The War on Drugs: How KSR v. Teleflex and Merck v. Integra continue the Erosion of Pharmaceutical Patent Protection*, 36 CAP. U. L. REV. 1029, 1041–43 (2008); see also Paul T. Nyffeler, *The Safe Harbor of 35 U.S.C. § 271(e)(1): The End of Enforceable Biotechnology Patents in Drug Discovery?* 41 U. RICH. L. REV. 1025, 1029–1030 (2007).

9. 545 U.S. 193 (2005).

Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹⁰ This clause is often referred to as the Intellectual Property Clause. Later, patent protection laws were enacted to embody the rights conferred in the Constitution, and state that:

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.¹¹

The U.S. government made the compromise of giving an inventor the right to exclude others from making, using, or selling their invention for a limited time in return for full disclosure of the invention.¹² This compromise has the purpose of promoting innovation as well as making the research and development of new products more efficient¹³. If the right of exclusive use is violated within the given time period, the patent holder has a cause of action for patent infringement in a Federal Court.¹⁴ However, the right to exclude others from using the invention was narrowed slightly by the courts using a common law research exception in an effort to further balance the public-private (disclosure-for-protection) bargain between the inventor and the U.S. government.¹⁵ Under the common law research exception, the use of a patented invention for research purposes, included using the invention for experimental purposes, re-creating the invention to see if it works as claimed, and using research tools in drug delivery, was not considered infringement.¹⁶ In *Whittemore v. Cutter*, Judge Story stated that, “it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its

10. U.S. CONST. art. I, § 8, cl. 8.

11. 35 U.S.C. § 154(a)(1) (2009).

12. See FTC, *supra* note 3.

13. See Wolrad Prinz zu Waldeck und Pyrmont, *Research Tool Patents After Integra v. Merck—Have They Reached a Safe Harbor?*, 14 MICH. TELECOMM. & TECH. L. REV. 367, 371–72 (2008).

14. See 35 U.S.C. § 271(a) (2009).

15. *Whittemore v. Cutter*, 29 F.Cas. 1120, 1121 (C.C.D. Mass. 1813).

16. Katherine A. Helm, *Outsourcing the Fire of Genius: The Effects of Patent Infringement Jurisprudence on Pharmaceutical Drug Development*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 153, 167 (2006).

described effects.”¹⁷ In this case, the plaintiff brought suit for the infringement of a machine used for making cotton and wool cards, and the court returned a verdict for the plaintiff. The defendant appealed because he only made the machine for experimental purposes and never intended to sell it for any profit, and therefore, the reviewing reversed the decision. Later, in *Poppenhusen v. Falke*, the court upheld the research exception to infringement stating, “an experiment with a patented article for the sole purpose for gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee.”¹⁸ Financial motivation seemed to be the driving force behind these decisions. If a person had no intention of gaining financially from the endeavor, then no infringement had taken place.¹⁹

On the other hand, if there was to be some commercial benefit from the use of the invention, courts were reluctant to allow the research exception as a defense. In *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*, the court held that the defendant’s use of a patented freezing apparatus on a commercial fishing boat constituted infringement.²⁰ Although the court agreed the invention was being used experimentally, because the boat was engaged in a commercial operation, the research exception did not apply.²¹ In a similar holding, the court held in *Embrex, Inc. v. Service Engineering Corp.* that even the slightest commercial implication would render the experimental use exception inapplicable.²² Embrex was the exclusive licensee for a patented method for immunizing birds against disease in vitro.²³ The defendants used the method in an attempt to build their own inoculating machine and no sales directly resulted from the use.²⁴ Despite this, the court upheld the idea that any commercial use of a patented invention, despite the research aspects of the use, made the research exception inapplicable.²⁵

The common law research exception was employed by courts to help balance the private interests of the inventor with the public interests of society. However, since the exception was rarely applied when there was any indication of commercial use, pharmaceutical companies who began performing the required research to receive FDA approval on a competing generic drug could not successfully use the common law

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

18. 19 F.Cas. 1048, 1049 (C.C.S.D.N.Y. 1861).

19. Gina C. Freschi, *Navigating the Research Exemption’s Safe Harbor: Supreme Court to Clarify Scope-Implications for Stem Cell Research in California*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 855, 859 (2005).

20. 322 F.2d 34, 37 (9th Cir. 1963).

21. *Id.*

22. *See* 216 F.3d 1342, 1352 (Fed. Cir. 2000).

23. *Id.* at 1349.

24. *Id.*

25. *Id.* at 1352.

research exception as a defense to infringement.²⁶ Therefore, a company could not begin to develop a generic version of any drug until the patent term for that drug expired. This resulted in the patent holder enjoying a *de facto* patent term extension while other companies sought approval to put competitive products on the market. This problem became apparent in *Roche v. Bolar*.²⁷ Roche Product, Inc. sought to enjoin Bolar Pharmaceutical Co., from taking the statutorily required steps necessary to market the brand name version of Roche's drug Dalmane.²⁸ Dalmane had achieved high financial success and because FDA approval of a generic version can take years, Bolar did not wait for the patent to expire before performing the necessary experiments needed for approval.²⁹ Bolar claimed as a defense that their use of the patented technology was simply "experimental," and therefore did not constitute infringement.³⁰ The court disagreed, however, and found infringement because Bolar's intended use was not for amusement but solely for business purposes.³¹ In reaching their conclusion, 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."³²

B. *The Statutory Safe Harbor Provision: 271(e)(1)*

The holding in *Roche v. Bolar* made apparent that pharmaceutical companies who wished to market a generic version of any drug would have to wait until the patent term expired and then seek FDA approval.³³ With this strict limitation in place, some argued that the private-public balance had shifted too far in favor of patent protection because patent

26. All pharmaceutical compounds are required to receive FDA approval before being placed on the market, which includes any generic version. "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application...is effective with respect to such drug." 21 U.S.C. § 355(a) (2009). The complete FDA approval process takes approximately eight and half years to complete. Six years are devoted to the necessary phase investigations while the approval process takes another two and half. For an overview of the review process, see Drugs.com, *New Drug Approval Process*, <http://www.drugs.com/fda-approval-process.html> (last visited Mar. 1, 2010).

27. 733 F.2d 858, 860 (Fed. Cir. 1984); see also Daniel J. Ford, *Merck v. Integra: Implications for the common Law and Statutory Exemptions*, 7 LOY. LAW & TECH. ANN. 123, 131 (2007).

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

29. *Id.*

30. *Id.* at 861.

31. *Id.* at 863.

32. *Id.*

33. Rebecca Lynn, *Merck KGaA v. Integra Lifesciences I, Ltd.: Judicial Expansion of § 271(e)(1) Signals a Need for a Broad Statutory Experimental Use Exemption in Patent Law*, 21 BERKELEY TECH. L.J. 79, 82 (2006).

holders enjoyed a patent term extension.³⁴ Critics of the *Roche* holding argued the rights of a patent holder to a pharmaceutical drug patent should be balanced with a market approach that allowed generic versions of the drug to compete as soon as possible.³⁵ Introducing generic versions into the market could lower drug prices and make it more affordable for the public.³⁶ Therefore, addressing this *de facto* patent term extension became vital to many in Congress.³⁷

To compensate for the *de facto* patent term extension, the legislature enacted the Drug Price Competition and Patent Term and Restoration Act of 1984, which is often referred to as the Hatch-Waxman Act.³⁸ Part of this act, codified as 35 U.S.C. § 271(e)(1) (often called the safe harbor provision) provides that:

[I]t shall not be an act of infringement to make, use, offer to sell, or sell . . . 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.³⁹

Effectively, the act allowed a company to begin the required tests to seek FDA approval before the end of a patentee's term.⁴⁰ This allowed companies to receive FDA approval early and begin to market a generic form of a drug when the patent term on the original drug ended.⁴¹ Congress believed this would put an end to the *de facto* patent term extension that patentees received as a result of the patent laws and the holding in *Roche v. Bolar*.⁴²

Despite the narrow reasoning for Congress's enactment of

34. The CAFC recognized the problem of a *de facto* patent term extension and invited congress to change the law in this area. *Roche*, 733 F.2d at 863. See also Brendan M. O'Malley, *Merck v. Integra and its Aftermath: A Safe Harbor for the Commercial Use of Biotechnology Research Tools?*, 23 CARDOZO ARTS & ENT. L.J. 739, 745 (2006).

35. Lynn, *supra* note 33.

36. For a detailed investigation into the effect of the Hatch-Waxman act on pharmaceutical prices, see CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998), available at <http://www.cbo.gov/doc.cfm?index=655&type=0>.

37. Lynn, *supra* note 33.

38. Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (2009); 21 U.S.C. §§ 301 note, 355, 360cc (2009); 28 U.S.C. § 2201 (2009); 35 U.S.C. §§ 156, 271, 282 (2009)).

39. 35 U.S.C. § 271(e)(1) (2009).

40. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process* 54 FOOD & DRUG L.J. 187, 190 (1999), available at http://www.fdpi.org/pubs/Journal%20Online/54_2/art2.pdf.

41. *Id.*

42. See O'Malley, *supra* note 34, at 746.

271(e)(1), courts began to construe this section very liberally and granted a large amount of protection to those who claimed to be operating under the safe harbor provision.⁴³ The language of the “safe harbor” section of 271(e)(1) was limited to generic drug manufacturers or to drug patents, but was expanded to include other inventions and products.⁴⁴ In addition, the types of “infringing” activities that qualified under the exception were also expanded.⁴⁵

II. CASE LAW: THE SAFE HARBOR STATUTE PROTECTION IS DEFINED

A. *The Judicial Expansion of Protection Under 271(e)(1)*

The first major judicial expansion of § 271(e)(1) came in *Eli Lilly and Co. v. Medtronic, Inc.*⁴⁶ Here, Eli Lilly sought to enjoin Medtronic from testing and marketing an implantable cardiac defibrillator, a medical device used in the treatment of heart patients.⁴⁷ Medtronic defended by claiming that its actions were reasonably related to the development and submission of information needed for FDCA approval.⁴⁸ The District Court rejected this argument, holding that § 271(e)(1) does not extend to medical devices.⁴⁹ A jury trial then found for Eli Lilly.⁵⁰ The Court of Appeals for the Federal Circuit reversed holding that “respondent’s activities could not constitute infringement if they had been undertaken to develop information reasonably related to the development and submission of information necessary to obtain regulatory approval under the FDCA.”⁵¹

The Supreme Court agreed stating that, “[t]he phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions, not drug-related inventions alone.”⁵² In addition, the Court disagreed with Eli Lilly’s interpretation of the phrase “a Federal law which regulates the manufacture, use or sale of drugs,” as referring to only those provisions that regulate drugs.⁵³ Instead the court interpreted it to refer to the entirety of any Act, including the FDCA, at least some of whose

43. Lynn, *supra* note 33, at 86.

44. Helm, *supra* note 16, at 176.

45. *Id.*

46. 496 U.S. 661 (1990).

47. *Id.* at 664.

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.* at 665.

53. *Id.*

provisions regulate drugs.⁵⁴ The Court believed that had Congress intended for medical device patents to be excluded from the protection of the Safe Harbor statute, “there were available such infinitely more clear and simple ways of expressing that intent that it is hard to believe the convoluted manner petitioner suggests was employed would have been selected.”⁵⁵ In the end, the Court held that actions taken that are reasonably related to the FDCA approval of medical devices were covered under § 271(e)(1), and would be exempt from infringement.⁵⁶ The ultimate effect of the holding in *Eli Lilly* was to expand the protection of the safe harbor exception to include medical device patents as well as drug patents.

Another judicial expansion of the safe harbor statute came in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*⁵⁷ In this case, Ventritex began clinical testing on its implantable defibrillator before Telectronics’ patent had expired.⁵⁸ Ventritex received approval from the FDA to sell devices, at cost, for implantation into patients in order to conduct the required clinical trials.⁵⁹ The president of Ventritex referred to the ongoing clinical trials in fund-raising efforts and Ventritex mailed Private Placement Memorandums that also referred to the ongoing clinical trials in order to raise money to continue with the clinical experiments and for manufacturing equipment.⁶⁰ Telectronics brought suit claiming that Ventritex’s actions were not exempt under § 271(e)(1) because the data obtained from the clinical trials was used for commercial purposes and these purposes were not solely related to FDA approval.⁶¹ The District court granted summary judgment for Ventritex.⁶²

The Federal Circuit Court held, however, that the actions Ventritex had taken were solely for uses reasonably related to FDA approval, and therefore exempt from infringement under § 271(e)(1).⁶³ The court concluded that using information from clinical trials to obtain further funding did not in turn make the original activities infringing ones.⁶⁴ In concluding this, the court stated, “[Telectronics’] case here is based on the theory that the statute requires that the original exemption of the making, using and selling activities be revoked when the resulting data is later used for non-FDA reporting purposes. We do not read the statute

54. *Id.*

55. *Id.* at 667.

56. *Id.* at 679.

57. 982 F.2d 1520 (Fed.Cir. 1992).

58. *Id.* at 1521.

59. *Id.*

60. *Id.* at 1521–22.

61. *Id.* at 1522.

62. *Id.*

63. *Id.* at 1525.

64. *Id.* at 1524.

as implying any such limitation.”⁶⁵ This holding allowed companies to use information for commercial purposes, as long as the data was originally obtained solely for purposes reasonably related to FDA approval and not for commercial purposes.

Although both of these cases expanded the safe harbor exception to infringement, arguably both results were consistent with Congressional intent. Both Eli Lilly and Telectronics would have enjoyed the *de facto* patent term extension if their competitors were required to wait before receiving federal approval until after patent expiration. However, the Court expanded the safe harbor provision even further when deciding *Merck KGaA v. Integra Lifesciences*.⁶⁶

B. *Merck KGaA v. Integra Lifesciences: The Supreme Court’s clarification of “Reasonably Related”*

One of the largest judicial expansions in protection offered by the safe harbor statute came in the Supreme Court decision in *Merck KGaA v. Integra Lifesciences*. Integra owns five patents related to a single letter notation tripeptide, known as the “RGD peptide.”⁶⁷ Before the end of these patent terms, Merck, together with Scripps Research Institute, performed angiogenesis research by *in vitro* and *in vivo* testing of RGD peptides.⁶⁸ The tests focused on EMD 66203 and two closely related derivatives, EMD 85189 and EMD 12194, and measured the efficiency, and toxicity of the peptides as angiogenesis inhibitors.⁶⁹ Later, Merck “initiated a formal project to guide one of its RGD peptides through the regulatory approval process.”⁷⁰ Integra filed suit, claiming infringement of their patents.⁷¹ Merck replied by claiming their activity did not infringe Integra’s patents and even if it did, their research was exempt from infringement under 35 U.S.C. § 271(e)(1).⁷² The District Court held that Merck had failed to show their actions were protected by § 271(e)(1) and awarded damages to Integra.⁷³ The Federal Circuit agreed, holding, “the Scripps work sponsored by [petitioner] was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds.”⁷⁴ In addition, the

65. *Id.*

66. 545 U.S. 193 (2006).

67. *Id.* at 197.

68. *Id.*

69. *Id.* at 198–99.

70. *Id.* at 199.

71. *Id.* at 200.

72. *Id.*

73. *Id.* at 201.

74. *Id.* (quoting *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 866 (Fed. Cir. 2003)).

Federal Circuit felt that limited construction of the safe harbor exception was needed in order to protect research tool patents from being depleted of value and did not think the statute included pre-FDA approval experiments that would never actually be submitted to the FDA.⁷⁵

The Supreme Court came to a different conclusion. The Court held that the “271(e)(1) exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA.”⁷⁶ The Court found this to include preclinical studies of compounds in the preparation of submissions to the FDA.⁷⁷ In addition, the Court noted that just because experimental information is not reported to the FDA does not mean it is an infringing activity, stating, “the relationship of the use of a patented compound in a particular experiment to the ‘development and submission of information’ to the FDA does not become more attenuated simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA.”⁷⁸ However, the Court only slightly limited its holding by agreeing with the Federal Circuit that the safe harbor exception does not reach all experimental activity and does not protect basic scientific research.⁷⁹ However, the extent of experimental activity that would be exempt from infringement was not qualified.

C. *Proveris Scientific Corp v. Innovasystems, Inc.: A Restriction to the Safe Harbor Provision*

Following the holding in *Merck*, holders of research tool patents became increasingly concerned about the value of their patents.⁸⁰ The Federal Circuit attempted to address this problem and other issues left pending after *Merck* in *Proveris*.⁸¹ Proveris is the owner of a patent describing a system and apparatus for characterizing aerosol sprays commonly used in drug delivery devices.⁸² The spray characterization is often used to calibrate drug delivery methods in order to maximize efficiency and effectiveness of the drug.⁸³ Although the inhaler-based

75. *Id.* at 201, 205 n.7.

76. *Id.* at 202. (emphasis removed).

77. *Id.*

78. *Id.* at 207.

79. *Id.* at 206.

80. There are two basic types of patents in the pharmaceutical industry: research tool patents and pioneer drug patents. Research tool patents are directed to the research and development of new drugs and can include drug targets, cell lines, transgenic animals, drug screening assays and large libraries of potential drugs. *See* Helm, *supra* note 16, at 5.

81. *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008).

82. *Id.* at 1258.

83. *Id.*

drug delivery devices this invention can be used to test are subject to FDA approval, the systems and apparatus claimed in Proveris's invention are not.⁸⁴ Innova makes and sells an Optical Spray Analyzer (OSA) that measures the physical parameters of aerosol sprays used in nasal spray drug delivery systems.⁸⁵ Proveris filed suit against Innova, alleging infringement of its patent. Innova responded by claiming its actions were exempt from infringement under § 271(e)(1) because their OSA devices are used by third parties solely for the development and submission of information to the FDA.⁸⁶ The District Court held however, that Innova's manufacture and sale of the OSA devices are not immunized under the safe harbor provision of 35 U.S.C. § 271(e)(1), and Innova appealed.⁸⁷

The Federal Circuit agreed with the district court and held that the sale and manufacture of the OSA devices was not immunized by § 271(e)(1).⁸⁸ In reaching this conclusion, the court first explained the two basic reasons behind the Hatch-Waxman Act in which the safe harbor provision is found. First, a *de facto* patent term reduction exists due to the amount of time required to obtain FDA approval.⁸⁹ Because a patent is usually filed in the early years of the regulatory review, but market entry is delayed waiting for approval, early years of a patent term are spent obtaining FDA approval rather than making profit.⁹⁰ The Act dealt with this by granting patent term extensions to those "products" claiming delays due to the FDA approval process.⁹¹ Second, a *de facto* patent term extension existed because other companies had to wait until a patent had expired before experiments could be performed in order to get FDA approval.⁹² This was the reason § 271 (e)(1) was put in place.⁹³ The Federal Circuit emphasized this point stressing that the safe harbor provision only applied to those inventions that were required to seek FDA approval before being placed on the market.⁹⁴

In this case, the invention itself was not subject to FDA approval. And although it was used for the development and submission of information to the FDA, the information is not regarding the invention itself.⁹⁵ In other words, Innova is not the party seeking FDA approval

84. *Id.*

85. *Id.* at 1259.

86. *Id.* at 1259–60.

87. *Id.* at 1260.

88. *Id.* at 1265

89. *Id.* at 1260–61.

90. *Id.* at 1261.

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.* at 1265.

95. *See id.*

before entry into the market in order to compete with Proveris. The court stated, "because the OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration, Innova is not a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second distortion."⁹⁶ Viewing it from the other side as well, prior to the enactment of the Hatch-Waxman Act, Proveris would not have been granted a *de facto* patent term extension because Innova could enter the market immediately upon the patent term expiration.⁹⁷ For these reasons, Innova's actions were not exempt from infringement under the safe harbor exception.

The decision in *Proveris* was the first major judicial limitation to the safe harbor exception since its enactment in 1984. Although the Court had previously alluded to some limitations in the protection the exception granted, there had never been any cognizable upper bounds. *Proveris* helped to provide the upper bounds by holding that not all research and experimental activities were protected from infringement claims simply because it was related to FDA approval. The scope of the exception was narrowed slightly to include a requirement that the research, and the FDA approval, be focused on the invention at issue. The court focused on the legislative intent of the safe harbor provision, to eliminate the *de facto* patent term extension that some patent holders enjoyed, and reasoned that any activity outside of this scope could still be considered infringement.

III. DISCUSSION

A. *Problems with Merck: Does Proveris Address Any of the Issues Left Pending?*

Eli Lilly, *Telectronics*, and *Merck* all expanded the exemption from infringement available under 35 U.S.C. § 271(e)(1) drastically from the original common law research exemption. It seemed from the Supreme Court's holding in *Merck* that, as long as the research was eventually used for FDA approval, the use of a patented invention was allowed.⁹⁸ Following the decision in *Merck*, there was substantial controversy surrounding the Court's interpretation of the safe harbor exception. Many commentators suggested that defining the bounds of the exception should be left up to Congress.⁹⁹ If such were the case, large

96. *Id.*

97. *See id.*

98. *See Lynn, supra* note 33.

99. Harold C. Wegner, *Post-Merck Experimental Use and The "Safe Harbor,"* 15 FED. CIR. B.J. 1, 13-17 (2005).

pharmaceutical companies would no doubt lobby for large amounts of protection in order to utilize patented tools and drug intermediates in the ongoing research and development of the new pharmaceuticals.¹⁰⁰ The owners of research tool patents, however, would most likely lobby to restrict the safe harbor exception in order to protect the value of their patents, especially since the Court in *Merck* failed to address how the broad interpretation of the safe harbor exception would affect research tool patents. Congress has not yet set out to define the limits.

However, it has also been suggested that the decision in *Merck* was not consistent with legislative intent to begin with.¹⁰¹ Section 271(e)(1) was enacted in order to prevent *de facto* patent term extension that resulted from the decision in *Roche*. Congress intended that the safe harbor provision would allow immediate public access to generic medications upon expiration of a patent.¹⁰² The purpose was not simply to allow patented inventions to be used in any type of research. As evidence of this, comments were made in the House Committee Report that strongly suggest the safe harbor provision was intended to have a minimal impact.¹⁰³ The exception was only to be applied to “a limited amount of testing so that generic manufactures can establish the bioequivalency of a generic substitute.”¹⁰⁴ In addition it states, “all that the generic [manufacturer] can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is *de minimis*.”¹⁰⁵ It seems contrary to Congress’s intent to construe a safe harbor that permits any activity as long as it is somehow related to drug discovery.

The research in *Merck* was in the pre-FDA approval process and was not directly for the submission of information to the FDA.¹⁰⁶ The experimental use of a patented compound for pre-submission research is not stated in the legislative goals underlying § 271(e)(1).¹⁰⁷ Therefore, the Court of Appeals for the Federal Circuit focused on this legislative intent in determining that Merck’s research was not within the scope of § 271(e)(1) and constituted infringement.¹⁰⁸ The Supreme Court, on the other hand, almost completely ignored the legislative intent reasoning argued by the Federal Circuit and instead went on the offensive and

100. *Id.*

101. See Mike Rothwell, *A Snapshot of an Industry: The Biotechnology Sector and the Judicial Misgivings of a General Court*, 8 CHI.-KENT J. INTELL. PROP. 141, 143 (2008).

102. See Helm, *supra* note 16.

103. See H.R. REP. NO. 98-857, at 8 (1984).

104. *Id.*

105. *Id.* at 30.

106. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 195 (2006).

107. Rothwell, *supra* note 101.

108. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003).

expanded the safe harbor exception to include “all uses of patented inventions that are reasonably related to the . . . submission of any information under the FDCA.”¹⁰⁹ Such a rule clearly does not have a “de minimis” effect as Congress had intended. The Court argued that to narrowly define the exception as the Federal Circuit did, “is effectively to limit assurance of exemption to the activities necessary to seek approval of a generic drug . . . [and] the statutory text does not require such a result.”¹¹⁰ However, the Federal Circuit’s limitation seems to be exactly in line with what was indicated by the House Committee Report and the circumstances that caused the enactment of § 271(e)(1) to begin with.¹¹¹

The decision on *Proveris*, on the other hand, seems to be directly in line with Congress’s intent. It is clear from the House Committee Report that Congress never intended § 271(e)(1) to apply to the use of a patented instrument, not subject to FDA approval, in conducting research on an unrelated drug, even if the research was to be used for FDA approval.¹¹² This would be simply going too far. However, the decision in *Proveris* only helps to set the very upper bounds to the safe harbor exception. It does little to limit the overbroad protection granted by the Supreme Court in *Merck*.

Even putting the legislative intent argument aside, there are still several more issues that the decision in *Merck* left lingering. *Proveris* was able to provide clarity on some of the issues, but some are still left unanswered. First, the Court’s decision in *Merck* failed to address the implications of their decisions on research tool patents.¹¹³ Many feared that the value of research tool patents would diminish significantly as a result.¹¹⁴ However, *Proveris* seems to suggest that many research tool patents will retain their value. If the research tool is not subject to FDA approval, as was the case in *Proveris*, then it is possible that the tool could not be used in research without a license agreement to do so. The language used in the decision in *Proveris* seems to suggest that any use without such agreement would constitute infringement because it was not the legislature’s intent to protect this type of use in establishing the safe harbor exception. Whether or not this is true is a little unclear, however. The defendant in *Proveris* was not using the research tool for their own research, but instead was manufacturing and selling it to third parties for their use in research.¹¹⁵ Specifically, the court framed their

109. *Merck*, 545 U.S. at 201.

110. *Id.* at 208.

111. Rothwell, *supra* note 101, at 141–42.

112. See H.R. REP. NO. 98-857 at 8 (1984).

113. Ford, *supra* note 27, at 134–35.

114. *Id.*

115. *Proveris Scientific Corp v. Innovasystems, Inc.*, 536 F.3d 1256, 1259 (Fed. Cir. 2008).

analysis by asking, “whether section 271(e)(1) immunizes the manufacture, marketing, or sale of Innova’s OSA, which is used in the development of FDA regulatory submissions, but is not itself subject to the FDA premarket approval process.”¹¹⁶ Therefore, if the facts were different and Innova was using the tool for their own research, the outcome might have been different. However, the Federal Circuit’s desire to limit the safe harbor exception and the need to return some exclusive rights to the patent holder seems to suggest this would not be the case.¹¹⁷ Specifically, the court stated:

Because the OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration, Innova is not a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second distortion. For this reason, we do not think Congress could have intended that the safe harbor of section 271(e)(1) apply to it.¹¹⁸

The court never qualified this holding by stating that this conclusion was only true because Innova manufactured and sold the devices. This seems to indicate that the holding would be the same if Innova were the party to use the device.¹¹⁹ However, because the question was framed to exclude the term “use,” the door was left slightly open for a defendant to use the safe harbor exception if they were not manufacturing and selling the tool, but instead using it in research themselves.¹²⁰ Due to the large amount of ambiguity in this, it is important for Congress to clarify the safe harbor provision.

In addition to the ambiguity surrounding the status of research tool patents, a second criticism of the holding in *Merck* is that it failed to clearly define the “reasonably related requirement.”¹²¹ Both the Federal Circuit in *Telectronics* and the Supreme Court in *Merck* discussed the “reasonably related requirement,” but in neither place were the requirements clearly defined, leaving some confusion in this area.¹²² In *Merck*, the Court held that “reasonably related” did not require the information actually be submitted to the FDA.¹²³ As discussed previously, it was enough that the information be obtained because the party “reasonably believed” that the compound may work and therefore

116. *Id.* at 1265.

117. *See id.*

118. *Id.*

119. *See id.*

120. *See id.*

121. Ford, *supra* note 27.

122. *See id.*

123. *Proveris*, 536 F.3d at 1259.

instigated pre clinical trial studies.¹²⁴ The court in *Proveris*, however, did not go into any more detail about what might be required to satisfy the “reasonably related requirement” than was stated in *Merck*. The court in *Proveris* indicated that the manufacture and sale of a device that is not subject to FDA approval to third parties is not “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.”¹²⁵ However, the court did not explicitly state this.¹²⁶ Instead, their decision was premised on the intentions of the legislature.¹²⁷ Therefore, the decision in *Proveris* does little to clarify the requirements for the “reasonably related” part of the exception. Because both *Merck* and *Proveris* fail to define “reasonably related,” Congress should clarify what types of activities are exempt from infringement under the safe harbor provision.

Another area left uncovered by the decision in *Merck* was the status of the common law research exception.¹²⁸ Four years earlier, when the Federal Circuit decided *Madey v. Duke University*, many questions remained as to whether the common law research exception was still good law.¹²⁹ The plaintiff in *Madey* was the owner of a patent for free electron laser technology.¹³⁰ Madey was a tenured professor with Duke University and was the director of the Free Electron Laser lab.¹³¹ The lab used some of the technology covered by Madey’s patents and had much success in obtaining grant money and achieving scientific success.¹³² Following a dispute over Madey’s management of the FEL lab, Madey retired from Duke.¹³³ But the university continued to use the lab that contained the technology held in Madey’s patents.¹³⁴ Madey brought suit for patent infringement and Duke defended with the common law research exception, stating that they only used the equipment for educational research purposes.¹³⁵ The District court found for Duke University holding that the experimental use defense covered uses that were “solely for research, academic or experimental purposes.”¹³⁶ The Federal Circuit disagreed and overturned the decision holding that the

124. *See id.*

125. *See id.* at 1266.

126. *See id.*

127. *See id.*

128. Ford, *supra* note 27, at 135.

129. *Id.*

130. *Madey v. Duke Univ.*, 307 F.3d 1351, 1352 (Fed. Cir. 2002).

131. *Id.* at 1352.

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.* at 1354.

136. *Id.* at 1355 (citation omitted).

experimental research defense only covered research for amusement.¹³⁷ The effect of the decision was to prevent non-profit organizations from using the experimental research defense even though the research was being performed for academic purposes.

The Court in *Merck* declined to address the status of the common law research exception.¹³⁸ And while the decision in *Proveris* did limit the safe harbor exception, the court also refrained from addressing the status of the common law research exception, leaving the question open still.

However, the decision in *Madey* may have positive aspects in the area of research tool patents.¹³⁹ The intended purpose of the technology Madey patented was for a research tool and that is what the FEL laboratory used it for.¹⁴⁰ If Duke University were allowed to use the device without licensing the technology, Madey would be deprived of the revenue from his patent.¹⁴¹ This in turn would make a research tool patent less valuable and thus the incentive to research and develop new research tools would be much lower.¹⁴² Therefore the decision in *Madey* helped to protect this incentive.¹⁴³ The decision in *Proveris* could be seen as accomplishing the same goal. If companies were allowed to use research tools, designed for research, without licensing them, revenue would again be lost. By limiting the safe harbor exception, most research tool patents retain their value and there are still large incentives to develop new research tools.

B. Decision Post Merck: Should the Reasoning Behind the Decision in Proveris Have Influenced the Outcome?

Given Congress's lack of clarity in the language of section 271(e)(1) and the ambiguous decisions in *Merck*, courts scrambled to interpret the safe harbor provision in other fact situations. Many of these cases cite *Merck* but the Federal Circuit decision in *Proveris* and a consideration of Congressional intent may have influenced the outcomes, or at least warranted discussion. One such case is *Classen Immunotherapies, Inc. v. Biogen IDEC*.¹⁴⁴ Classen was the owner of several patents dealing with the mechanism for evaluating the effectiveness of vaccine administration schedules.¹⁴⁵ Classen claimed that several companies, namely Biogen and

137. *Id.* at 1356.

138. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 195 (2006).

139. Ted Hagelin, *The Experimental use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 486 (2006).

140. *Id.* at 502.

141. *Id.*

142. *Id.*

143. *See id.*

144. 381 F. Supp. 2d 452, 454 (D. Md. 2005).

145. *Id.*

GSK infringed on his patents when they began studies in the late 1990s to determine the correlations between childhood vaccinations and influenza and diabetes. Biogen and GSK defended by claiming their actions were solely for purposes reasonably related to the development of information for submission to the FDA.¹⁴⁶ However, Classen claimed the defense was inapplicable in this case because the drugs had already received FDA approval.¹⁴⁷ The court agreed with Biogen and GSK and dismissed the claims for infringement, stating “[b]ecause their alleged participation in a study evaluating risks associated with various vaccination schedules was reasonably related to the development and submission of information required under the Federal Food, Drug, and Cosmetic Act, GSK and Biogen's motion to dismiss . . . will be granted.”¹⁴⁸

The court in *Classen* focused on the “reasonably related” requirement of the safe harbor exception while the court in *Proveris* focused on the legislative intent. Because the drugs that were being tested in *Classen* had already received FDA approval, there would have been no problem with the *de facto* patent term extension. The technology in Classen’s patents was meant to be research tools and because Biogen and GSK were able to use the patented technology without licensing it, revenue that Classen should have obtained was lost. This is exactly the kind of outcome that the decisions in both *Madey* and *Proveris* tried to avoid. Even though GSK and Biogen were preparing information for the FDA, they could have licensed the technology from Classen in order to perform the experiments. The type of experimentation was not to seek FDA approval so that they could compete with Classen’s product on the market the moment their patents had expired. Therefore, the intent of the legislature seems to have been lost in this decision.

In another example, *Amgen, Inc. v. Roche Holding LTD*, Amgen accused Roche of infringement because Roche was importing certain recombinant human erythropoietin and derivatives thereof (EPO) in the United States from Europe.¹⁴⁹ Amgen is the owner of a family of patents for the “EPO” compounds and their production.¹⁵⁰ They claimed that Roche’s manufacture of these compounds in Europe was covered by one or more of their claims within these patents and therefore Roche should not be allowed to import them into the country.¹⁵¹ Amgen brought their

146. *Id.*

147. *Id.* at 455.

148. *Id.* at 456.

149. 565 F.3d 846, 847 (Fed. Cir. 2009).

150. *Id.* at 1345.

151. *Id.*; Preventing the importation of products covered by a patent owners patent is one of the rights granted to a patent holder under 35 U.S.C. See 35 U.S.C. § 271(a). The patent holder does not have a right to enforce a U.S. patent in foreign countries but can prevent that

complaint to the Federal Trade Commission under Section 337 of the Tariff Act of 1930.¹⁵² In response, Roche claimed that their importation of the EPO was exempt from infringement under § 271(e)(1) because the EPO was used for the purposes of development and submission of information to the FDA.¹⁵³ The Commission granted Roche's motion for nominal infringement on these grounds and Amgen appealed.¹⁵⁴

On appeal, Amgen argued that at least some of Roche's activities were not exempt from infringement under the safe harbor statute.¹⁵⁵ Amgen stated that they did not bring this action until after Roche had completed its submission of information to the FDA.¹⁵⁶ By then, Roche had entered the post Biologics License Application (BLA) stage in which complete data have been received and analyzed by the FDA.¹⁵⁷ Amgen argued further that by the time they had brought this action, Roche had shifted its attention in the United States to analysis experiments, market-seeding trials, and litigation-related activity; activities that should not be exempt from infringement under the safe harbor statute.¹⁵⁸

The Court of Appeals for the Federal Circuit stated that, "[t]he Commission appears to have assumed that all otherwise infringing activities are exempt if conducted during the period before regulatory approval is granted. That assumption is incorrect"¹⁵⁹ The court cited the rule in *Merck* that requires each of the activities to be evaluated separately to determine whether the exemption applies.¹⁶⁰ The court continued by stating, "it is apparent that commercial and marketing studies are more clearly subject to separate evaluation for application of the exemption."¹⁶¹ The court remanded the case to the Commission to consider the exempt status of each study for which the question of infringement had reasonably been raised.¹⁶²

On remand, if the facts indicate that Roche's studies were not for the development and submission of information to the FDA, then Roche should be prohibited from importing their infringing EPO into the United States. To decide that studies performed were exempt from infringement under § 271(e)(1) simply because they were performed

product from being imported into the United States. *See id.*

152. *Amgen, Inc. v. Int'l Trade Comm'n* 565 F.3d 846, 848 (Fed. Cir. 2009).

153. *Id.*

154. *Id.*

155. *Id.* at 850.

156. *Id.*

157. *Id.*

158. *Id.*

159. *Id.* at 852.

160. *Id.*

161. *Id.*

162. *Id.* at 855.

before FDA approval was granted would be clearly contrary to legislative intent.¹⁶³ Such a decision would also seem contrary to the decision in *Roche*.¹⁶⁴ Even in *Merck*, the court recognized that the information had to be for submission to the FDA.¹⁶⁵ To decide anything contrary would be to create an even broader infringement exception under the safe harbor statute than the one created by *Merck* and most likely contrary to Congressional intent. However, both these cases demonstrate the problems courts face in interpreting the safe harbor provision in light of the ambiguous decision in *Merck*. Congressional clarification is needed to prevent further confusion and inconsistent decisions.

C. Did Proveris Do Enough: The Implication of an Overly Broad Research Exception

The biotechnology industry that is most affected by the safe harbor statute is a robust industry that actively contributes to the U.S. economy.¹⁶⁶ Biotechnology companies are also the leading area of innovation in science and medicine which can drastically increase the quality of life for not only American citizens, but globally as well.¹⁶⁷ On the economic side, American biotech companies produced over \$39 billion dollars in total revenue in 2003.¹⁶⁸ In addition, biotech companies employ over 200,000 workers, skilled and unskilled, as well as attract venture capitalists and investors.¹⁶⁹ It is clear to see that biotech companies are an integral part of the American economy and way of life.

However, this benefit does not come cheaply. It now costs an average of \$800 million dollars to develop a new pharmaceutical.¹⁷⁰ In addition, only 22% of compounds that enter clinical trials will ever receive FDA approval, and even fewer will ever reach the market place.¹⁷¹ Research tools also take a large amount of time and money in order to develop new technology. Advancement in this area can dramatically aid in the ongoing research into new pharmaceuticals, and therefore it is important to incentivize ongoing advancement in this area.¹⁷² The better the research tools are, the better and more efficiently research can be performed. However, given the large cost and lengthy amount of time it

163. See H.R. REP. NO. 98-857, at 8 (1984).

164. See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2006).

165. See *id.*

166. Rothwell, *supra* note 101, at 155.

167. *Id.*

168. S. Sivakumar, *The Economics of Biotechnology*, REDIFF, Sept. 8, 2004, <http://www.rediff.com/money/2003/sep/08guest2.htm>.

169. *Id.*

170. *Id.*

171. *Id.*

172. See Freschi, *supra* note 19.

takes to develop new drugs, biotech companies place a large amount of importance upon patentability of potential technology.¹⁷³ Biotech companies rely on the monopoly of the market that is granted with a patent in order to make a profit and legitimize the large amount of time and money spent on development.¹⁷⁴ In addition, many biotech companies, especially research tool companies, receive a large amount of revenue through licensing their technology to others.¹⁷⁵ Without the monopoly protection that patents provide, the licensing revenue could not be realized.¹⁷⁶

On the other hand, generic versions of drugs do play some importance in the market place.¹⁷⁷ After giving the original inventor a monopoly for a limited time, generic drugs can increase competition and therefore drive the cost of pharmaceuticals down, making them more affordable to health care providers and the general public.¹⁷⁸ Congress realized the importance of generic drugs when deciding to enact § 271(e)(1) into law. It was important to allow a generic drug to enter the market immediately upon expiration of the patent in order to compete once the monopoly granted to the patent holder is over.¹⁷⁹ This is why limited amounts of research can be done on generic drugs in order to receive FDA approval, and why this type of activity is exempt from infringement under the safe harbor statute.¹⁸⁰

However, generic versions of drugs are much less costly to develop since most of the work in developing the drug has been done, and disclosed, by the patent holder.¹⁸¹ This is the main reason why generic drugs can be placed on the market for a lower price than the original and still realize a profit.¹⁸² In finding the correct balance between monopoly and economy, the two competing ideologies of allowing a patent holder to realize the profits from time and money spent developing new technology and competition in the market place to keep prices down need to be balanced. However, it is Congress's job to do the balancing. In their role as policy makers, congress decided that a small exception to infringement was necessary but it was important for the impact to be small.¹⁸³ Therefore congress concluded that while it is important to allow

173. Rothwell, *supra* note 101.

174. *See id.*

175. Freschi, *supra* note 19, at 895.

176. *See id.*

177. Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.F. 171, 172 (2008).

178. *Id.*

179. *Id.*

180. *See Ford, supra* note 27.

181. Savakumar, *supra* note 168.

182. *Id.*

183. *See H.R. REP. NO. 98-857*, at 8 (1984).

generic drugs to enter the market to eventually lower prices, it would be unjust to allow the generic manufacture to enter the market before the patentee's term expired or participate in activity that were not directly related to development of information for submission to the FDA. Both activities eat away at the profits promised to the patentee in exchange for full disclosure of the invention.

Unfortunately, the broad infringement exception that the decision in *Merck* created also had the effect of reducing the value of a biotech patent and taking away revenue that should belong to the patent holder.¹⁸⁴ By allowing competing companies to take part in activities that Congress did not intend to be exempt under the safe harbor statute, licensing revenue that should go to the patent holder was dramatically reduced if not eliminated.¹⁸⁵ And because patent holders no longer have the right to prevent these activities, the value of their patents is reduced. Even if such a large exception to infringement were intended by the legislature, the ambiguous decision in *Merck* still left a lot of questions about what types of activities actually fit within the exception.¹⁸⁶ These ambiguities in patent protection weigh heavily upon the direction and development of technology in the biotechnology industry.¹⁸⁷

Research tools seem to be effected even more by a broad reading of the safe harbor statute.¹⁸⁸ Research tool patents primarily get their worth from licensing revenue.¹⁸⁹ If a researcher wants to use the newest technology in research tools, this technology has to first be licensed from the patent holder. However, if researchers can use research tools in development of information for submission to the FDA, a large amount of licensing revenue will be lost.¹⁹⁰ Although *Proveris* suggests that the exception will not apply to research tools that are not themselves subject to FDA approval, there still remains a question as to how much this decision will be able to protect the value of research tool patents.¹⁹¹

D. *Proposal for Reformation*

Due to the large amount of confusion and complaints that resulted from the decision in *Merck*, it is clear that some form of reformation of the statute is needed. The first step is for Congress to clarify how far the exception to infringement under § 271(e)(1) should go. Legislation that

184. See Rockwell, *supra* note 101.

185. *Id.*

186. Ford, *supra* note 27.

187. Rockwell, *supra* note 101.

188. Freschi, *supra* note 19, at 895.

189. *Id.*

190. *Id.*; see also Prinz zu Waldeck und Pyrmont *supra* note 13, at 380.

191. See *Proveris Scientific Corp v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008).

continues to allow generic drug manufactures to perform research for development and submission of information to the FDA is crucial. However, Congress needs to specify what type of activities fall within this exception. To preserve the value of patents and to continue to incentivize research, it would be best to limit activities to the development of information for direct FDA approval. Therefore, research performed after all information has been submitted to the FDA, but before approval is granted, should not be exempt. In addition, research done before actual testing of a generic drug, or early drug stage development, should also not be exempt from infringement. However, Congress should also make it clear that "patented invention" includes any invention that would be subject to Federal Approval before entering the market place.

With respect to research tools, Congress should make it clear that this exception does not apply to research tools, even if the tool is being used in the development and submission of information to the FDA. Research tools depend almost completely on license revenue and to allow use of these inventions without compensation completely reduces their value. In addition, Congress should make it clear that the exception does not apply to the use of an invention that is not subject to FDA approval, no matter why it is being used.

Finally, courts should make a concerted effort to apply the protection provided by the safe harbor statute conservatively. This will help to protect the value of patents and promote the policies behind granting patents. In addition, the safe harbor statute should be applied by interpreting its face value but also by keeping the legislative intent of the statute in mind.

CONCLUSION

In the wake of *Merck* and *Proveris*, one is left wondering exactly how far the safe harbor statute extends. It is clear that a generic manufacturer can begin research of the competing invention before the end of the patent term in order to receive FDA approval. This was clearly Congress's intention. But what other types of activities are exempt from infringement? Pre-FDA approval experiments? Use of patented research tools in the development of information for the FDA on a pharmaceutical? It is not clear that Congress intended the safe harbor statute to protect these types of activities. However, the broad ruling in *Merck* makes it unclear whether patent holders could prevent these types of activities. Although *Proveris* attempted to set a limit, this upper bound is not as helpful for all the activities left in between. The only thing that is clear is that more clarification from Congress is needed in order to resolve the question.