

**PROVERIS SCIENTIFIC V. INNOVASYSTEMS:
BROADENING THE SCOPE OF THE
HEALTHCARE CRISIS BY NARROWING THE
SCOPE OF THE GENERIC DRUG
MANUFACTURER'S PATENT INFRINGEMENT
PROTECTION UNDER 35 U.S.C. § 271(E)(1)**

I.	INTRODUCTION.....	233
II.	THE DEVELOPMENT AND INTERPRETATION OF 35 U.S.C. § 271(E)(1).....	234
	A. <i>Time Period Necessary for FDA Approval Process</i>	235
	B. <i>The Pioneer-Generic Drug Relationship Prior to the Enactment of 35 U.S.C. § 271(e)(1)</i>	236
	1. <i>Roche Products, Inc. v. Bolar Pharmaceutical</i>	236
	2. <i>Pre-Roche Dilemma on Patent Monopolies</i>	238
	C. <i>The Enactment of 35 U.S.C. § 271(e)(1)</i>	238
	D. <i>Defining "Patented Invention" under 35 U.S.C. § 271(e)(1)</i>	240
	1. <i>Eli Lilly and Co. v. Medtronic, Inc.</i>	240
	2. <i>Medical Devices Fall Within the Scope of § 271(e)(1)</i>	240
	3. <i>Classifying Medical Devices</i>	241
	4. <i>AbTox, Inc. v. Exitron Corp.</i>	242
	E. <i>Interpreting "solely for uses reasonably related" under 35 U.S.C. § 271(e)(1)</i>	242
	1. <i>Telectronics Pacing Systems v. Ventitrex, Inc.</i>	243
	2. <i>Merck KGaA v. Integra Lifesciences I</i>	244
III.	<i>PROVERIS SCIENTIFIC CORPORATION V. INNOVASYSTEMS, INC.</i>	246
	A. <i>Facts</i>	246
	B. <i>The Complaint</i>	246
	C. <i>The Opinion</i>	247
IV.	PLACING <i>PROVERIS</i> UNDER A MICROSCOPE AND IDENTIFYING THE POTENTIAL HEALTHCARE DANGERS OF THE DECISION.....	248
	A. <i>Scrutinizing the Federal Circuit Opinion in Proveris</i>	248
	1. <i>Applying the Literal Meaning of "patented invention" to 35 U.S.C. § 271(e)(1)</i>	249

2.	Improper emphasis given to 35 U.S.C. § 156(f) when interpreting "patented invention" under § 271(e)(1).....	250
3.	Terminating the evolving presumption that 35 U.S.C. § 271(e)(1) applies to research tools used in the submission of data to the FDA.....	251
4.	Application of the "reasonably related" standard in 35 U.S.C. § 271(e)(1).....	253
B.	<i>Dangers of Narrowing the Scope of the Generic Drug Manufacturer's Patent Infringement Protection under 35 U.S.C. § 271(e)(1)</i>	254
1.	Possible Loss of Generic Pharmaceutical Development to Foreign Countries.....	254
2.	Potential Inflation of Pharmaceutical Products....	255
3.	Implicit Denial of Affordable Healthcare to Americans	256
V.	PROPOSITION: BALANCING THE NEED FOR A STRONGER GENERIC HEALTHCARE MARKET WITH THE RIGHTS OF PATENT HOLDERS.....	258
A.	<i>Congressional legislation clearly defining the term "patented invention" under 35 U.S.C. § 271(e)(1) to incorporate all patented inventions</i>	258
B.	<i>Federal Circuit or Supreme Court decision incorporating into 35 U.S.C. § 271(e)(1) all patented inventions that are inherent to the manufacture of a product requiring FDA approval....</i>	260
VI.	CONCLUSION	261

I. INTRODUCTION

The healthcare debate has been one of the leading topics in American politics as of late.¹ President Obama has stated that the "biggest threat" to the United States' economy is the "skyrocketing cost of healthcare."² Lowering the cost of pharmaceutical products is one approach that has been used by

1. Cf. Lesley Alderman, *It's Time for the Annual Task of Choosing Your Insurance Plan*, N.Y. TIMES, Oct. 10, 2009, at B6 (observing that major changes in health plans will not likely occur because "employers are waiting to see what shakes out from the health care debate in Washington before they take any big cost-saving steps").

2. Atul Gawande, *The Cost Conundrum: What a Texas town can teach us about health care*, THE NEW YORKER, June 1, 2009, available at http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande.

the Obama Administration in an attempt to improve the American healthcare system.³

One approach to lowering the cost of pharmaceutical products is increasing the availability of generic drugs to the American public.⁴ Generic drugs become more readily available to the public as patents on prescription drugs expire.⁵ Consequently, many expensive brand name drugs suffer a reduction in market consumption as consumers begin to buy a cheaper generic version.⁶

Analysts predict that over the next couple of years the availability of generic drugs will increase because patents on prescription drugs will expire.⁷ Furthermore, the introduction of generic drugs to the market place could lower the cost of healthcare in that specific sector by up to 80%.⁸

This note is centered around *Proveris Scientific Corp. v. Innovasystems, Inc.*, a recent decision issued by the Federal Circuit that limits the ability of generic drug manufacturers to use patented inventions designed solely to enhance the research and development of their generic drug.⁹ Furthermore, this note examines what potential effect this decision will have on the American healthcare system and pharmaceutical industry.

II. THE DEVELOPMENT AND INTERPRETATION OF 35 U.S.C. § 271(E)(1)

Before the enactment of 35 U.S.C. § 271(e)(1), the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.* held that there was no exemption from patent infringement if a patented product was used to perform tests to obtain FDA approval for pharmaceutical products.¹⁰ The Court acknowledged the extensive time period necessary to obtain FDA approval for a new pharmaceutical product.¹¹ Congress

3. David M. Herszenhorn, *White House and Hospitals Are Reported to Be Near Deal*, N.Y. TIMES, July 7, 2009, at A11 (reporting that the White House announced an agreement to lower drug costs, while Pharmaceutical Research and Manufacturers of America pledged \$80 billion in an effort to improve the health care system).

4. Stephanie Saul, *More Generics Slow the Surge In Drug Prices*, N.Y. TIMES, Aug. 8, 2007, at A1.

5. *Id.*

6. *See id.* (noting that, in American medicine cabinets, "[p]rescription bottles bearing catchy brand names like Zolof and Flonase are being pushed aside by tongue-twisting generics like sertraline and fluticasone propionate").

7. *Id.*

8. *Id.*

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

10. *Roche Prods., Inc. v. Bolar Pharm. Co., Inc.* 733 F.2d 858, 863 (Fed. Cir. 1984).

11. *Id.* at 864 (noting that the time period could take between seven and ten years).

eventually enacted legislation that allowed generic drug manufacturers to use patented inventions if the use was solely to obtain FDA approval of a new drug.¹² The Supreme Court broadly interpreted the language of 35 U.S.C. § 271(e)(1) and found all medical devices and compounds to fit within the scope of the statute if used in a submission process to the FDA.¹³

Because the use of a patented invention has to be reasonably related to the submission of information to the FDA in order to receive infringement protection under the statute,¹⁴ the issue of what uses are categorized as "reasonably related" has been heavily litigated.¹⁵ The Supreme Court recently reduced the significance of the "reasonably related" standard when it held in *Merck KGAA v. Integra Lifesciences I, Ltd.* that the use of a patented invention does not need to actually result in a submission to the FDA to fall within the standard.¹⁶ However, before fully comprehending 35 U.S.C. § 271(e)(1) and the broad interpretation given to the statute before the Federal Circuit opinion in *Proveris*, it is important to understand the lengthy process for obtaining FDA approval for a pharmaceutical product.

A. *Time Period Necessary for FDA Approval Process*

All pharmaceutical and medical products that are manufactured and marketed in the United States must be regulated by the Food and Drug Administration (FDA).¹⁷ Furthermore, the Federal Food, Drug, and Cosmetic Act (FDCA) mandates that a widespread investigatory process of a new drug be conducted by the manufacturer in order to obtain FDA approval.¹⁸

If the manufacturer of a new drug anticipates achieving FDA approval, then an Investigational New Drug (IND) Application must be submitted by a sponsor in order to conduct a clinical investigation.¹⁹ The clinical investigation of a previously

12. 35 U.S.C. § 271(e)(1) (2006).

13. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665 (1990); see also *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997) (including all medical devices regardless of class to be covered under 35 U.S.C. § 271(e)(1)).

14. 35 U.S.C. § 271(e)(1) (2006).

15. See, e.g., *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523-25 (Fed. Cir. 1992) (issuing a fairly broad interpretation of "reasonably related" when holding that demonstrating a device at a medical conference fell within the contours of the statute).

16. See *Merck KGAA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005).

17. *Jian Xiao, Carving Out A Biotechnology Research Tool Exception to the Safe Harbor Provision of 35 U.S.C. § 271(E)(1)*, 12 TEX. INTELL. PROP. L.J. 23, 27 (2003).

18. *Id.*

19. See 21 C.F.R. § 312.20(a) (2010).

untested drug is generally divided into three phases.²⁰ The first phase is designed to detect potential health and safety problems that humans may encounter with the drug.²¹ This alone takes approximately one to two years.²² The second phase in obtaining IND status is designed to "evaluate the effectiveness of the drug" for the intended use while also detecting "short term side effects and risks that are associated with the drug."²³ The second phase takes approximately two to three years.²⁴ The third phase gathers the additional information needed to examine the "benefit-risk relationship of the drug."²⁵ Overall, the completion of these three phases typically can range anywhere from two to five years.²⁶

After completion of the third phase, "the company can file a New Drug Application ('NDA')."²⁷ However, the FDA considers many factors in determining if the drug or pharmaceutical product is safe for marketing and applies extensive scrutiny in making its decision.²⁸ Overall, the process of receiving FDA approval for a new drug or pharmaceutical product can take anywhere between seven and ten years.²⁹

B. *The Pioneer-Generic Drug Relationship Prior to the Enactment of 35 U.S.C. § 271(e)(1)*

1. *Roche Products, Inc. v. Bolar Pharmaceutical*

The early decision in *Roche* held that patent infringement occurs if: (1) a patented ingredient is used to perform tests necessary to obtain FDA approval, (2) the use does "not fall

20. *Id.* § 312.21.

21. *Id.* § 312.21(a)(1) (denoting that the studies are "designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness").

22. *See* Xiao, *supra* note 17, at 27.

23. *See* 21 C.F.R. § 312.21(b) (2010).

24. *See* Xiao, *supra* note 17, at 27.

25. 21 C.F.R. § 312.21(c) (2010) ("Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained . . . Phase 3 studies usually include from several hundred to several thousand subjects.").

26. *See* Xiao, *supra* note 17, at 27-28.

27. *Id.* at 28.

28. *Id.*; *see* 21 U.S.C. § 355(b)(1) (2006) (declaring that the NDA shall consist of "(A) full reports of investigations which have been made to show whether or not a drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug," among other things).

29. *Roche Prods., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 864 (Fed. Cir. 1984).

within the experimental use exception to the patent laws," and (3) "public policy does not require that [an] exception be created for those using the patented ingredient to create a generic drug. . . ." ³⁰

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, Roche Products ("Roche") sought to enjoin Bolar Pharmaceutical Co., Inc. ("Bolar") from taking the regulatory steps necessary to market a generic version of Roche's patented brand name drug during the life of the patent.³¹ Roche was assigned U.S. Patent No. 3,299,053 (the '053 patent) which contained flurazepam hydrochloride, the active ingredient in Dalmane, Roche's brand name prescription sleeping pill.³² Bolar realized that "a generic drug's commercial success is related to how quickly it is brought on the market after a patent expires . . . [and rather than] waiting for the '053 patent to expire, [it] immediately began its effort to obtain federal approval to market its generic version of Dalmane."³³ During the life of the '053 patent, Bolar began its effort to gain "federal approval to market its generic version of Dalmane" by obtaining the necessary data to submit a NDA to the FDA from dosages of flurazepam.³⁴

When Roche brought suit against Bolar to enjoin its usage of flurazepam, Bolar argued that public policy favors generic drugs and mandates the creation of a new exception in order to allow FDA required drug testing.³⁵ Bolar also argued that an exception should be granted based on a "liberal interpretation of the traditional experimental use doctrine."³⁶

The Federal Circuit held that patent infringement existed in the present case and refused to accept Bolar's public policy argument because Congress had previously enacted legislation to address these arguments.³⁷

30. *Id.* at 858.

31. *Id.* at 860.

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.* at 862-64 (stating that Bolar argued that the FDCA was "only intended to assure safe and effective drugs for the public, and not to extend a pharmaceutical company's monopoly for an indefinite and substantial period of time while the FDA considers whether to grant a pre-marketing clearance," and therefore, patent laws should be applied differently to drugs).

36. *Id.* at 862; *see also* *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (proclaiming that the experimental use defense is not valid if the alleged infringer conducts uses "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry").

37. *Roche*, 733 F.2d at 865 (citing the Drug Price Competition Act of 1983, H.R. 3605, 98th Cong. (1983) (which "amend[ed] 21 U.S.C. § 355(b) to allow faster marketing of new generic drugs equivalent to approved new drugs")). *But see id.* (citing Patent Term

2. Pre-Roche Dilemma on Patent Monopolies

Prior to *Roche*, the Supreme Court held that a generic copy of an "already-approved, pioneering drug was a 'new drug.'"³⁸ Generic drugs therefore "had to duplicate the expensive NDA process that the inventor and pioneering manufacturer had undergone" before entering the market.³⁹ As a result, this "delayed entry of generic drugs into the market," which theoretically extended the period of the inventor's patent on the pioneer drug.⁴⁰

However, there was a constructive counterbalance with the generic drug's delayed market entry. After patent terms began running, pioneer patent holders could not market their new drugs before going through "a lengthy FDA approval process, which significantly shortened the length of the effective patent terms."⁴¹

C. *The Enactment of 35 U.S.C. § 271(e)(1)*

Pioneer and generic drug manufacturers were dissatisfied with the effect that the FDA approval process had on patent terms and appealed to Congress for a remedy.⁴² However, while the pioneer manufacturers wanted to extend patent terms, the generic developers wanted to shorten the terms, if only for the purpose of preparing generic drugs for release.⁴³

As a result, the Hatch-Waxman Act was passed on September 24, 1984.⁴⁴ There are two relevant titles to the bill.⁴⁵

Restoration Act of 1983, S. 1306, 98th Cong.(1983) (which "amend[ed] 35 U.S.C. § 155 to add to the patent grant a period of time equivalent to that lost due to regulatory delay").

38. Thomas F. Poché, *The Clinical Trial Exemption From Patent Infringement: Judicial Interpretation of Section 271(E)(1)*, 74 B.U. L. REV. 903, 912 (1994) (referring to the holding in *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983)).

39. *Id.*

40. *Id.* at 912-13.

41. Xiao, *supra* note 17, at 28.

42. See Susan Kopp Keyack, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147, 154-55 (1989).

43. Xiao, *supra* note 17, at 30. According to Xiao, "[p]ioneer drug developers lobbied for extended patent terms in order to compensate for the time they spent on the FDA approval process. Generic drug developers, on the other hand, argued that they should gain access to the FDA approval process before the pioneer drug patents expired so that generic products could be brought to the market immediately after expiration of the patent." *Id.*

44. Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1989) (codified as amended in scattered sections of 21, 28, 35, and 16 U.S.C.); see generally Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187-88 (1999) (discussing the creation of the Hatch-Waxman Act and its relevance to pioneer and generic drug manufacturers).

Title I allows a generic manufacturer to submit an application for approval to the FDA before the pioneer drug patent expires.⁴⁶ Title I thereby provides an "Abbreviated New Drug Approval . . . procedure whereby generic drug firms can introduce copies of pioneer drugs to the marketplace without repeating expensive and lengthy clinical trials."⁴⁷

The second title of the bill provides for both a patent term extension provision and a safe harbor provision to the general prohibition against patent infringement.⁴⁸ The patent term extension provision came about because Congress recognized that the FDA approval process requirements reduced the patent term on the pioneer drug.⁴⁹ Therefore, if certain conditions are met, the life of a patent may be extended.⁵⁰

The safe harbor provision overruled the *Roche* holding by creating a fair-use doctrine if the use of the pioneer drug during the patent term is for the submission of data to the FDA.⁵¹ The safe harbor provision is codified in 35 U.S.C. § 271(e)(1) and 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[.]⁵²

The Hatch-Waxman Act was drafted in order to reduce the amount of time between a generic drug entering the market and the expiration of a patented pioneer drug, while also developing a

45. See H.R. REP. No. 98-857, pt. 2, at 3 (1984).

46. See *id.* at 5 ("In order to complete this application the generic manufacturer must conduct certain drug tests. In order to facilitate this type of testing . . . a generic manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval.").

47. Xiao, *supra* note 17, at 30.

48. See H.R. REP. No. 98-857, pt. 2 at 5; see also 35 U.S.C. §§ 156, 271(e)(1) (2006).

49. See H.R. REP. No. 98-857, pt. 2, at 5-6 ("[P]roponents of this type of legislation have argued that the reduction of the effective market life of a patent because of federal regulatory review should be restored through an extension of the patent term Thus, it is argued that patent term extensions will create incentives for increased research expenditures.").

50. 35 U.S.C. § 156(a)(1)-(5) (2006).

51. See 35 U.S.C. § 271(e)(1) (2006); see also *supra* notes 10-12 and accompanying text.

52. 35 U.S.C. § 271(e)(1) (2006).

new motivation for pioneer manufacturers to create.⁵³ By creating an Abbreviated New Drug Application (ANDA), the Act allows for a generic drug to achieve FDA approval during the patented life of the pioneer drug while halting effective approval until the end of the patent life.⁵⁴

D. *Defining "Patented Invention" under 35 U.S.C. § 271(e)(1)*

1. *Eli Lilly and Co. v. Medtronic, Inc.*

In *Eli Lilly and Co. v. Medtronic, Inc.*, Eli Lilly and Co. ("Eli Lilly") filed an action to enjoin Medtronic, Inc. ("Medtronic") from testing and marketing an implantable cardiac defibrillator on the grounds that the activity infringed on Eli Lilly's patent.⁵⁵ Medtronic's defense was that its activities were "reasonably related to the development and submission of information under the FDCA, and thus exempt from a finding of infringement under 35 U.S.C. § 271(e)(1)."⁵⁶ The Supreme Court held that Medtronic's testing fell within Congress's intent when enacting the statute, and therefore, the use was allowed and was not patent infringement.⁵⁷

2. *Medical Devices Fall Within the Scope of § 271(e)(1)*

Section 201 of the Hatch-Waxman Act "established a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval."⁵⁸ This provision was codified in 35 U.S.C. § 156.⁵⁹ The eligible products that fall under the scope of this provision are human drug products and

53. See Courtenay C. Brinkckerhoff, *Can the Safe Harbor of 35 U.S.C. § 271(e)(1) Shelter Pioneer Drug Manufacturers?*, 53 FOOD & DRUG L.J. 643, 645-46 (1998).

54. H.R. REP. No. 98-857, pt. 1, at 27 ("The Committee recognizes that some ANDA's will be submitted and ready for approval before the patent on the listed drug has expired. To deal with this situation and to assure that the FDA concerns itself solely with the safety and effectiveness of the generic drug, [a statutory provision] permits the FDA to approve an ANDA but make the approval effective at some later date when appropriate.")

55. 496 U.S. 661, 664 (1990). Eli Lilly had two patents on its cardiac defibrillator: U.S. Patent No. Re 27,757 and U.S. Patent No. 3,942,536. *Id.*

56. *Id.*

57. See *id.* at 679.

58. *Id.* at 670.

59. See H.R. REP. No. 98-857, pt. 1, at 37 (1984)(explaining the section 156 provision that "the product must have been subjected to a regulatory review period under an applicable federal law, and approved, before the product was allowed to be commercially marketed" as a condition for patent extension); see also 35 U.S.C. § 156 (2006).

any "medical device, food additive, or color additive subject to regulation" under the FDCA.⁶⁰ However, Section 202 of the Hatch-Waxman Act addressed the 35 U.S.C. § 271(e)(1) exclusion from patent infringement.⁶¹

Eli Lilly argued that medical devices should not fall within the scope of section 271(e)(1) because the specific provisions requiring regulatory approval for medical devices are not provisions requiring regulatory approval for drugs, even though they are included in the FDCA.⁶²

The Court reasoned that the products defined in Section 201 of the Act should also apply to the patent infringement prohibition of Section 202.⁶³ The reasoning was based on the perception that medical devices are subject to the same distortions as drugs and therefore should enjoy the same benefits of the Hatch-Waxman Act.⁶⁴ Writing for the majority, Justice Scalia held that the phrase "patented invention" in section 271(e)(1) is "defined to include all inventions, not drug-related inventions alone."⁶⁵

3. Classifying Medical Devices

There are three classes of medical devices that are defined by statute.⁶⁶ Class III medical devices are subjected to the most thorough premarketing approval process, and satisfy the criteria

60. *Eli Lilly*, 496 U.S. at 670-71. The term human "drug product" means "the active ingredient of a new drug, antibiotic drug, or human biological product . . . including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient." 35 U.S.C. § 156(f)(2) (2006).

61. *Eli Lilly*, 496 U.S. at 671.

62. *Id.* at 672.

63. *Id.* at 673-74. "All of the products eligible for a patent term extension under § 201 are subject to § 202, since all of them — medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products — are subject to premarket approval under various provisions of the FDCA. . . . And the products subject to premarket approval under FDCA and the Act . . . that are *not* made eligible for a patent term extension under § 201 . . . are excluded from § 202 as well." *Id.* at 674 (emphasis in original) (internal citation omitted).

64. *Id.* at 672-73.

65. *Id.* at 665.

66. Class I devices are general control devices, devices for "which insufficient information exists to determine that the controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1) (2006). Class II devices are special control devices for which "there is sufficient information to establish special controls to provide such assurance." *Id.* Class III devices are subject to premarket approval to provide reasonable assurance of its safety and effectiveness because it "is purported or represented to be for a use in supporting or sustaining human life" or "presents a potential unreasonable risk of illness or injury." *Id.*

laid out in 35 U.S.C. § 156(a).⁶⁷ However, because Class I and Class II medical devices are subject to an accelerated approval process, they do not fall under 35 U.S.C. § 156.⁶⁸ Using the analysis in *Eli Lilly*, if the device does not fall within the scope of 35 U.S.C. § 156, then it does not necessary fall under the section 271(e)(1) patent infringement exclusion provision.

4. *AbTox, Inc. v. Exitron Corp.*

In *AbTox, Inc. v. Exitron Corp.*, MDT Corporation ("MDT") was hired by Exitron Corporation ("Exitron") to conduct tests on a device covered by a patent held by AbTox, Inc. ("AbTox") during Exitron's development of a plasma sterilizer.⁶⁹ AbTox held U.S. Patent No. 4,321,232 (the '232 patent) and claimed MDT had infringed on this patent by conducting limited tests consistent with the collection of data necessary to file an application with the FDA.⁷⁰ The '232 patent was a Class II medical device and did not fall under the scope of 35 U.S.C. § 156; therefore, it was undetermined if section 271(e)(1) was applicable.⁷¹

The Supreme Court did not specifically address this issue. Instead, the Court deferred to its prior interpretation of the statute in *Eli Lilly* and held that "all classes of medical devices fall within the plain meaning of section 271(e)(1)."⁷² Therefore, under *AbTox*, any medical device, no matter what class it falls under, is awarded the protection of the safe harbor clause of 35 U.S.C. § 271(e)(1).

E. *Interpreting "solely for uses reasonably related" under 35 U.S.C. § 271(e)(1)*

When the legislature enacted 35 U.S.C. § 271(e)(1), courts "relied heavily on the legislative history of the statute and limited the application to the use of an invention for the sole

67. See Xiao, *supra* note 17, at 34; 35 U.S.C. § 156(a) (2006) (outlining conditions under which an extension of patent term shall be granted).

68. Xiao, *supra* note 17, at 34; see *supra* note 67 and accompanying text.

69. 122 F.3d 1019, 1027 (Fed. Cir. 1997).

70. *Id.* at 1020, 1027. The '232 patent discloses "devices which sterilize medical instruments in a partially ionized gas, known as plasma." *Id.* at 1020-21.

71. See *id.* at 1027; *supra* note 67 and accompanying text.

72. *Id.* at 1029. The court noted that "Ultimately, this court must follow the Supreme Court's broader holding, which remains in force despite a potential conflict with its own narrower reasoning." *Id.* The broader holding was that "all classes of medical devices fall within the plain meaning of § 271(e)(1)." *AbTox*, 122 F.3d at 1029. The narrower holding has been interpreted as allowing only Class III devices to fall within § 271(e)(1). *Id.*

purpose of obtaining FDA approval."⁷³ However, case law has recently broadened the scope of the statute.

1. *Telectronics Pacing Systems v. Ventritex, Inc.*

One case which expanded the scope of 35 U.S.C. § 271(e)(1) was *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.* In that case, Telectronics Pacing Systems ("Telectronics") claimed that Ventritex, Inc. ("Ventritex") had engaged in activities that were not exempt under 35 U.S.C. § 271(e)(1) because the activities were not "reasonably related" to obtaining FDA approval.⁷⁴ The court disagreed and held that Ventritex's activities fell within the meaning of the statute and were therefore precluded from being subject to patent infringement.⁷⁵

Ventritex sold an implantable defibrillator⁷⁶ "for implantation in patients in order to obtain data on the device's clinical operation."⁷⁷ The defibrillator was displayed at medical conferences and demonstrated to both physicians and non-physicians while an abstract was also sent for clinical trial results.⁷⁸ Conversely, the president of Ventritex described the clinical trials to investors, analysts, and journalists in an attempt to raise funds to be used for continuing clinical trials and manufacturing equipment.⁷⁹ Telectronics claimed that these acts had nothing to do with "the development and submission of information"⁸⁰ under § 271(e)(1), and that allowing a clinical trial exemption when the data gathered from the clinical trials was used for commercial purposes totally unrelated to FDA reporting went against the legislative intent of the statute.⁸¹

In its logic, the court first determined whether Ventritex's activities fell under the § 271(a) definition of patent infringement.⁸² Such a determination was necessary before

73. Xiao, *supra* note 17, at 37.

74. 982 F.2d 1520, 1521 (Fed. Cir. 1992).

75. *Id.* at 1525.

76. Telectronics contended that making, using, or selling this implantable defibrillator would infringe upon five of its patents: U.S. Patent No. 4,390,021, U.S. Patent No. 4,488,553, U.S. Patent No. 4,488,554, U.S. Patent No. 4,398,536, and U.S. Patent No. 4,408,606. *Id.* at 1522 & n.l.

77. *Id.* at 1521. Ventritex was acting pursuant to an Investigational Device Exemption from the FDA; the data Ventritex received was required by the FDA for securing premarket approval of the implantable defibrillator. *Id.*

78. *Id.*

79. *Id.* at 1521-22.

80. *Id.* at 1523.

81. *See id.* at 1522-24.

82. *Id.* at 1523. "[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any

deciding if the acts were exempt under subsection (e)(1).⁸³ The court found that the demonstrations at medical conferences were the only infringing activity under § 271(a); however, they were exempt under § 271(e)(1) because such activity was reasonably related to obtaining FDA approval, and Ventritex was attempting to find investigators to conduct clinical trials.⁸⁴

The court also held that the fundraising events were not infringing activities under § 271(a).⁸⁵ The court reasoned that because Congress intended to place competitors in a position to market their products as soon as legally possible, the statute was broad enough to encompass fundraising activities.⁸⁶

2. *Merck KGaA v. Integra Lifesciences I*

In *Merck KGaA v. Integra Lifesciences I*, the Supreme Court further broadened the interpretation of "solely for uses reasonably related [to FDA approval]" by holding that the activity does not require actual submission of information to the FDA.⁸⁷

Merck KGaA ("Merck") "provided funding for angiogenesis research conducted by Dr. David Cheresh at the Scripps Research Institute (Scripps)" using cyclic RGD peptides.⁸⁸ Dr. Cheresh successfully reversed tumor growth in chicken embryos using the cyclic RGD peptide provided by Merck.⁸⁹

Under a new three-year contract with Merck, "Dr. Cheresh directed *in vitro* and *in vivo* experiments on the RGD peptides" in an attempt to "evaluate the suitability of each of the peptides as potential drug candidates."⁹⁰ However, Scripps determined that organic mimetics provided a similar function as RGD peptides

patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (2006).

83. See *Telectronics*, 982 F.2d at 1523.

84. *Id.* at 1523.

85. *Id.* at 1523-24.

86. See *id.* at 1525.

87. 545 U.S. 193, 207 (2005). The court noted that "the use of a patented compound in experiments that are not themselves included in a 'submission of information' to the FDA does not . . . render the use infringing. 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." *Id.*

88. *Id.* at 197. "Angiogenesis is the process by which new blood vessels sprout from existing vessels; it plays a critical role in many diseases, including solid tumor cancers, diabetic retinopathy, and rheumatoid arthritis." *Id.*

89. *Id.*

90. *Id.* at 198. "[These] tests measured the efficacy, specificity, and toxicity of the particular peptides as angiogenesis inhibitors, and evaluated their mechanism of action and pharmacokinetics in animals." *Id.* at 198-99.

and began using the RGD peptides as controls against which to measure the effectiveness of the mimetics.⁹¹ The use of the RGD peptides was not included in any IND or NDA because the peptides were not used in testing human safety, but rather were only tested on animals and used as controls.⁹²

Integra Lifesciences I, Ltd. ("Integra") filed a patent-infringement suit against Merck, Scripps, and Dr. Cheresch, alleging that Merck "willfully infringed and induced others to infringe [Integra's] patents by supplying the RGD peptide to Scripps".⁹³ Integra further claimed that Dr. Cheresch and Scripps similarly infringed by using the RGD peptide in angiogenesis experiments.⁹⁴

Writing for the majority, Justice Scalia rejected Integra's argument that pursuant to section 271(e)(1) "the only preclinical data of interest to the FDA is that which pertains to the safety of the drug in humans."⁹⁵ The Supreme Court held that § 271(e)(1)'s exemption from infringement is broad enough under certain circumstances to include: "(1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA."⁹⁶

The deciding factor in whether an experiment is exempt from patent infringement under § 271(e)(1) is the *reasonable* basis for the belief that a patented compound may work, not whether it is actually submitted to the FDA.⁹⁷

91. *Id.* at 199.

92. *See id.* at 203 (explaining Integra's argument "that the only preclinical data of interest to the FDA is that which pertains to the safety of the drug in humans," and that "preclinical studies related to a drug's efficacy, mechanism of action, pharmacokinetics, and pharmacology are not reasonably included in an IND or an NDA, and are therefore outside the scope of the exemption").

93. *Id.* at 200. Integra owned five patents related to the RGD peptide: U.S. Patent Nos. 4,988,621 (filed Jan. 29, 1991), 4,792,525 (filed Dec. 20, 1988), 5,695,997 (filed Dec. 9, 1997), 4,879,237, (filed Nov. 7, 1989) and 4,789,734 (filed Dec. 6, 1988). *Id.* at 197. Merck does not contest that the cyclic RGD peptides developed by Merck were covered by Integra's patents. *Id.* at 197 n.3.

94. *Id.* at 200.

95. *Id.*; *see also id.* at 203 (noting that "the FDA requires that applicants include in an IND summaries of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals"). The court also rejected Integra's argument that experiments failing to conform to FDA guidelines are not covered under § 271(e)(1)'s exemption. *Id.* at 204-05.

96. *Id.* at 206.

97. *See id.* at 207. According to the court, "[p]roperly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to

III. *PROVERIS SCIENTIFIC CORPORATION V. INNOVASYSTEMS, INC.*A. *Facts*

Proveris Scientific Corporation ("Proveris") owned U.S. Patent No. 6,785,400 (the '400 patent), which was "directed to a system and apparatus for characterizing aerosol sprays commonly used in various drug delivery devices[.]"⁹⁸ The spray characterization measurements described in the '400 patent played an important role in the FDA regulatory approval process for drug delivery devices.⁹⁹ Inhaler-based drug delivery devices are subject to FDA approval; however, the system and apparatus in the '400 patent are not.¹⁰⁰

Innovasystems, Inc. ("Innova") made and sold a device called the Optical Spray Analyzer (OSA) which was not subject to FDA approval for the same reasons as the '400 patent; however, the OSA was used in connection with the FDA regulatory submissions of drug delivery devices.¹⁰¹

B. *The Complaint*

Proveris filed a patent-infringement suit against Innova alleging that the OSA had infringed the '400 patent for the same reasons the '400 patent was not subject to FDA approval.¹⁰² In response, Innova asserted that activities were protected under section 271(e)(1) because "its OSA devices [were being] used by third parties *solely* for the development and submission of information to the FDA."¹⁰³

Proveris responded by stating § 271(e)(1) does not immunize infringement on laboratory or manufacturing equipment but only drug products, medical devices, food additives, and color

include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under . . . Federal law.'" *Id.* (quoting 35 U.S.C. § 271(e)(1)).

98. *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1258 (Fed. Cir. 2008).

99. *Id.* ("[S]pray characterization measurements are frequently used to calibrate drug delivery devices in accordance with the exact physical properties of a particular drug, in order to maximize the efficiency and effectiveness of drug delivery.")

100. *Id.*

101. *See id.* at 1259. The OSA measured "the physical parameters of aerosol sprays used in nasal spray drug delivery devices" which were subject to FDA approval under the FDCA. *Id.*

102. *See id.* at 1259-60.

103. *Id.* at 1259-60 (emphasis added).

additives because these were the "products" defined in § 156(f).¹⁰⁴ Proveris also asserted that the "reasonably related" standard did not apply to Innova because Innova's infringement was "not for purposes of its own FDA-related research, but rather for commercial sale to third parties engaged in such research."¹⁰⁵

C. *The Opinion*

The Federal Circuit held that § 271(e)(1) did not apply to Innova's OSA and therefore did not immunize Innova from infringement.¹⁰⁶ The court based its holding on the Supreme Court's approach in *Eli Lilly* and determined that Innova's OSA did not fall under the second distortion resolved by the Hatch-Waxman Act.¹⁰⁷ The second distortion was the extension of the effective patent life at the end of the pioneer drug's patent due to the FDA premarket approval process.¹⁰⁸

With the second distortion as the focal point of its analysis, the Federal Circuit found that FDA premarket approval was only required for the aerosol drug delivery product whose spray was measured by the OSA.¹⁰⁹ Therefore, Innova's OSA device alone was not subject to FDA premarket approval.¹¹⁰

Because the OSA failed to face any "regulatory barriers to market entry upon patent expiration" such as the FDCA, the court reasoned that Innova was "not a party who, prior to the enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second distortion."¹¹¹ The court concluded that Congress did not intend for § 271(e)(1) to apply to the OSA because the OSA failed to face regulatory barriers to market entry upon expiration of the the '400 patent.¹¹²

104. *Id.* at 1264 (explaining Proveris' analysis that the safe harbor provision of § 271(e)(1) extends only to other "products" as defined by § 156(f) and to other patented inventions that are inherent to the development of "products").

105. *Id.*

106. *Id.* at 1265.

107. *Id.* at 1265 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-74 (1990)) (noting the Supreme Court in *Eli Lilly* examined the language of § 271(e)(1) with regard to the statute as a whole, including § 156, because the two sections were enacted in order to eradicate two inadvertent distortions of the effective patent term resulting from premarket approval required of certain products pursuant to the FDCA); *see generally Eli Lilly*, 496 U.S. at 669-74.

108. *Eli Lilly*, 496 U.S. at 670.

109. *Proveris*, 536 F.3d at 1265.

110. *Id.*

111. *Id.*

112. *Id.* (stating that "insofar as its OSA device is concerned, Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief").

In addition, the court stated that Innova's § 271(e)(1) defense was invalid because Proveris was not a party who, "prior to the enactment of the [Hatch-Waxman Act], could be said to have been adversely affected by the first distortion."¹¹³ The court came to this conclusion because the '400 patent was not subject to the premarket approval process required by the FDCA.¹¹⁴ The Federal Circuit concluded that both distortions addressed in the Hatch-Waxman Act work jointly in determining whether or not a product is awarded a § 271(e)(1) defense.¹¹⁵

The Federal Circuit failed to give weight to Innova's argument that because the OSA was 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,"¹¹⁶ it should be awarded protection under the safe harbor provision.¹¹⁷ The court rejected this argument because the device claimed in the '400 patent was not a "patented invention" under the language of § 271(e)(1).¹¹⁸

IV. PLACING *PROVERIS* UNDER A MICROSCOPE AND IDENTIFYING THE POTENTIAL HEALTHCARE DANGERS OF THE DECISION

A. *Scrutinizing the Federal Circuit Opinion in Proveris*

The Federal Circuit held that Innova's OSA was not protected by 35 U.S.C. § 271(e)(1) because the OSA was not subject to regulatory barriers upon entrance into the marketplace.¹¹⁹ However, in reaching this conclusion the court failed to give weight to the literal meaning of the statute, failed

113. *Id.* The first distortion "was the reduction of effective patent life caused by the FDA premarket approval process." *Id.*

114. *Id.* at 1265. The court used the *Eli Lilly* interpretation of "patented invention in section 271(e)(1) to include all products listed in section 156(f) as producing a perfect product fit between the two provisions." *Id.* (internal quotation marks omitted) (quoting *Eli Lilly*, 496 U.S. at 672).

115. *Id.* at 1265-66 ("Because Proveris' patented product is not subject to a required FDCA approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because Innova's OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1).").

116. 35 U.S.C. § 271(e)(1) (2006).

117. *See Proveris*, 536 F.3d at 1266. The court noted, "Innova's position is that its offering for sale and its sale of the OSA device fit squarely within the statutory language because, like the product claimed in the '400 patent, the OSA is used in a way which is 'reasonably related' to 'the development and submission of information' pertinent to the FDA premarket approval required for inhaler-based drug delivery devices." *Id.*

118. *Id.*

119. *Id.*

to acknowledge judgments rendered by district courts, and failed to examine whether Innova's use was "reasonably related" to the development and submission of information to the FDA.¹²⁰

1. Applying the Literal Meaning of "patented invention" to 35 U.S.C. § 271(e)(1)

When interpreting a statute, generally, the court must apply the literal meaning of the statute if the language is clear and unambiguous.¹²¹ Therefore, first and foremost the Federal Circuit should have attempted to apply the literal meaning of 35 U.S.C. § 271(e)(1) to Innova's use of the OSA before reading into the distortions addressed by the Hatch-Waxman Act.¹²²

For the Federal Circuit to give weight to the literal meaning of 35 U.S.C. § 271(e)(1), it must read the statute in its entirety.¹²³ Section 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.¹²⁴

Instead of first giving weight to the literal meaning of the statute, the Federal Circuit compared Innova's OSA with the

120. See discussion *infra* Part IV.A.1-4.

121. See, e.g., *K MART Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) ("If the statute is clear and unambiguous that is the end of the matter, for the court . . . must give effect to the unambiguously expressed intent of Congress.") (internal quotation marks omitted) (quoting *Bd. of Governors, FRS v. Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986)); *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) ("Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'") (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240 (1989)).

122. See *Robinson*, 519 U.S. at 340 (looking first to the plain meaning of the statute in order to determine whether a former employee may bring suit against a past employer for postemployment actions in violation of Title VII of the Civil Right Act of 1964); *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002) (starting with the plain language of the statute to determine whether "the Coal Act...[allows] the Commissioner to assign beneficiaries to the successor in interest of a signatory operator").

123. See *Robinson*, 519 U.S. at 341.

124. 35 U.S.C. § 271(e)(1) (2006) (stating that "patented invention" does not refer to a new animal drug or veterinary biological product (as used in the FDCA and the Act of March 4, 1913) which "is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques").

distortions that were addressed by the Hatch-Waxman Act.¹²⁵ Yielding to a literal interpretation of the statute might have led the court to a completely different holding.

In *Proveris*, the Federal Circuit failed to give "patented invention" a literal interpretation under 35 U.S.C. § 271(e)(1) and instead applied the meaning of "patented invention" under another statute, 35 U.S.C. § 156.¹²⁶ When read literally, "patented invention" applies to all patented inventions except for veterinary biological products and new animal drugs manufactured using DNA, RNA, or other genetic manipulation techniques.¹²⁷ Under this interpretation, Innova's OSA falls under the meaning of "patented invention" because its only purpose was to measure the physical parameters of aerosol sprays.¹²⁸

2. Improper emphasis given to 35 U.S.C. § 156(f) when interpreting "patented invention" under § 271(e)(1)

Even if the Federal Circuit determined in *Proveris* that literal interpretation was not applicable because the statutory language was not clear and unambiguous, deferring to its holding in *AbTox* would most likely result in Innova's OSA being classified as a "patented invention."¹²⁹ The *AbTox* court implicitly held that when interpreting the language of 35 U.S.C. § 271(e)(1) it is not necessary that § 156(f) be used as a guide in determining which inventions fall under the statute.¹³⁰ However, the *Proveris* court reached its holding in an attempt to create "symmetry" between the two sections.¹³¹

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

126. See *id.* at 1265-66 (rationalizing that under 35 U.S.C. § 156, *Proveris* did not have an invention that was affected adversely by the regulatory barriers (FDA approval process) and, therefore, Innova's OSA was not a "patented invention" under 35 U.S.C. § 271(e)(1)).

127. See 35 U.S.C. § 271(e)(1) (2006).

128. Compare *Proveris*, 536 F.3d at 1259 (illustrating that Innova's OSA was a device that "measures the physical parameters of aerosol sprays used in nasal spray drug delivery devices"), with 35 U.S.C. § 271(e)(1) (implying that the only patented inventions that do not fall under this safe harbor clause are new animal drugs or veterinary products "primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques").

129. See *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997) (holding that all medical devices fall under 35 U.S.C. § 271(e)(1) and not only Class III medical devices, which are regulated under 35 U.S.C. § 156).

130. See *id.*

131. See *Proveris*, 536 F.3d at 1265 (deriving its conclusion based on a "symmetry," which was first introduced in *Eli Lilly*, between the products listed in 35 U.S.C. § 156(f) and 35 U.S.C. § 271(e)(1)).

The Federal Circuit in *Proveris* relied heavily on *Eli Lilly* when deciding to use a symmetrical approach between the two statutes;¹³² however, *Eli Lilly* was a broad holding stating that all products in 35 U.S.C. § 156(f) should be applied to § 271(e)(1).¹³³

Therefore, while the *Eli Lilly* court held that there needs to be symmetry between the two statutes, the more recent Federal Circuit decision in *AbTox* held that § 156(f) does not provide an exclusive list of patented inventions applicable to § 271(e)(1).¹³⁴ For that reason, applying the more recent reasoning in *AbTox* instead of the former reasoning in *Eli Lilly* might have lead the Federal Circuit to conclude that Innova's OSA was a "patented invention"¹³⁵ under the statutory language.¹³⁶

3. Terminating the evolving presumption that 35 U.S.C. § 271(e)(1) applies to research tools used in the submission of data to the FDA

Before the decision in *Proveris*, there existed case law that supported the proposition that research tools used in connection with the submission of data to the FDA were exempt from infringement under 35 U.S.C. § 271(e)(1).¹³⁷

In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, Rhone-Poulenc Rorer (RPR) filed suit against Bristol-Myers Squibb Company (Bristol) for use of RPR's patented chemical intermediates in Bristol's research and development program.¹³⁸

132. *See id.*

133. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 673-74 (1990).

134. *Compare Eli Lilly*, 496 U.S. at 673-74 (holding that all the inventions in § 201 of the Hatch-Waxman Act (codified in 35 U.S.C. § 156) should apply to § 202 (encoded in 35 U.S.C. § 271(e)(1))), *with AbTox*, 122 F.3d at 1029 (holding that, when interpreting § 271(e)(1), it is not required that § 156 be used as an exclusive guide). *See also Proveris*, 536 F.3d at 1263 (noting that the *AbTox* court adopted the broader holding that a "patented invention" under § 271(e)(1) "includes any medical device, regardless of its eligibility for patent term extension under § 156").

135. 35 U.S.C. § 271(e)(1) (2006).

136. *See Proveris*, 536 F.3d at 1265 (indicating that *Eli Lilly* was used as a guide in determining whether symmetry between the statutes was mandatory).

137. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95-CV-8833, 2001 WL 1512597, at *7 (S.D.N.Y. Nov. 28, 2001) (explaining that "[t]he case law holds that subsequent use of data developed for FDA approval does not violate Section 271(e)(1)"); *see also Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 466 F. Supp. 2d, 621, 625 n.2 (D. Md. 2006) ("Although the Classen process could be considered a 'research tool' the Court finds extension of the safe harbor to cover the use of these tools warranted by the language of *Merck* and a plain reading of the statute.").

138. *Bristol-Myers*, 2001 WL 1512597, at *1. RPR held U.S. Patent Re. No. 34,277 (the '277 patent) which "discloses and claims semi-synthetic processes for preparing the drug taxol . . . and four intermediates . . . obtained during and used in process claim 1." *Id.*

RPR claimed "[these] patented intermediates were used to assist Bristol's basic researchers in developing a structure-activity relationship . . . database, an important tool used by Bristol in its research."¹³⁹ Bristol's actions were designed for the eventual submission of the drugs to the FDA.¹⁴⁰

The district court determined that Bristol's use of RPR's patented intermediates in pharmaceutical discovery was exempt from infringement under 35 U.S.C. § 271(e)(1).¹⁴¹ The *Proveris* court implicitly overruled district court cases like *Bristol-Myers* and *Classen*.¹⁴² The court did so by holding that the test for "patented invention[s]"¹⁴³ eliminates safe harbor protection for certain research tools incorporated into drug products subject to FDA regulatory approval.¹⁴⁴ Under the *Meyers* decision, a patented research tool falls under the scope of "patented invention[s]"¹⁴⁵ and is protected by 35 U.S.C. § 271(e)(1).¹⁴⁶ However, under the *Proveris* standard, the use of a patented chemical intermediate is not protected because these intermediates are not "products" within the meaning of the patent term extension provision.¹⁴⁷ The aerosol sprays in *Proveris* were subject to FDA regulatory approval even though they incorporated the use of a research tool, Innova's OSA.¹⁴⁸ Although the OSA is not a "product" under the patent term extension provision, it should be considered a "patented invention" under § 271(e)(1) because it becomes an inseparable

139. *Id.* at *4.

140. *Id.* at *5.

141. *Id.* at *8.

142. *See Classen Immunotherapies*, 466 F. Supp. 2d at 625 n.2 (noting that the Supreme Court's language in *Merck* and a literal interpretation of the statute warrants that, although the *Classen* process could be considered a "research tool," the safe harbor provision of 35 U.S.C. § 271(e)(1) covers the use of these tools).

143. 35 U.S.C. § 271(e)(1) (2006).

144. *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008).

145. 35 U.S.C. § 271(e)(1) (2006).

146. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95-CV-8833, 2001 WL 1512597, at *2 (S.D.N.Y. Nov. 28, 2001) (stating that "[n]othing in the text of Section 271(e)(1) indicates that Congress intended to restrict the scope of the term 'patented invention' to those products covered by Section 156. . . . [P]atented invention in 271(e)(1) is defined to include all inventions, not drug-related inventions alone").

147. *See* 35 U.S.C. § 156(f) (declaring that a "product" consists of a drug product, medical device, food additive, or color additive that requires regulation under the FDCA); *Proveris*, 536 F.3d at 1265-66.

148. *Proveris*, 536 F.3d at 1259, 1265 (noting that the OSA measured the physical parameters of aerosol sprays used in nasal spray drug delivery devices which are subject to FDA approval).

factor in the development of a drug product that is subject to FDA approval.¹⁴⁹

4. Application of the "reasonably related" standard in 35 U.S.C. § 271(e)(1)

The Federal Circuit rejected Innova's argument that the OSA was exempted from infringement because it was "solely for uses reasonably related to the development and submission of information" to the FDA.¹⁵⁰ Focusing squarely on Innova's use of the OSA would demand that the Federal Circuit reverse its holding and allow protection from infringement under 35 U.S.C. § 271(e)(1). A literal interpretation of the statute would exempt the use of a patented invention from infringement as long as the sole use is reasonably related to the development and submission of information to the FDA (Federal law).¹⁵¹ However as seen before, "reasonably related" is a standard that has historically been fulfilled rather easily.¹⁵²

Innova manufactured and sold its OSA device to third parties "solely for the development and submission of information to the FDA."¹⁵³ As long as Innova had a reasonable basis to believe that the OSA would be used in tests that would be appropriate to include in a submission to the FDA, it should be awarded the protection of § 271(e)(1).¹⁵⁴ Given the precedent set by the United States Supreme Court in *Merck*, the *Proveris* Court should have held that Innova's use of the OSA was exempted from infringement under § 271(e)(1)'s "reasonably

149. *Cf. Bristol-Myers*, 2001 WL 1512597, at *5 (noting the possible creation of new drugs via the use of analogs that incorporate structural changes to existing drugs in order "to acquire additional knowledge about how structural changes and features affect the activity and properties of compounds.").

150. *See Proveris*, 536 F.3d at 1266 (rejecting Innova's argument because it was based on the faulty premise that the device claimed in the '400 patent was a "patented invention" under section 271(e)(1)).

151. *See* 35 U.S.C. § 271(e)(1) (2006).

152. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206-07 (2005) (holding that § 271(e)(1)'s exemption from infringement is broad enough to include experimentation on drugs that are not ultimately the subject of an FDA submission or use of patented compounds in experiments that are not ultimately submitted to the FDA); *see also* *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992) (holding that the demonstration of a patented invention at a medical conference to find investigators to conduct clinical trials was reasonably related to the development and submission of information).

153. *Proveris*, 536 F.3d at 1260.

154. *See Merck*, 545 U.S. at 206-07 (declaring that "a reasonable basis for believing" that a product will be used in the submission is all that is necessary to be awarded the protection of 35 U.S.C. § 271(e)(1)).

related" standard because it fit "squarely within the statutory language."¹⁵⁵

B. *Dangers of Narrowing the Scope of the Generic Drug Manufacturer's Patent Infringement Protection under 35 U.S.C. § 271(e)(1)*

The *Proveris* decision supports the concept that a patented invention, which itself is not subject to FDA approval prior to market entry, but was designed solely to enhance the quality of research and development of a drug that is subject to FDA approval, is not awarded protection under 35 U.S.C. § 271(e)(1).¹⁵⁶ This loss of protection and increase in liability will decrease the incentive for generic drug manufacturers to innovate in the pharmaceutical industry.¹⁵⁷ Furthermore, narrowing the scope of infringement protection under § 271(e)(1) could lead to higher prices for pharmaceutical products and an implicit denial of affordable healthcare to many Americans.

1. Possible Loss of Generic Pharmaceutical Development to Foreign Countries

The United States will risk losing its generic pharmaceutical industry to foreign markets if a stronger form of statutory protection for innovative research is not established.¹⁵⁸ Compared to the United States, foreign countries like Japan have broad research and experimental exceptions that permit the use of a patented product.¹⁵⁹ The broad research exceptions to patent infringement in foreign countries enable both pioneer and generic drug manufacturers "to perform preclinical research abroad,

155. See *Proveris*, 536 F.3d at 1266 (noting Innova's argument that "its offering for sale and its sale of the OSA device fit squarely within the statutory language because, like the product claimed in the '400 patent, the OSA is used in a way which is 'reasonably related' to the 'development and submission of information' pertinent to the FDA premarket approval required for inhaler-based drug delivery devices"). The Court declined to accept this argument because it found the OSA was not a "patented invention" under § 271(e)(1). *Id.*

156. See *id.*

157. Cf. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) ("The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'").

158. Alison Ladd, *Integra v. Merck: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & POL'Y 311, 353 (2005) (proposing that the loss of the pharmaceutical industry to foreign countries could be prevented by either "applying a research exemption to new drug development or by implementing a low-cost tool licensing program").

159. *Id.*

beyond the reach" of the U.S. patent infringement statutes.¹⁶⁰ For instance, the Federal Circuit's opinion in *Proveris* would make it more beneficial for a generic drug manufacturer to innovate in Japan rather than in the United States.¹⁶¹ Contrary to the United States system, the Japanese experimental use exception is not limited to inventions that require FDA or other government approval.¹⁶² In Japan, the exception to infringement covers both "experiments that result in an advancement in technology," and those for research, including research that does not advance technology.¹⁶³

Contrary to the narrow application of 35 U.S.C. § 271(e)(1) in *Proveris*, the broad application of the Japanese experimental use exception authorizes many advantageous experimental uses such as "investigating the patentability of an invention, analyzing the function of an invention, and developing and improving on an invention."¹⁶⁴ Therefore under *Proveris*, it would be beneficial for the pioneer drug manufacturer to patent in the United States; however, the generic drug manufacturer who intends to use a patented invention which is not subject to FDA approval would more likely find it beneficial to innovate in a country like Japan.

2. Potential Inflation of Pharmaceutical Products

The cost of pharmaceutical drugs is a concern for most American consumers, as the pharmaceutical drug market has become an industry with sales well over \$100 billion a year.¹⁶⁵ As long as a pioneer drug manufacturer has exclusive control of the market because of a patent, it can effectively set the price of the pharmaceutical product without the threat of competitive prices.¹⁶⁶ Moreover, this control over the marketplace is so

160. *Id.*

161. *Compare* *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008) (ruling that the OSA was not exempt from infringement because the device in the '400 patent was not subject to FDA approval), *with* Jennifer A. Johnson, *The Experimental Use Exception in Japan: A Model for U.S. Patent Law?*, 12 PAC. RIM L. & POLY J. 499, 519 (2003) (explaining that Japan's statutory experimental use exception covers all inventions and is not expressly limited to experimentation in generic drug testing or inventions requiring government approval).

162. Johnson, *supra* note 161, at 519.

163. *Id.* (stating that "this requirement may not be difficult to satisfy, as making a generic drug formulation of a patented drug is not a monumental scientific accomplishment").

164. *Id.*

165. David Noonan, *Why Drugs Cost So Much*, NEWSWEEK, Sept. 25, 2000, at 22.

166. See Laura Giles, *Promoting Generic Drug Availability: Reforming the Hatch-Waxman Act to Prevent Unnecessary Delays to Consumers*, 75 ST. JOHN'S L. REV. 357, 360 (2001).

important to pioneer drug manufacturers that there have been instances of negotiations whereby generic drug companies receive a large payout in exchange for not releasing their products.¹⁶⁷

Because *Proveris* restricts a generic drug manufacturer from using a patented product that itself is not subject to FDA approval, it will be harder for the generic manufacturer to enter the marketplace.¹⁶⁸ As a result, most pioneer drug manufacturers are able to maintain "significant price premiums over their generic competitors."¹⁶⁹ By not allowing a generic drug manufacturer to use all patented products in an attempt to achieve FDA approval, it will be more challenging for the generic manufacturer to get the generic drug into the marketplace. Any delay in the marketing of generic drugs is of direct interest to a consumer because "availability of a generic alternative can mean a price savings for consumers equal to one quarter of the price of the brand-name drug."¹⁷⁰ The fact of the matter is that generic drugs are capable of capturing "80-90% of the market, often within months of entering the marketplace" after a pioneer drug patent expires.¹⁷¹ The *Proveris* decision has the potential of prolonging this generic drug entry into the marketplace, and thus maintaining the pioneer manufacturer's control over inflated drug price

3. Implicit Denial of Affordable Healthcare to Americans

In the past decade, the United States healthcare debate has shifted some of its focus to patent law.¹⁷² Former President George W. Bush proposed new regulations in an attempt to bring cheaper drugs to the market more quickly by "removing legal loopholes that pioneer drug companies have exploited" to theoretically extend their patent monopolies.¹⁷³ There stands an

167. See *id.* at 369-70 ("Pioneer companies collude with generics as a market control strategy to prevent competition.").

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

169. Mark P. McKenna, *An Alternative Approach to Channeling?*, 51 WM. & MARY L. REV. 873, 883 (2010).

170. Andrew A. Caffrey & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA. J.L. & TECH. 1, 3 (2004); see also Saul, *supra* note 4.

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

172. Johnson, *supra* note 161, at 499; see also Saul, *supra* note 4.

173. Johnson, *supra* note 161, at 499 (recognizing that these proposed regulations were to "reduce the cost of prescription drugs in America by billions of dollars and ease

immeasurable significance in containing the cost of healthcare in a reform proposal with the cost and availability of generic drugs.¹⁷⁴ As long as a pioneer drug is able to maintain exclusive control over the marketplace with its patented drug through settlements with generic drug manufacturers, the growing cost of healthcare will persist.¹⁷⁵ Therefore, if the Obama Administration persists on providing public healthcare, a reasonable goal for the administration would be to explore "access to cheaper biologic therapies whose patent terms have expired."¹⁷⁶

However, there must be a balance in placing cheaper generic solutions on the market with protecting the pioneer drug manufacturer's Constitutional right to exclusivity.¹⁷⁷ The *Proveris* holding tilts the balancing scale in the direction of protecting the pioneer drug manufacturer's right to exclusivity by disallowing generic drug manufacturers to use third party patent infringing inventions designed to enhance the quality of research for submitting an ANDA to the FDA.¹⁷⁸ As a result, the generic drug manufacturer will have to use additional methods of testing its drug which will result in a delay to market entry.¹⁷⁹ Any delay in market entry by generic manufacturers will theoretically extend the length of the pioneer patent,¹⁸⁰ which in turn will result in unaffordable healthcare for many Americans because the pioneer drug will have exclusive control of the market for a lengthier time period.¹⁸¹

the financial burden for many citizens, especially our seniors"); see generally Poché, *supra* note 38, at 912-13 (recognizing that delayed entry of generic drugs into the market place theoretically extended the period of the inventor's patent on the pioneer drug).

174. See Saul, *supra* note 4.

175. See, e.g., Rochelle Cooper Dreyfuss & Lawrence S. Pope, *Dethroning Lear? Incentives to Innovate After MedImmune*, 24 BERKELEY TECH. L.J. 971, 990 (2009) (comparing situations when generic drug manufacturers are paid not to challenge patents on pharmaceutical products with the price of healthcare and the specific pharmaceutical product).

176. John A. Tessensohn & Shusaku Yamamoto, *Japanese Biotech Patenting Strategies in the Era of Follow-On Biologics*, 28 BIOTECHNOLOGY L. REP. 483, 484 (2009).

177. See Mary Ann Liebert, *Dean Argues for 12-Year Term on Biologics Patents*, 28 BIOTECHNOLOGY L. REP. 529, 529 (2009) (referring to a speech given by former Governor of Vermont Howard Dean stating "although competition [in the pharmaceutical industry] can expand access to and reduce the cost of cutting-edge drugs, if the initial breakthroughs are not supported by adequate patent protection, innovation in America will die").

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

179. See *id.* at 1265-66.

180. See discussion *supra* Part II.B.2.

181. See discussion *supra* Part IV.B.2.

V. PROPOSITION: BALANCING THE NEED FOR A STRONGER
GENERIC HEALTHCARE MARKET WITH THE RIGHTS OF PATENT
HOLDERS

Affordable healthcare via inexpensive pharmaceutical products has a conflicting correlation with disallowing generic drug manufacturers to use patented inventions that are not subject to FDA approval in their research.¹⁸² Differing views on how to address this correlation include expanding the scope of the experimental use exception,¹⁸³ establishing research tool patent consortiums,¹⁸⁴ and establishing mandatory licensing of research tool patents.¹⁸⁵ These views address the more specific problem in biotechnology research and the use of patented products not subject to FDA approval used in the research. However, a solution that benefits the public in the healthcare and pharmaceutical industries is needed. Moreover, this solution must allow generic manufacturers to use all "patented invention[s]"¹⁸⁶ when developing data to submit to the FDA while also adequately protecting the rights of patent holders.

A. *Congressional legislation clearly defining the term "patented invention" under 35 U.S.C. § 271(e)(1) to incorporate all patented inventions*

As discussed above, affordable healthcare supports the proposition that generic drug manufacturers will be able to use all patented inventions during their research and development of

182. See Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 585 (2003) (suggesting that the Act was enacted as a "compromise between the competing interest of promoting innovation and fostering competition in the pharmaceutical industry"); see also H.R. REP. NO. 98-857, pt. 2, at 30 (1984) (noting "[t]he committee has merely done what the Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering public interest").

183. See Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 9 (2001) (suggesting a broadening interpretation of the experimental research exception because of the increasing difficulty in accessing research tools in the increasing patent activity in biotechnology).

184. See Thomas P. Noud & Paul T. Meiklejohn, *The Developing Law of Pharmaceutical Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 921, 962-63 (2005) (recognizing that development of new drugs requires complex research tools) (citing Brief for Invitrogen Corp., et al., as Amici Curiae In Support Of Respondents at 9, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S.Ct. 2372 (2005) (No. 03-1237)).

185. See, e.g., Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 89-91 (2004) (suggesting a mandatory licensing system for patented inventions used in research that includes a period of exclusivity ensued by the mandatory licensing period).

186. See 35 U.S.C. § 271(e)(1) (2006).

information to submit to the FDA.¹⁸⁷ However, the *Proveris* decision limited the term "patented invention"¹⁸⁸ to consist only of the products listed in § 156(f).¹⁸⁹ The *Proveris* Court would have to give authority to the literal meaning of § 271(e)(1) if it felt that it was clear and unambiguous.¹⁹⁰ Therefore, if Congress was to amend the language of § 271(e)(1), generic drug manufacturers would be able to use any patented invention in their research and development.¹⁹¹

If Congress clearly defined "patented invention" under § 271(e)(1) to include all patented inventions, this would encompass those inventions that are not subject to FDA approval themselves, but designed to enhance the quality of the research conducted on products that are subject to FDA approval.¹⁹² Legislation establishing that all patented inventions fall within § 271(e)(1) will lower the transactional fees with pharmaceutical research and development programs.¹⁹³ This reduction in transactional fees will allow generic manufacturers to get a generic drug on the market quicker, which in turn will reduce the price of drugs.¹⁹⁴ Because § 271(e)(1) only applies to manufacturers who must submit information to the FDA prior to market entry, allowing the use of all patented inventions will have a minimal effect on the patent holder.¹⁹⁵ Furthermore, if the research performed by a generic drug manufacturer is not "reasonably related" to the development and submission of information to the FDA, the patent holder will have a cause of action against the manufacturer.¹⁹⁶ This legislation will also protect the patent holders whose patents are being used if the

187. See discussion *supra* Part IV.B.3.

188. See 35 U.S.C. § 271(e)(1) (explaining that the term "patented invention" refers to what can be used by generic drug manufacturers in their research and development for submitting data to the FDA); *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008).

189. See *Proveris*, 536 F.3d at 1265 (referring to *Eli Lilly* and stating that there must be a "perfect product fit" between § 156(f) and § 271(e)(1)).

190. See discussion *supra* Part IV.A.1.

191. See *id.*

192. See 35 U.S.C. § 271(e)(1) (2006).

193. See Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 152 (2004) (discussing the cost in obtaining a patent).

194. See *id.* ("The potential monopoly power that a patent provides allows the patentee to increase a patented invention's price beyond the competitive market price, thus reducing the supply of the patented invention."); see also discussion *supra* Part IV.B.2.

195. See 35 U.S.C. § 271(e)(1) (2006); see also *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1260-61 (Fed. Cir. 2008).

196. See 35 U.S.C. § 271 (e)(1).

use continues after FDA approval is granted.¹⁹⁷ In conclusion, Congressional legislation amending what constitutes a patented invention under § 271(e)(1) to include all patented inventions will make healthcare more affordable via providing easier marketability of cheaper generic drugs, while also providing adequate protection to the patented invention being used.

B. *Federal Circuit or Supreme Court decision incorporating into 35 U.S.C. § 271(e)(1) all patented inventions that are inherent to the manufacture of a product requiring FDA approval*

Another solution to the healthcare dilemma pioneered by the *Proveris* decision is incorporating all patented inventions that are inherent to the manufacture of "products" as defined in § 156(f) into § 271(e)(1).¹⁹⁸ Not only will this provide broader protection for generic drug manufacturers seeking FDA approval, but will also be in harmony with the earlier Supreme Court decision in *Merck*.¹⁹⁹ A judicial opinion of this magnitude would not only decrease the cost of pharmaceutical drugs and hence lower the cost of healthcare,²⁰⁰ but it would provide many of the same protections to a patent owner whose invention is being used as the amended Congressional legislation previously mentioned.²⁰¹

Because all patent-related cases are appealed to the Federal Circuit, only the Federal Circuit and the Supreme Court of the United States have the power to render such a judicial opinion overruling *Proveris*.²⁰² If either the Federal Circuit or Supreme Court incorporate into 35 U.S.C. § 271(e)(1) all patented inventions that are inherent to the manufacture of a product

197. See Stephen B. Maebius & Harold C. Wegner, *Merck v. Integra: The Impact of a Broader "Safe Harbor" Exemption on Nanobiotechnology*, 2 NANOTECH. L. & BUS. 254, 257 (2005).

198. Recall that the *Proveris* Court held that Innova's OSA was not exempt from infringement because it was not a product intended to be protected under 35 U.S.C. § 156. See *Proveris*, 536 F.3d at 1265.

199. See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2004) (implying that as long as a patented invention is reasonably related to the submission of data to the FDA the use is protected under § 271(e)(1)).

200. If a generic drug manufacturer is allowed to use all patented inventions inherent to the development of its generic drug (a "product" covered in § 156(f)), then the generic drug will have a more effective and faster entry to the market, resulting in lower drug prices. See discussion *supra* Part IV.B.2.

201. These protections include limiting the use of a patent only to those seeking FDA approval of product and maintaining a cause of action if the patented product is used after FDA approval is granted. See discussion *supra* Part V.A.

202. See BLACK'S LAW DICTIONARY 672 (3rd Pocket ed. 2006) (defining *stare decisis*: "[t]he doctrine of precedent, under which . . . a court must follow earlier judicial decisions when the same points arise again in litigation").

requiring FDA approval, a decrease in the cost of pharmaceutical products and healthcare is almost evident to result.²⁰³

VI. CONCLUSION

The Federal Circuit narrowed the scope of 35 U.S.C. § 271(e)(1) by excluding inventions that are not themselves subject to FDA approval, even if the use of this invention was to submit information to the FDA.²⁰⁴ This exclusion will cause generic drug manufacturers to find other, and perhaps more expensive, ways to get their drugs approved by the FDA.²⁰⁵ As a result, pharmaceutical drugs and healthcare in general will become more expensive.²⁰⁶ The solution to this increase in cost of pharmaceutical products and healthcare is Congressional legislation²⁰⁷ or judicial action²⁰⁸ incorporating all patented inventions in general in 35 U.S.C. § 271(e)(1). An alternative solution would be incorporating all patented inventions that are inherent to the manufacture of products as defined in 35 U.S.C. § 156(f).²⁰⁹

Christopher Scurry

203. See discussion *supra* Part IV.B.2-3.

204. See *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008).

205. See discussion *supra* Part IV.B.2.

206. See *id.*; see also discussion *supra* Part IV.B.3.

207. See discussion *supra* Part V.A.

208. See discussion *supra* Part V.B.

209. *Id.*