Medical Device Eligibility for the Statutory Experimental Use Exception to Patent Infringement

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Medical Device Eligibility for the Statutory Experimental Use Exception to Patent Infringement

by

VERONICA LANIER*

Table of Contents

I. Background ............................................. 707
   A. History of Medical Device Regulation ............. 707
   B. Roche v. Bolar ................................ 710
II. The Drug Price Competition and Patent Term Restoration Act of 1984 ................................ 711
   A. Patent Term Extension .......................... 712
   B. Experimental Use Exception ..................... 713
III. Judicial Interpretation of the Statutory Experimental Use Exception ............................... 714
   A. Lilly v. Medtronic ................................ 714
   B. Baxter v. AVL .................................. 718
IV. Proposed Eligibility Determination for the Experimental Use Exception ......................... 721
   A. Statutory Basis .................................. 721
   B. Judicial Interpretations of Experimental Use Exception Support Proposed Eligibility Determination ................................................. 725
      1. Lower Courts .................................. 725
      2. Supreme Court ................................ 726
         a. Analysis of Statutory Framework .......... 726
         b. Infant Formula Regulations ............ 729
         c. Medical Device Classification .......... 731
   C. Public Policy ..................................... 732
      1. Commentators ................................ 732
      2. Congress .................................... 734
V. Conclusion ............................................. 736

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Introduction

The federal patent laws grant to an inventor the right of exclusive manufacture, use, or sale of his patented invention.\(^1\) Any unauthorized activities constitute infringement. However, early nineteenth century courts formulated an exception to patent infringement for "philosophical experiment[s]," or activities undertaken to "ascertain the verity and exactness of the specification[s]" of the patented invention.\(^2\) As the common law experimental use doctrine developed, the infringement inquiry came to focus on the harm to the pecuniary interest of the owner of the patented invention.\(^3\) Later courts defined infringement in terms of the pecuniary gain to the infringer or the pecuniary loss to the patentee.\(^4\)

In contrast to the common law, the Patent Act of 1952\(^5\) codifies the infringement provision\(^6\) but does not recognize any court-created exception. The Drug Price Competition and Patent Term Restoration Act of 1984\(^7\) (1984 Act) carves out a limited experimental use exception for products for which commercial exploitation is delayed by regulatory requirements imposed by the Federal Food, Drug, and Cosmetic Act (FDCA).\(^8\)

Although the statutory language of the 1984 Act clearly extends the experimental use exception to drug products,\(^9\) the threshold requirements for the exception leave questions about the eligibility of
other products regulated by the FDCA, such as medical devices. The Supreme Court, in *Eli Lilly & Co. v. Medtronic, Inc.*, held that medical devices are eligible for the experimental use exception, but did not address the application of the exception to particular classes of medical devices. This distinction is crucial, because eligibility for the experimental use exception hinges on FDCA regulatory approval requirements. While all new drug products must undergo extensive pre-approval clinical testing, medical devices are subject to varying premarket requirements under the FDCA. One court's interpretation of the 1984 Act restricts the experimental use exception to medical devices subject to the same premarket testing requirements as drugs.

This Note proposes an alternate analysis to determine applicability of the experimental use exception to medical devices. The Note begins by reviewing the history of medical device regulation under the FDCA. The Note then examines the codification of an experimental use exception to infringement and analyzes pertinent judicial interpretations of the exception. The author argues that the eligibility inquiry for a medical device should be based on a case-by-case analysis of the pre-approval requirements for the particular medical device, and concludes by demonstrating legislative, judicial, and public policy support for this interpretation of the statutory experimental use exception.

I

Background

A. History of Medical Device Regulation

The 1976 Medical Device Amendments to the FDCA define a medical device as:

an instrument, apparatus, implement, machine, contrivance, implant . . . or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . [or] intended to affect the structure or any function of the body of man . . . and which does not achieve any of its principal intended purposes through chemical action within or on the body.

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11. *Id.* at 673, 678.
12. See discussion of the 1984 Act infra part II.B.
Medical devices have been subject to some rudimentary regulation since 1938, but not until the passage of the 1976 Amendments did Congress establish a comprehensive regulatory scheme for medical devices. The 1976 Amendments direct the Food and Drug Administration (FDA) to assign each medical device to one of three categories based on the degree of regulatory oversight the Agency considers necessary to ensure safety and efficacy. Requirements necessary to ensure safety and effectiveness are to be determined on a case-by-case basis by conducting a risk-benefit analysis to assess the potential reasonable risk of illness or injury.

Under the classification scheme established by the 1976 Amendments, Class I devices require only general controls, such as good manufacturing practices and protection against adulteration and mislabeling, to provide sufficient assurance of safety and efficacy. Class I controls also require manufacturer and product registration with the FDA, and impose general recordkeeping and reporting requirements on the manufacturer of the medical device.

Under the 1976 Amendments, all Class II medical devices are regulated by performance standards established by the FDA to assure safety and effectiveness. Performance standards include any re-

17. The 1938 Act extended federal regulatory authority to medical devices, but neither the 1938 Act nor the 1962 Amendments, requiring medical device manufacturers to demonstrate both safety and efficacy of their products, contained any provisions for premarket review and approval of medical devices. Action could be taken against the manufacturer of a medical device only after the device was commercially marketed and after it was shown to be misbranded or adulterated. 21 U.S.C. § 360f (1988 & Supp. V 1993).


19. “For purposes of determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval . . . the Secretary shall classify all such devices into . . . the classes established.” 21 U.S.C. § 360c(b)(1) (1988).

20. Id. § 360c(a).

21. Class I medical devices include such simple instruments as tongue depressors and thermometers.

22. Id. § 360c(a)(1)(A). Class I controls also require registration of the device and manufacturer, and impose general recordkeeping and reporting requirements on the medical device manufacturer.


24. Examples of Class II medical devices are hearing aids, catheters, and most in vitro diagnostic instruments, such as x-ray machines.

25. Id. § 360c(a)(1)(B). At the time of the litigation between Lilly and Medtronic, performance standards for medical devices were discretionary with the FDA—even, pre-
requirement FDA considers necessary. For example, there are provisions regarding the “construction, components, ingredients, and properties” of a device, provisions for testing the device and measuring performance characteristics, and requirements that results of any mandatory testing actually establish that the device is in compliance with the applicable performance standard. After a performance standard has been established for a medical device, a device may not be marketed unless it is in compliance with the requirements of the performance standard. Class II controls can require the submission of clinical data as part of the premarket notification requirements for a device.

Class III medical devices are those devices for which there is insufficient data to establish performance standards or other blanket requirements to assure safety and efficacy, or they are devices used in a life-support or other critical medical system. Class III devices require clinical investigations involving human subjects to establish their safety and efficacy.

sumably, upon a determination that they were necessary to ensure safety and efficacy. When, as of 1987, the FDA had not promulgated a single performance standard for any medical device, it became clear that the statutory requirement of performance standards would be unworkable in practice. A 1990 amendment to the FDCA now provides for the establishment of such “special controls” as the FDA considers necessary to provide “reasonable assurance” of safety and efficacy of a Class II or Class III medical device. The special controls required of Class II and applicable Class III devices may include performance standards, patient registries, postmarket surveillance, and FDA guidelines for use. Id. § 360c(a)(1)(B).

26. Id. § 360d(a)(2)(B).
29. Id. § 360c(a)(1)(C).
30. 21 C.F.R. § 812.3(p), (h) (1994).
31. 21 U.S.C. § 360e(c)(1) (1988). Clinical investigations require an Investigational Device Exemption (IDE) and Institutional Review Board approval from each institution at which clinical studies are to be conducted. An IDE exempts the medical device from requirements such as reporting, registration, and proof of safety while the pre-approval clinical investigations are being conducted. Although an IDE is generally associated with the approval requirements for a Class III device, the statute and FDA regulations anticipate that any medical device can require an IDE to conduct the studies necessary to establish safety and efficacy. 21 U.S.C. § 360j(g) allows the FDA to exempt a device from registration and reporting requirements (applicable to devices in all classes), performance standards and special controls (applicable to Class II and Class III devices), and the premarket approval requirements for Class III devices. FDA regulations promulgated pursuant to § 360j apply the IDE requirements to most medical devices introduced after the passage of the 1976 Amendments. 21 C.F.R. § 812.2 (1980).
B. Roche v. Bolar

The common-law experimental use doctrine is rarely invoked successfully as a defense to infringement, although courts disagree on the breadth of the exception. The Ninth Circuit Court of Appeals, for example, has allowed the experimental use defense only in rare cases where it finds no commercial purpose—but that court has usually found some ultimate commercial purpose in any activity by a commercial enterprise. In contrast, the Second Circuit Court of Appeals focused its inquiry on enrichment to the accused infringer. This inquiry allowed for broader application of the experimental use exception.

Shortly after its creation in 1982, the Court of Appeals for the Federal Circuit addressed the issue of interpreting the experimental use exception. In Roche Products, Inc. v. Bolar Pharmaceutical Co.—a case of first impression—the Federal Circuit adopted the Ninth Circuit’s narrow interpretation. Roche Corporation held the patent on a drug which Bolar Pharmaceutical imported to conduct the clinical investigations required for obtaining FDA approval to market a generic version of Roche’s drug. When Roche sued for patent infringement, Bolar argued that because its generic drug would not be introduced until after the expiration of Roche’s patent, its activities were not infringing because there was no pecuniary gain or loss to either party during the term of the patent. Bolar also defended its activities by arguing that Congress did not intend the approval requirements for heavily regulated products (such as drugs) to effectively grant the patent holder a de facto monopoly past the statutory 17-year term by preventing lower-cost generic alternatives from

32. Israelsen, supra note 3, at 460. See also Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017, 1019 (1989). Eisenberg would interpret the experimental use exception to allow subsequent use in basic research. Id. at 1017. Israelsen would allow development and patenting of improved inventions and designing around patented inventions, regardless of commercial motivation. Israelsen, supra note 3, at 475.

36. Roche, 572 F. Supp. at 256.
37. Id. at 257.
reaching the market immediately upon the expiration of a patent. The district court broadly interpreted the common-law experimental use exception, finding that "commercial experiments without profit, manufacture, or sale during the patent term" did not constitute patent infringement.

Roche appealed and the Federal Circuit reversed, rejecting both of Bolar's arguments. First, the court found a patentee's rights violated by any unauthorized use "solely for business reasons... conducted with a view to the adaptation of the patented invention to the experimenter's business." The court concluded that the scientific inquiry protected by the common-law experimental use exception did not extend to activities with "definite, cognizable, and not insubstantial commercial purposes." Addressing the special circumstances presented by regulatory requirements, the Federal Circuit declined to "engage in legislative activity proper only for the Congress" by carving out an infringement exception for drug patents. The court's reluctance was attributable in part to several bills that were then pending in Congress to address the regulatory delay, and to public policy issues raised by defendant Bolar. Nevertheless, the Federal Circuit's narrow interpretation of the experimental use exception and its refusal to dabble in judicial lawmaking was significant because it focused congressional attention on the effects of the increasing regulatory demands imposed by the FDCA.

II

The Drug Price Competition and Patent Term Restoration Act of 1984

Congress combined the two bills to which the Federal Circuit had deferred in Roche, and enacted them as the Drug Price Competition and Patent Term Restoration Act of 1984. Title I of the 1984 Act amends the food and drug laws to allow faster marketing of generic

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38. Id. At the time, testing and FDA approval of an equivalent for an already established drug could require more than two years. Id.
39. Id. at 258.
40. Roche, 733 F.2d at 863.
42. Roche, 733 F.2d at 864.
43. Id. at 865.
44. 1984 Act, supra note 7.
Title II contains two amendments to the 1952 Act. The first amendment adds § 156 to the patent term provision of the 1952 Act. This amendment allows the patent holder of a product “subject to a regulatory review period before its commercial marketing or use” to obtain an extension of the product’s patent term to partially compensate for the regulatory delay in obtaining marketing approval. The second amendment contained within the 1984 Act amends 35 U.S.C. § 271—the statutory patent infringement provision.

A. Patent Term Extension

Under § 156, only drug products, medical devices, food additives, or color additives subject to regulation under the FDCA are eligible for patent term extension. The regulatory review period that is a prerequisite for patent term extension is defined for a medical device as the sum of the testing phase and the approval phase. Regulations define the regulatory review period specifically in terms of approval requirements for a Class III medical device.

In addition, the patent term restoration provision of the 1984 Act imposes various other restrictions on patent term extension: new animal drugs and veterinary biological products are specifically excluded; the patent holder must pursue FDA approval with due diligence; and the patent holder may only recoup one-half of the patent term lost during the testing phase. Finally, the term of the extension is limited to five years regardless of the length of time actually lost to the regulatory review period.
B. Experimental Use Exception

The statutory experimental use exception, § 271(e)(1), provides that “[i]t shall not be an act of infringement to make, use, 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.”56 Unlike the patent term extension provision, the language of the experimental use exception does not identify the products eligible for the exception. House Reports from both the Committee on Energy and Commerce57 and the Committee on the Judiciary58 accompanying the bill mention only an experimental use exception for drugs.

The Energy and Commerce Committee report explains that the purpose of § 271(e)(1), the experimental use exception, is “to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.”59 The report specifically addresses the Federal Circuit’s holding in Roche which found such use infringing: “[i]t is the Committee’s view that experimental activity does not have any adverse economic impact on the patent owner’s exclusivity during the life of a patent, but prevention of such activity would extend the patent owner’s exclusivity beyond the patent expiration date.”60 A minority view found Roche “sound law” and argued against cutting back on patent rights granted by the 1952 Act.61

The Judiciary Committee report also discusses § 271(e)(1) only in terms of drugs. The purpose of the provision, according to the Judiciary Committee, is to create a “general exception to the rules of patent infringement” for a generic manufacturer to conduct clinical tests required to establish bioequivalency with a pioneering drug.62 “Thus, 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 these tests is to submit an application to the FDA for approval.”63 The report cautions, however, that “the only activity which will be permitted by the bill is a limited amount of testing so that the generic manufacturer can establish bioequivalency of a generic prod-

56. Id. § 271(e)(1).
60. Id. at 46.
61. Id. at 74-75.
63. Id.
uct.” With those restrictions, the report concludes, “the nature of the interference is de minimis” and “necessitated by the very nature of the industry involved.”

III
Judicial Interpretation of the Statutory Experimental Use Exception

Early litigation over the interpretation and application of the statutory experimental use exception focused exclusively on patented drug products, and the exception was narrowly interpreted. More recently, courts, including the Federal Circuit, have acknowledged Congressional intent to create a broad exception to patent infringement. In 1990 the Supreme Court, in *Eli Lilly & Co. v. Medtronic, Inc.*, held that the statutory experimental use exception of the 1984 Act extended to medical devices.

A. *Lilly v. Medtronic*

Plaintiff Eli Lilly held the patent for an implantable cardiac defibrillator, a Class III medical device. During the term of Lilly’s patent, defendant Medtronic developed and began clinical trials on its own defibrillator which improved on Lilly’s technology but was not independently patentable. When Lilly sued for infringement under § 271, Medtronic defended by claiming that its activities were undertaken to develop and submit information required for premarket approval of the device under the FDCA, and thus were exempt under § 271(e)(1) from a finding of infringement. Lilly countered by arguing that the plain language of the statute denied the infringement excep-

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64. *Id.* at 8.
65. *Id.*
66. *Id.* at 30.
67. Scripps Clinic v. Genentech, Inc., 666 F. Supp. 1379, 1395-96 (N.D. Cal. 1987), rev’d on other grounds, 927 F.2d 1565 (Fed. Cir. 1991) (requiring any manufacture, use, or sale to be solely for uses related to obtaining FDA approval for a generic product).
71. *Id.* See also *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404 (Fed. Cir. 1989) (reviewing the history of litigation in the lower court).
tion to medical devices.\textsuperscript{72} The district court agreed, finding that § 271(e)(1) applied to drug products only.\textsuperscript{73}

The Federal Circuit reversed, finding the statutory language "fraught with ambiguity,"\textsuperscript{74} and based its holding on interpretation of Congressional intent. The court concluded that "[t]he clear intent of Congress was to create an \textit{FDA experimental use exception} for use which \textit{Roche} had held would constitute infringement under section 271(a)."\textsuperscript{75} The Supreme Court granted certiorari to resolve the question whether 35 U.S.C. § 271(e)(1) protects from infringement those activities undertaken for the purpose of developing and submitting information to the FDA to obtain premarket approval for a Class III medical device.\textsuperscript{76}

The controversy specifically involved the interpretation of the reference in the statutory exception to "a Federal law which regulates the manufacture, use, or sale of drugs."\textsuperscript{77} Lilly argued that the phrase referred only to the individual statutory provisions regulating drugs in a federal law; Medtronic maintained that the phrase referred to the entirety of any federal law that contained provisions regulating drugs.\textsuperscript{78} The Court acknowledged that either interpretation was possible, but characterized Medtronic's as “preferable,” finding that the passage “more naturally summons up the image of an entire statutory scheme of regulation.”\textsuperscript{79} On the other hand, the Court acknowledged, it was also difficult to imagine why Congress would want to open the experimental use exception to any patented invention regulated by any federal law that also happened to contain even a single provision

\textsuperscript{72} Lilly was not without support for its contention. An early commentary on the 1984 Act concluded that “[h]is provision is limited to human drug products, and does not include medical devices, animal drugs, food additives, color additives, or other related products.” Ellen J. Flannery & Peter Barton Hutt, \textit{Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984}, 40 \textit{Food Drug Cosm. L.J.} 269, 308 (1985).

\textsuperscript{73} \textit{Lilly}, 5 U.S.P.Q.2d at 1761. “Nowhere in the legislative history is there any indication that Congress had a broader intention to include medical devices within the coverage of § 271(e)(1). Rather, the legislative history evinces the narrow purpose of Congress to advance the quickened entry of generic drugs onto the market.” \textit{Id.} at 1762.

\textsuperscript{74} \textit{Lilly}, 872 F.2d at 405.

\textsuperscript{75} Id. at 406 (emphasis added).

\textsuperscript{76} \textit{Lilly}, 496 U.S. at 663-64. Throughout its opinion, however, the Court framed the dispute as whether § 271(e)(1) exempts the use of patented inventions “to develop and submit information for marketing approval of medical devices...”—without any reference to classification. \textit{See}, \textit{e.g.}, \textit{id.} at 665.


\textsuperscript{78} \textit{Lilly}, 496 U.S. at 664.

\textsuperscript{79} \textit{Id.} at 666. The Court also noted that if Congress intended to exclude medical devices from infringement protection, “there were available... infinitely more clear and simple ways of expressing that intent” than the way that Lilly suggested. \textit{Id.} at 667.
regulating drugs. The Court concluded the statutory language was not "plainly comprehensible" under either party's reading, and that the legislative history failed to cast any "clear light" on the controversy.

The Court then focused its inquiry on the intent of Congress in drafting the patent-related provisions in Title II of the 1984 Act. The Court determined that Congress was correcting two unintended distortions in the patent term for some products subject to regulation under the FDCA. The first distortion would occur when the holder of a patent was required by law to conduct clinical studies and obtain regulatory approval before marketing a product containing a patented invention. The approval process could take up a significant part of the seventeen-year patent term, during which time an inventor would be unable to derive any profit from the product. The second distortion would occur when the patent term was effectively extended by the regulatory requirement that a generic equivalent of the product also obtain regulatory approval before marketing.

The Court recognized that under Medtronic's interpretation of the language of § 271(e)(1), there might be "isolated instances" where the holder of a patent would benefit from the term extension provi-

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80. Id. at 668.
81. Id. at 669. For example, Lilly pointed out that House Reports describing the 1984 Act's infringement exception contained no reference to medical devices but mentioned only drugs. Medtronic responded by pointing to the patent term extension provision where, even though medical devices are explicitly included in the statutory language, the legislative history refers almost exclusively to drugs.
82. Id. at 670-73.
83. Id. at 669-70. See also *House Report*, part 2, supra note 48, for the Judiciary Committee's recognition of the necessity for correcting particular distortions that had been introduced into the effective patent term of products subject to FDA regulation.
84. Id. at 669-70.
85. Id. at 669. Lilly applied for a patent on its implantable defibrillator in 1967. The patent issued in 1971, but the device required nine more years of product development before human clinical investigations started, and another five years before the FDA granted premarket approval. Brief of Amicus Curiae Ventritex, Inc. at 4, Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) (No. 89-243). See also Flannery & Hutt, supra note 72, at 301-02 (concluding from their analysis that the FDA testing and approval process alone can require seven to thirteen years (after the grant of a 17-year patent)).
86. Lilly, 496 U.S. at 670. Although the 1984 Act provided for an abbreviated approval process for drugs and allowed clinical studies reported in the literature to be submitted in support of some drug approval applications, there were no corresponding provisions for new Class III medical devices such as Medtronic's cardiac defibrillator. With a few narrow exceptions, each Class III medical device was required to duplicate the full FDA approval process as if it were a pioneering device. Adler, supra note 27, at 513 n.16 ("data from one pre-market approval [PMA] application cannot be used to support another PMA without the express consent of the manufacturer") (citing David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 358 (1987)).
sion without the disadvantage of the exception for competitors, and perhaps other cases where the opposite would be true. The Court pointed out, however, that under Lilly's interpretation all patented inventions except drugs (including food and color additives, and medical devices) would benefit from the patent term extension provision without being subject to the disadvantage (to the patent holder) of the experimental use exception. The Court found it "most implausible" that Congress intended to correct both distortions in the patent term only for drugs, and only to extend the patent term for other groups of eligible patented products regulated by the FDCA.

The Court also found indications in the text of the 1984 Act that § 156, the patent term restoration provision, and § 271(e)(1), the experimental use exception, were meant to be "generally" complementary, and to provide a "product" fit between the two provisions. As an example, the Court pointed to the specific exclusion of new animal drugs and veterinary biological products from both the patent term extension and experimental use exception provisions, although both groups are subject to regulatory approval under the FDCA. The Court found even more convincing evidence of Congressional intent in a 1988 law that added most new animal drugs and veterinary biological products to the patent term extension provisions of § 156 and simultaneously made them eligible for the experimental use exception of § 271(e)(1).

The Court concluded that, despite "legislative imprecision" in drafting the statutory experimental use exception, Congress intended to extend eligibility for infringement protection to the same products that the statute made eligible for patent term extension, and upheld

87. Lilly, 496 U.S. at 671-72.
88. Id. at 672. Lilly's interpretation would have the effect of "positively aggravating distortion of the 17-year patent protection" for all products except drugs. Id. at 672-73.
89. Id. at 672.
90. Id. at 673-74. The Court actually made this observation to rebut Lilly's assertion that the two sections were not complementary. Petitioner's Reply Brief at 8, Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) (No. 89-243). Ironically, this textual framework argument would later become the mainstay of the case for restricting, rather than expanding, the experimental use exception.
91. The Court found this to indicate that "a Federal law regulating drugs" implicated an "entire regulatory scheme" rather than any specific provisions governing drugs. Lilly, 496 U.S. at 671. Under the latter interpretation, there would be no need for express statutory language specifically excluding those two types of patents, since there were no provisions in the FDCA that simultaneously regulated human drugs and either of the two specifically excluded groups of products. If, on the other hand, Congress meant the phrase to refer to any law containing provisions dealing with drugs, then the specific statutory exclusion would be necessary to clarify legislative intent.
the Federal Circuit's judgment. The 1984 Act thereby created an "FDA experimental use exception" to infringement that included medical devices.

B. Baxter v. AVL

For several years after Lilly, litigation over the experimental use exception for medical devices involved Class III devices, to which the infringement exception unarguably applied. The first litigation over the application of the experimental use exception of § 271(e)(1) to a medical device not clearly qualifying for patent term extension involved Baxter Laboratory's study of the feasibility of incorporating patented technology into a medical diagnostic instrument for conducting blood culture analyses.

Baxter began conducting preliminary studies to explore the possibility of developing an instrument for determining the presence and concentration of bacteria in blood using optical sensor technology. One of the optical sensors Baxter evaluated was patented by AVL, and AVL sued for patent infringement. Baxter moved for summary judgment, citing the statutory experimental use exception created by the 1984 Act.

Baxter argued that its use of the patented sensor technology in an experimental blood culture instrument was solely to evaluate the feasibility of the instrument as a first step toward generating data to submit for regulatory approval; therefore, its activities were specifically exempt from infringement under § 271(e)(1). AVL maintained that Congress intended the statutory experimental use exception to apply only to Class III medical devices. Both parties agreed that the medical device under development by Baxter would eventually be classified either Class I or Class II by the FDA.

The district court refused summary judgment on the question of infringement, following the Lilly court's reasoning that Congress intended for § 156 (patent term extension) and § 271(e)(1) (experimental use exception) to provide parallel exceptions to the relevant

93. Lilly, 496 U.S. at 679.
96. Id. at 617.
97. Id. at 613. Baxter acknowledged that it was aware of the AVL patent. Id. at 617.
98. Id. at 617.
99. Id. at 619.
100. Id.
101. Id.
provisions of the patent laws. Now, under the 1984 Act, patent term extension eligibility for medical devices extends only to devices submitted for approval under the specific section of the FDCA detailing the premarket approval requirement for a Class III medical device. Considering that statutory restriction, the district court reasoned that

since only Class III medical devices must endure the requisite 'regulatory review period'... Congress only intended to provide a patent-term extension for Class III medical devices. Although Class I or Class II devices may be subject to some limited form of premarket notification, they are not subject to the 'regulatory review period' necessary for patent-term extension.

Furthermore, since the plain language of § 156 limits patent term extension to Class III medical devices, the district court concluded that only Class III devices would be eligible for the experimental use exception. The court held that manufacture, use, or sale of a patented invention related to the development of data for FDA approval of a Class I or II medical device is not protected from infringement under § 271(e)(1).

Unfortunately, the Baxter court, while citing the Supreme Court's finding of complementarity between the patent term extension provision and the experimental use exception provision, ignored the plain language of the statutory provisions and misinterpreted the Lilly Court's application of that language to the eligibility requirements for the statutory experimental use exception. Moreover, the particular facts of Baxter raised another question, one overlooked by the district court: If the experimental use exception is limited to a particular class of medical devices, how can it be applied before classification of the medical device itself?

The problem arises because Congress, in the 1976 Amendments, delegated to the FDA the task of classifying all medical devices intended for human use as well as the task of assigning device classifi-
cations, either by a finding of substantial equivalence108 or by initiating reclassification of a medical device.109 Limiting § 271(e)(1) to Class III medical devices, however, would force parties such as Baxter and AVL to litigate the classification of a medical device along with the infringement action.

Baxter's development process for a new medical device consisted of four main stages.110 First, in a feasibility stage, Baxter would explore existing technology for possible applications in a medical device.111 Any number of ideas might be pursued and discarded during this stage.112 Next came an applied research phase where a particular technology that had shown promise would be incorporated into a prototype instrument.113 During the third phase, the approval phase, the prototype would be used to gather information for submission to the FDA in pursuit of marketing approval.114 After FDA approval a medical device would enter the fourth phase of development, the market introduction phase, where a limited number of devices would be made for market testing and introduction.115 The AVL suit was lodged during Baxter's feasibility testing of the sensor technology, long before any prototype development or preparation of premarket notification submission pursuant to FDA regulations.116

Baxter would not apply for FDA approval for any medical device until after the idea had been thoroughly explored in the feasibility phase, and the new technology was incorporated into a prototype instrument during the applied research phase.117 Any medical device developed as a result of the feasibility studies and development process would not be assigned a device classification until after application for FDA approval.118 Thus, at the feasibility phase, there would

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108. Id. § 360c(i).
109. Id. § 360(f)(2)(A).
111. Id. at 617.
112. In fact, Baxter scientists testified that attempts to incorporate AVL's patented sensor into Baxter's blood culture instrument were abandoned during the feasibility stage. Id.
113. Id.
114. Id.
115. Id.
116. Congress clearly intended to provide infringement protection for activities undertaken during these early stages of product research and development. House Report, part I, supra note 48, at 45 states that "a party which develops such information, but decides not to submit an application for approval, is protected as long as the development was done to determine whether or not an application for approval would be sought."
118. 21 U.S.C. § 360(b) directs FDA to classify all medical devices on the market into classes established in § 360(a). 21 U.S.C. § 360(a)-(b) (1988 & Supp. V 1993). A manufacturer seeking to introduce a new medical device must either convince the FDA that its new device is substantially similar to a device that the FDA has already classified as Class I or
be no assignment of a classification upon which protection under § 271(e)(1) could be determined. The Baxter court’s limitation of the experimental use exception to Class III medical devices would in effect require parties to litigate the question of the class to which the FDA would ultimately assign a medical device—for which an application might be years in the future—in order to apply § 271(e)(1).  

IV  
Proposed Eligibility Determination for the Experimental Use Exception

The Baxter court misinterpreted medical device eligibility requirements for the experimental use exception. Congress intended eligibility for the statutory experimental use exception to be determined by the submission requirements imposed on a medical device by the FDCA. This intention is clearly reflected in the 1984 Act, which sets different eligibility standards for patent term extension and infringement protection. Eligibility for the statutory experimental use exception of § 271(e)(1) is to be determined by a case-by-case analysis of the pre-approval requirements for a particular device. Otherwise infringing uses of a patented invention by a medical device manufacturer may be protected if they are related to the development and submission of information to the FDA as a prerequisite to obtaining marketing approval of the medical device.

A. Statutory Basis

The 1984 Act distinguishes between the eligibility standards for patent term extension and for infringement protection. The most apparent distinction between the two standards is in the statutory language setting the eligibility requirements for each provision. Section 156 of the patent statute limits eligibility for patent term extension to only a few of the products regulated by the FDA: medical devices, drug products, food additives, and color additives. In addition § 156 requires that the product must have been "subject to a regula-

Class II or must undergo the full premarket approval process for a Class III device. See Mary G. Boguslaski, Classification and Performance Standards Under the 1976 Medical Device Amendments, 40 FOOD DRUG COSM. L.J. 421, 426-27 (1985).

119. It is also possible that a plaintiff would not have a cause of action for infringement until a device classification order were issued by the FDA, after proper application by the defendant. If so, this might raise subject matter jurisdiction questions that would preclude a federal court from considering the claim.

120. 35 U.S.C. § 156(f)(1)(B) (1988). Food, infant formula, and cosmetics are not included. These exclusions actually played prominently in the reasoning by which the Lilly court distinguished the two exceptions.
tory review period before its commercial marketing or use."\textsuperscript{121} The regulatory review period for the application of § 156 is defined relative to the date that an application was initially submitted for premarket approval of a Class III medical device.\textsuperscript{122} Finally, § 156 allows a manufacturer to recoup only half the time spent conducting the testing required for FDA approval.\textsuperscript{123} The plain language of the statute makes it clear that Congress did not intend to compensate fully a manufacturer for time spent in seeking FDA marketing approval for a Class III medical device.\textsuperscript{124}

On the other hand, § 271(e)(1) provides that activities are not infringing if they are "reasonably related to the development and submission of information" to the FDA.\textsuperscript{125} Here, Congress enacted an exception to the infringement provision of the patent laws that is limited only by the reasonable relationship of the otherwise infringing activities to fulfilling federal regulatory requirements for marketing at the expiration of the patent term.\textsuperscript{126} Congress did not relate the infringement exception either to any specific regulatory review period or premarket approval requirements.\textsuperscript{127} For example, Congress could have provided an exception for uses reasonably related to obtaining premarket approval under a Federal law, or could have used parallel language to indicate eligibility for the patent extension and the infringement exception by creating protection "for uses reasonably related to fulfilling regulatory review requirements under Section 515 [35 U.S.C. § 360e, setting forth the approval procedure for Class III devices]."\textsuperscript{128} Congress did neither. It exempted activities reasonably related to the development and submission of information under a federal law.\textsuperscript{129}

\textsuperscript{121} Id. § 156(a)(4).
\textsuperscript{122} Id. § 156(c)(2).
\textsuperscript{123} Id. § 156(g)(3)(B).
\textsuperscript{124} Id. § 156(c)(2). Besides granting only partial compensation for the testing period, § 156 caps the length of the patent term extension at five years for any eligible product. Id. § 156(g)(b). See also House Report, part 1, supra note 48, at 15; House Report, part 2, supra note 48, at 6.
\textsuperscript{127} Compare the statutory chain in § 156: The patent term may be extended only for a medical device for which there is a regulatory review period, which is defined as the period beginning with human clinical trials and ending with the submission of an application for FDA approval for a Class III medical device. 35 U.S.C. § 156(g)(3)(B) (1988).
\textsuperscript{128} The statutory language of § 156 defines the regulatory review period in terms of application for approval "under section 515." Id. § 156(g)(3)(B).
Further evidence of congressional intent to distinguish the two provisions can be found in the defeat of a proposed amendment to the § 271(e)(1) experimental use exception. The amendment would have tied the exception directly to patent term extension under § 156, rather than providing infringement protection for all patents. According to the authors of the amendment, "[A]ny limit on exclusivity [of manufacture, use, or sale] would only apply to patents whose term had been extended." Moreover, "the waiver of exclusivity would be effective only during the last year of the extended term of the patent." Congress rejected both these restrictions of the experimental use exception.

It is also arguable that the distinction between Class III and other classes of medical devices is too artificial to form the basis for settlement of patent-related issues. For example, a new Class III device does not necessarily require the full premarket approval (PMA) process before commercial distribution, because a manufacturer may obtain regulatory approval for a medical device by demonstrating that its device is substantially equivalent to another medical device already on the market.

Furthermore, in the 1976 Amendments, Congress established the alternative approval process requiring only premarket notification before commercial distribution of a medical device. Under the 1976 Amendments, a medical device is automatically classified as Class III unless the manufacturer can show that the medical device is "substantially equivalent" to a medical device already on the market.

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131. Id. Admittedly, the amendment would have narrowed the field of products eligible for infringement protection beyond even the Baxter court's limitation, but its proposal and defeat indicate that Congress expressly refused to tie infringement protection directly to term extension.
132. Id. Note that the amendment would have narrowed the field of products eligible for infringement protection beyond even the Baxter court's limitation, but its proposal and defeat indicate that Congress expressly refused to tie infringement protection directly to term extension.
133. Medtronic's briefs before the Court pointed this out, arguing that Congress did not intend for statutes regulating such matters as safety and efficacy to be applied by the courts and the FDA to determine wholly unrelated issues such as patent protection. Respondent's Brief at 11, Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) (No. 89-243).
135. Id. § 360(k). This premarket notification provision is known as the 510(k) requirement, after the relevant section of the FDCA. This section requires a manufacturer to report to the FDA at least 90 days before the date on which he introduces a medical device: 1) the device classification (established either through a claim of substantial equivalence or through reference to an FDA classification list of all medical devices), and 2) actions taken to comply with any general controls, performance standards or other requirements imposed on the device by its classification. Id.
A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics, or does not raise different questions of safety and efficacy from the predicate device. Although there are some statutory limitations on the establishment of substantial equivalence for Class III medical devices, a significant number of Class III devices have been approved under this provision rather than by the full PMA process. In 1986, for example, manufacturers introduced seventy-two Class III medical devices through the PMA process and 281 by establishing substantial equivalence with a pre-amendment device. Although it is likely that a greater proportion of Class III devices is approved today through the PMA process, this dual route to marketing approval established by Congress for Class III devices suggests that the PMA requirement was not intended to be dispositive on questions as far afield as eligibility for infringement protection.

On the other hand, if eligibility for infringement protection is interpreted to hinge on the information development and submission requirements, then the particular route to approval will not be determinative. This is because the substantial equivalence claim is made by a manufacturer as part of the premarket notification requirement of 21 U.S.C. § 360(k). Substantial equivalence is determined by the FDA.

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136. *Id.* § 360c(f)(1)(A). The term substantial equivalence means that FDA “by order” has found that the device meets the statutory requirements for substantial equivalence. *Id.* § 360c(i)(1)(A).

137. *Id.* § 360c(i)(1)(A). A medical device has different technological characteristics if there is a significant change in materials, design, energy source, or other features. *Id.* § 360c(i)(1)(B).

138. *Id.* § 360c(i)(1)(A).

139. *Id.*


141. 510(k) submission. The notification requirements are prescribed by FDA regulation. See 21 C.F.R. §§ 807.92-93 (1994). According to the FDA, the intent of § 360(k) is to “enable FDA to determine whether the device is substantially equivalent to one already in interstate commerce.” Alan H. Kaplan, *Through the Maze of 510(k)s*, 39 FOOD DRUG COSM. L.J. 160, 161 (1984) (quoting 42 Fed. Reg. 42,523 (1977) (preamble to regulations setting forth notification requirements)).

142. 21 U.S.C. § 360c(i)(1)(A) (Supp. V 1993). FDA regulations recently promulgated pursuant to a 1990 law strengthening the regulation of medical devices have expanded FDA regulatory authority over devices requiring premarket notification. For example, after review of a premarket notification claiming substantial equivalence with a predicate medical device, the FDA will 1) issue an order finding substantial equivalence with a predicate medical device, 2) issue an order finding no substantial equivalence to a predicate device (so that the medical device must be designated Class III), or 3) request additional information. “Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.” 21 C.F.R. § 807.100 (1994).
The premarket notification procedure was intended by Congress to be a pro-forma notification of intent to market a medical device, but it could not be effective until the FDA classified all medical devices on the market and established the general controls and performance standards mandated by the 1976 Amendments. The FDA, however, interpreted the premarket notification requirement as a submission to enable the FDA to make a substantial equivalence determination. As a result, the premarket notification procedure came to resemble a "mini-PMA" process more than a pro-forma notification. The FDA could require the submission of nearly any information it felt necessary to make a substantial equivalence determination (without which, of course, a device could not be marketed). Even if a manufacturer was seeking to market a device by showing that the device met established performance standards, the manufacturer still had to report to the FDA the action taken to comply with the performance standards. In either case, before obtaining FDA marketing approval, a manufacturer would have to 1) develop information about the medical device proposed for commercialization; 2) determine that the device met performance standards or was substantially equivalent to a predicate device; and 3) report this information to the FDA.

B. Judicial Interpretations of Experimental Use Exception Support Proposed Eligibility Determination

1. Lower Courts

District courts and the Federal Circuit Court of Appeals have recognized that, in contrast to the stringent requirements imposed on eligibility for § 156 patent term extension, Congress enacted § 271(e)(1) to grant broad infringement protection to manufacturers of products

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143. Kaplan, supra note 141, at 162.
144. Id. at 161-62.
145. See supra note 141.
146. Kaplan, supra note 141, at 162. For example, to establish substantial equivalence for soft contact lenses (a Class I medical device), the FDA requires a manufacturer to be prepared to demonstrate substantial equivalence in terms of design; composition; optical transmission (and homogeneity) and index of refraction; and other physical properties including oxygen permeability, chemical and physical stability, tensile and flexural strength; biocompatibility, including bacterial growth; impurities; leachables; heavy metal levels, preservative uptake and release; and lens care/cleaning regimen compatibility. [Also required is] a detailed description of the methods used in, and facilities and controls used for, the manufacture, processing, and packing of the device and how such methods, facilities, and controls meet the requirements of the regulations.

Boguslaski, supra note 118, at 430 (citing 47 Fed. Reg. 53,414 (1982)).
regulated by the FDA. In *Intermedics, Inc. v. Ventritex, Inc.*, a case involving an infringement action brought by the manufacturer of a Class III medical device, the district court interpreted the intent of Congress as allowing competitors “prior to the expiration of a patent, to engage in otherwise infringing activities reasonably related to obtaining regulatory approval.” The court found that the “primary concern” of Congress in enacting the experimental use exception to infringement was “to create a legal environment that would enable new, medically beneficial, cost-competitive products to reach the general marketplace in meaningful volume as soon as the undistorted operation of the patent laws would permit.” The district court concluded that Congress made a fully self-conscious choice between two directly competing interests: continuing full protection of the rights of patent holders, on the one hand, and, on the other, assuring access by the public to medically beneficial new products at truly competitive market prices . . . immediately after the expiration of the terms of relevant patents. In essence, Congress elevated the health care interests of the public above the pecuniary interests of the patent holders.

The Federal Circuit agreed, concluding that Congress intended to create a broad exception to infringement, limited only by the reasonable relation of the activities to producing data for the FDA.

2. Supreme Court

a. Analysis of Statutory Framework

In *Baxter v. AVL* the court based its eligibility requirement for both patent term extension and infringement protection on a strict reading of § 156, associating eligibility for extension with the FDCA requirement of premarket approval for Class III medical devices. However, *Baxter* reads too much into the Supreme Court's finding of “textual indications” that the § 156 patent term extension provision

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147. 775 F. Supp. 1269 (N.D. Cal. 1991). This case contains a particularly careful and complete consideration of the history and purpose of the infringement exception in the 1984 Act.
148. *Id.* at 1273.
149. *Id.*
150. *Id.* at 1276-77.
152. *See* discussion supra part III.B.
and § 271(e)(1) infringement exception "are meant generally to be complementary."\textsuperscript{153} The Supreme Court, unlike the Baxter court, recognized that the complementarity of the statute extended no farther than "general" types of products (drug products, medical devices, food additives, and color additives) and not to specific products or classes of products within a general type.\textsuperscript{154}

In Lilly the Court was aware of the 1976 Amendments and the establishment of medical device classes. In fact, defendant Medtronic itself drew this to the Court's attention, when Lilly argued that extending infringement protection to medical devices would seriously damage a patent holder's market for devices for which there is relatively little demand.\textsuperscript{155} Medtronic pointed out that CAT-scan devices, for example, "are Class II devices and normally do not undergo the type of testing that would enable a competitor to avail itself of the testing exemption of section 271(e)(1)."\textsuperscript{156} Medtronic estimated that "over 90% of medical devices brought to market do not require testing."\textsuperscript{157} Despite 1) Lilly's argument of pecuniary loss to patent holders during the term of the patent; 2) Medtronic's speculation that infringement protection was limited to Class III devices; and 3) the obvious limitation of patent term extension to Class III devices, the Supreme Court did not acknowledge, even in dictum, any class distinction in granting infringement protection to medical devices.

The Court did not disturb the statutory language requiring patent term extension eligibility to rest on the FDA requirement of "premarket approval" of Class III devices. It also did not hinge eligibility for infringement exception under § 271(e)(1) on the eligibility for patent term extension under § 156. In fact, the Court clearly recognized that patent term extension and infringement protection did not always go hand-in-hand.\textsuperscript{158}

In its argument to restrict the statutory experimental use defense to drugs, Lilly pointed out that § 156 and § 271(e)(1) were not coex-


\textsuperscript{154} The Court noted that the products eligible for patent term extension, such as medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products, are subject to premarket approval requirements under some provision of the FDCA, while products excluded from the patent term extension provision are also excluded from infringement protection. \textit{Id.} at 674.

\textsuperscript{155} Some examples of those devices with limited demand are computer-aided tomography (CAT) scanning devices and magnetic resonance imaging (MRI) instruments.


\textsuperscript{157} \textit{Id.}

\textsuperscript{158} \textit{Lilly}, 496 U.S. at 671-72.
The noninfringement provision would apply "whether the patent term is extended or not," and would apply even to "patents which cannot qualify for a term extension." The Court agreed, citing the example of patented "follow-up" drug products. The Federal Circuit had earlier held such reformulations ineligible for patent term extension under § 156 because they could be submitted for FDA approval under an abbreviated approval process. Eliminating the "substantial regulatory delay" at the beginning of the follow-up product's patent term would also remove the justification for term extension under § 156. The Supreme Court's agreement with this reasoning reinforced Lilly's assertion that particular products within a general product type can qualify for infringement protection under § 271(e)(1) without qualifying for patent term extension under § 156.

In fact, the Court recognized that although drug products as a group qualify for patent term extension, within the general group of drug products there are specific patented drug products (such as follow-up drug products) that do not qualify for patent term extension under § 156 but do qualify for infringement protection under § 271(e)(1). Consequently, it is highly unlikely that the Court would point out this distinction for drug products, yet not recognize it for medical devices, particularly after its holding that medical devices are eligible for infringement protection.

While the Lilly Court found a "premarket approval requirement" to be a prerequisite for infringement protection, the Court's use of the term "premarket approval" suggests that it considered the term to be associated with an approval process that required the development and submission of information to the FDA, not strictly with the premarket requirement for a Class III device. Although § 360e is entitled "premarket approval" and sets forth the regulatory review requirements for Class III medical devices, the Court also found that products not eligible for patent term extension were subject to

159. Petitioner's Reply Brief at 4, Lilly (No. 89-243).
160. Lilly, 496 U.S. at 672 n.4.
161. A follow-up drug patent is a patent for a new dosage of a drug whose active ingredient is already protected under a pioneering patent.
163. Lilly, 496 U.S. at 672 n.4. The process is the Abbreviated New Drug Application (ANDA) procedure established by Title I of the 1984 Act. Manufacturers of products that use the same active ingredient as a product that has already been approved are not required to duplicate the full clinical investigation process that the pioneering product has undergone.
164. Id. at 673 n.4.
premarket approval requirements that rendered them eligible for infringement protection.\footnote{165}

The \textit{Lilly} Court decided that products eligible for patent term extension under § 156 would be eligible for infringement protection under § 271(e)(1), because they are subject to premarket approval under some specific provision of the FDCA.\footnote{166} For medical devices, the premarket approval requirements of § 360e confer automatic eligibility for infringement protection. The Court found that most other products subject to regulatory control by the FDCA, such as food\footnote{167} and cosmetics,\footnote{168} were regulated only by "generally applicable standards" that did not confer infringement protection.\footnote{169} A detailed look at the regulatory requirements for these types of products will distinguish the two levels of approval requirements.

There are no statutory premarket submission requirements for manufacturers or marketers of cosmetics. Although the statute forbids marketing of adulterated cosmetics, there are no statutory provisions for premarket certification, nor any pre-approval requirement that the manufacturer provide assurance against adulteration.\footnote{170} Similarly, the standards governing food empower the FDA to promulgate regulations establishing various standards for identity, quality, and container fill, but again there are no premarket submission requirements for manufacturers or marketers of foods. The FDA is not empowered by statute to promulgate regulations requiring such premarket submissions. The regulatory requirements for these types of products are characterized by the lack of any provision requiring premarket certification of any of the characteristics or conditions mandated by statute, or premarket verification of the results of any testing that might be required under the statute.

b. Infant Formula Regulations

Infant formulas offer the clearest example of both exempting and non-exempting approval requirements. The 1984 Act subjected infant formulas only to generally applicable standards\footnote{171} that do not confer

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165. Infant formulas are the most striking example. \textit{See infra} part IV.B.2.b.
166. \textit{Lilly}, 496 U.S. at 674.
168. \textit{Id}., § 361 (defining adulteration of cosmetics).
170. For example, FDA regulations governing hexachlorophene in cosmetics provide that "\textit{shipments} of products . . . which are not in compliance with the guidelines . . . shall be the subject of regulatory proceedings." 21 C.F.R. § 250.250(g) (1994) (emphasis added).

infringement protection. In 1986 Congress added new regulatory requirements for infant formulas (1986 Act).\textsuperscript{172} The Court found these regulations to constitute premarket approval requirements and confer automatic eligibility for infringement protection.\textsuperscript{173}

In addition, the 1984 Act required the FDA to develop nutrient requirements for infant formulas and to establish good manufacturing practices, including quality control procedures, to prevent adulteration of the infant formula.\textsuperscript{174} The manufacturing practices and quality control procedures must include the following: requirements for testing each batch of infant formula before distribution; testing of samples of the infant formula during its shelf life; in-process testing to prevent adulteration; and internal audits conducted by the manufacturer to ensure compliance with the good manufacturing practices and quality control procedures set out by the FDA.\textsuperscript{175} The \textit{Lilly} Court considered these requirements insufficient to confer infringement protection under § 271(e)(1).\textsuperscript{176}

Significantly, the 1984 Act does not require a manufacturer of infant formula to verify, before marketing, that the product actually meets the statutory nutrient requirements, or that processing facilities actually employ the good manufacturing practices and quality control procedures established by the FDA. Without any such premarket reporting requirement, enforcement of the statute comes only through FDA inspection of products already on the market or inspection of production facilities during commercial operation.

Under the 1986 Act a prospective manufacturer of infant formula is required to register with the FDA the name, place of business, and each place of manufacture at least ninety days before marketing the infant formula.\textsuperscript{177} Before marketing, the manufacturer must also “make a submission”\textsuperscript{178} to the FDA that includes certain elements: the formulation of the infant formula; assurances that the formula will not be marketed until it meets the good manufacturing practices and quality control procedures imposed by the 1984 Act; and written verification of test results and records establishing compliance with the

\textsuperscript{173} \textit{Lilly}, 496 U.S. at 674.
\textsuperscript{175} \textit{Id.} § 350a(a)(2)(B).
\textsuperscript{176} \textit{Lilly}, 496 U.S. at 674 n.6.
\textsuperscript{178} \textit{Id.} § 350a(d)(1).
good manufacturing practices, quality control procedures, and the nu-
trient requirements established earlier by the 1984 Act.\textsuperscript{179}

Additionally, the \textit{Lilly} Court found that the registration, product
information, and premarket assurance and verification requirements
established by the 1986 Act automatically conferred § 271(e)(1) in-
fringement protection, regardless of eligibility for patent term restora-
tion.\textsuperscript{180} The Court’s distinction between generally applicable
regulatory standards and premarket approval requirements indicates
that eligibility for infringement protection hinges on the premarket
submission requirement for the particular product.

c. Medical Device Classification

In \textit{Lilly} the Supreme Court made no direct mention of classes of
medical devices anywhere in its opinion, although it had several op-
portunities to do so. For example, the Court distinguished patents
that would not qualify for patent term extension, even though they
qualified for the infringement exception. The Court proposed that the
two main reasons that a patent wouldn’t qualify for term extension
were because 1) the manufacturer did not make proper application for
the extension, and 2) the patent is a follow-on drug patent for a refor-
mulation or dosage change involving the same active ingredient as the
pioneering drug patent.\textsuperscript{181} If the Court had intended to distinguish
classes of medical devices, it would have been more natural to point
out that medical devices are not eligible for extension if the devices do
not require premarket approval under § 360e.\textsuperscript{182} Medical devices
would have provided a direct and timely example of the distinction
between eligibility for patent term extension and infringement protec-
tion because each class of medical device is governed by different stat-
utory provisions.\textsuperscript{183}

First, the Supreme Court could have distinguished Class I and II
medical devices from Class III devices by including them with the
groups of products regulated under the FDCA for which the generally
applicable standards for approval preclude eligibility for the infringe-

\begin{footnotes}
\item 179. \textit{Id.} § 350a(d).
\item 180. \textit{Lilly}, 496 U.S. at 674.
\item 181. \textit{Id.} at 673 n.4.
\item 182. The Supreme Court’s failure to mention this is all the more indicative of nonre-
strictive intent because the question presented to the Court specifically involved approval
of medical devices under § 360e (regulating Class III medical devices).
\item 183. In addition, most of the follow-on drug products are approved through the ANDA
procedures established in Title I of the 1984 Act. The ANDA process was put in place
specifically to remove the regulatory delays in approval, and therefore obviate the need for
patent term extension. \textit{Lilly}, 496 U.S. at 672 n.4.
\end{footnotes}
ment exception under § 271(e)(1). Again, the Court did not distinguish between classes of medical devices, but instead pointed to foods and cosmetics, and to the 1984 Act's regulation of infant formulas.

Second, the Court could have distinguished classes of medical devices by narrowing its holding to the call of the question. The question presented to the Court was whether 35 U.S.C. § 271(e)(1) renders activities that would otherwise constitute patent infringement noninfringing if they are undertaken for the purpose of developing and submitting to the Food and Drug Administration information necessary to obtain marketing approval for a medical device under § 515 of the Federal Food, Drug, and Cosmetic Act.\footnote{184. Id. at 663, 664. Section 515 of the FDCA is codified at 21 U.S.C. § 360e (Supp. V 1993).}

The Supreme Court rephrased this in a significant way: "The parties dispute whether this provision exempts from infringement the use of patented inventions to develop and submit information for marketing approval of medical devices under the FDCA."\footnote{185. Lilly, 496 U.S. at 665.}

Section 575 of the FDCA codifies the premarket approval requirements for a Class III medical device. The Supreme Court addressed a broader question—whether the statutory experimental use exception protected activities necessary to develop and submit information to the FDA. The FDA determines for each type of medical device the submission requirement necessary to ensure safety and efficacy.\footnote{186. \textit{See supra} note 146.}

C. Public Policy

The Constitution empowers Congress to grant exclusive rights to patent holders for a limited time.\footnote{187. U.S. CONST. art. I, § 8.} At the end of that time, the public interest is best served by encouraging immediate competition, rather than by promoting an indirect extension of patent exclusivity.

1. Commentators

The general debate over patent scope is more complex than a balancing of property rights against free access to ideas, for it depends on the best way to achieve the goal of the patent system, which is "[t]o promote the Progress of Science and useful Arts."\footnote{188. Id.} Commentators considering the appropriate breadth of patent scope, including the infringement exception granted in the 1984 Act, have come to diametri-
cally opposite conclusions about its proper application. Wheaton argues that a broad interpretation of the infringement exception will discourage innovation\(^{189}\) by reducing the period of market exclusivity for manufacturers of pioneering products.\(^{190}\) Such a broad interpretation prevents manufacturers from recouping their research and development costs before prices are forced down by competition from generic manufacturers who have not sustained such large development costs.\(^{191}\) A broad application of the statutory experimental use exception in the 1984 Act will introduce uncertainty over future returns on investment and create a disincentive among both pioneering and generic manufacturers to develop new uses and variations of patented drug inventions.\(^{192}\) Others argue for a broad patent scope to protect the "prospect function" posited to underlie the doctrines and practices of the patent system.\(^{193}\) Obtaining a patent, especially if it is early in a development process or is broad in scope, assures an inventor of the prospect of a return on investment without fear of competition, and allows more rational and efficient planning for future innovation.\(^{194}\)

Other commentators reach the opposite conclusion. For example, Merges and Nelson argue that diminished competition will decrease the incentive to innovate by discouraging a patent holder who controls a particular segment of a market from exploiting his prospect as aggressively as if he had competitors.\(^{195}\) They also argue that technological advances proceed in different ways for different industries, so that optimum patent scope depends on the nature of the technology in an industry.\(^{196}\) Biotechnology and medical diagnostics, they find, are primarily driven by advances in other areas of science.\(^{197}\) These "science-based technologies" advance most rapidly and most effectively through inventive races to apply new scientific findings, and in return, a new scientific or technological development yields the

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189. Innovation involves putting existing inventions to practical use, Eisenberg, supra note 32, at 1036, and is distinct from invention. Invention itself is often of no practical value whatever.

190. Wheaton, supra note 41, at 486.

191. Id.

192. Id. Although Wheaton interprets the infringement exception to apply only to drugs, his general argument of the interplay between market exclusivity and innovation is equally applicable to medical devices.


194. Id. at 286.


196. Id. at 843.

197. Id. at 883 n.188.
possibility of major advances in the field of medical technology.\textsuperscript{198} Thus, a broad patent scope may be particularly undesirable in these industries.\textsuperscript{199}

Another commentator argues for restricting patent scope, especially through broad application of an experimental use exception, where the public interest is furthered by promoting scientific progress.\textsuperscript{200} Eisenberg points to \textit{Scripps v. Genentech}\textsuperscript{201} as a case where infringement protection under § 271(e)(1) would have been in the public interest.\textsuperscript{202} There, a district court found that Scripps' patent for human clotting factor was infringed by Genentech's production of the factor using recombinant DNA technology, a significant scientific achievement.\textsuperscript{203} Genentech's method would have made human clotting factor more economical and safe, but a court held that Scripps' broad patent rights prevented it.\textsuperscript{204} Without a broad experimental use exception, Eisenberg concludes,

One can only speculate as to how much longer the public would have to wait for this and other improvements if patent holders could block their rivals from competing with them in research. Given that patent holders have an interest in prolonging the period of the public's dependence on patented technologies and the difficulty of foreseeing the outcome of future research projects in the fields of patented inventions, it seems imprudent to place this power in the hands of patent holders.\textsuperscript{205}

2. \textit{Congress}

Congress agreed that a broad application of the experimental use exception is desirable. The House Report accompanying the 1984 Act pointed out that infringement protection under § 271(e)(1) will substantially benefit the government and the public.\textsuperscript{206} The public, especially the poor, the under-insured, and the elderly, will benefit from the reduction in health care costs brought about by faster approval and marketing of generic substitutes for patented medical devices.\textsuperscript{207}

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\item 198. \textit{Id.} at 883-84.
\item 199. \textit{Id.} at 884.
\item 200. Eisenberg, \textit{supra} note 32, at 1081.
\item 202. Eisenberg, \textit{supra} note 32, at 1083.
\item 203. \textit{Id.} at 1082. Producing human clotting factor through recombinant technology "would obviate the need for a large donor pool and eliminate the risk of transmitting infectious agents from donors." \textit{Scripps}, 666 F. Supp. at 1384.
\item 204. The ruling was later overturned on other grounds, with the Federal Circuit rejecting the district court's interpretation of the statutory experimental use exception. \\textit{Eli Lilly & Co. v. Medtronic, Inc.}, 872 F.2d 402, 403 (Fed. Cir. 1989).
\item 205. Eisenberg, \textit{supra} note 32, at 1083.
\item 206. \textit{House Report, part 2, supra} note 48, at 29.
\item 207. \textit{Id.}
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\end{footnotesize}
The government itself, as purchaser of health products for various public programs, will also save money.\textsuperscript{208} Against the interests of the public and the government, the claims of pioneering product interests are, according to Congress, "much less tangible."\textsuperscript{209} However, Congress acknowledged "the nature of the industry" mandates the creation of broad exceptions to the normal operation of the patent laws for products that are both heavily regulated and particularly important to public health.\textsuperscript{210}

Furthermore, there are significant public benefits in access to improvements in medical device technology. Restricting infringement protection to developers of Class III medical devices would eliminate protection for ninety-seven percent of medical devices.\textsuperscript{211} Some of those devices left without protection would include diagnostic devices such as tissue imaging systems\textsuperscript{212} and microsurgical lasers.\textsuperscript{213} These devices are being swept along by rapid advances in other technical areas like miniaturized electronic circuitry, advanced power sources, and image collection systems. Medical devices that stand to offer the greatest benefit to the public are not necessarily Class III devices, which are by definition life-saving or life-sustaining products,\textsuperscript{214} but which might only have a very limited market. A Class I or Class II medical device can offer greater potential for significant impact on the quality of health care because one device may be used for the diagnosis or treatment of many people with different illnesses. As a result, the policy argument is compelling against categorical exclusion of Class I and Class II medical devices from statutory infringement protection.\textsuperscript{215}

\textsuperscript{208} Id.
\textsuperscript{209} Id.
\textsuperscript{210} Id. at 30.
\textsuperscript{211} In 1985 approximately 35% of the medical devices on the market were Class I, 62% were Class II, and 3% Class III. Boguslaski, \textit{supra} note 118, at 426. By 1988 there were over 41,000 medical devices on the market, produced in over 7000 establishments. Adler, \textit{supra} note 27, at 511.
\textsuperscript{212} Classified Class II in 21 C.F.R. § 84.2225 (1994).
\textsuperscript{213} Classified Class II in 21 C.F.R. § 74.4490 (1994).
\textsuperscript{214} A Class III device is one that "is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C) (Supp. V 1993).
\textsuperscript{215} See \textit{supra} notes 147-51, and accompanying text for a discussion of the \textit{Intermedics} court's interpretation of congressional policy goals in enacting the statutory experimental use exception.
V

Conclusion

The plain language of § 271(e)(1) extends infringement protection to activities reasonably related to the "development and submission of information" to the FDA. The statute, and FDA regulations promulgated pursuant thereto, require the development and submission of information for most medical devices as a prerequisite for FDA marketing approval or as part of a premarket notification submission. Consequently, the Baxter holding limiting infringement protection to medical devices that are also eligible for patent term extension (that is, to Class III medical devices) is incorrect.

Moreover, the Supreme Court in Lilly v. Medtronic distinguished the eligibility for patent term extension from the eligibility for infringement protection. Further, the Court recognized that a product might qualify for infringement protection without qualifying for patent term extension.

Therefore, the application of the statutory experimental use exception should involve an examination of the particular activities and medical devices involved in each case. Congress intended, by the plain language of § 271(e)(1), to base the infringement exception on whether the activities at issue were conducted to develop and submit information to the FDA to fulfill regulatory approval requirements. This individual inquiry best serves the public interest by neither enlarging nor restricting the proper application of the exception. More important, restricting infringement protection to manufacturers of Class III medical devices is not in the public interest because it will deny the public lower-cost health products and advances in medical device technology.