



January 2001

Understanding Patent Infringement under 35 U.S.C. 271(e): The Collisions Between Patent, Medical Device and Drug Laws

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ARTICLES

**UNDERSTANDING PATENT INFRINGEMENT
UNDER 35 U.S.C. § 271(e):
THE COLLISIONS BETWEEN PATENT, MEDICAL
DEVICE AND DRUG LAWS**

Shashank Upadhye[†]

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I. INTRODUCTION

Intellectual property, more particularly patent protection, is important. A patent protects an inventor’s creativity. In addition, patents push the frontiers of technology outwards such that society as a whole benefits from the technology push. However, patent protection is not without its attendant consequences. Patent law often collides with other legal regimes, such as antitrust,¹ sovereign immunity² or administrative law.³ In these past collisions, some

¹ Walker Process Equip. Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965).

² Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627 (1999).

³ See *Dickinson v. Zurko*, 527 U.S. 150 (1999) (stating that the scope of review of PTO’s findings is subject to the Administrative Procedure Act (APA), 5 U.S.C. § 706).

courts proved hostile to patents and invalidated patents at each instance. To remedy those collisions, Congress intervened. One such cure was the creation of the Federal Circuit Court of Appeals to unify the disparate patent law precedent of the various sister circuits.⁴

In particular, Congress sought to harmonize patent law with medical device and drug laws. In so doing, Congress enacted 35 U.S.C. § 271(e) to bridge the gap between patent and medical laws. As discussed below in greater detail, 35 U.S.C. § 271(e)(1) provides a safe harbor for a defendant⁵ in a patent infringement suit if that defendant engages in conduct to gain federal regulatory approval of a medical device or drug. This safe harbor provision, however, is not an unfettered right. Rather, there are some limitations imposed by the statute. Section 271(e)(1) basically states that:

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.

A quick, yet superficial, look at the statute indicates that the safe harbor provision applies *only* to infringing products⁶ that are utilized for gaining federal approval of some sort.

The theme of this article relates to the interaction of the laws of patents, medical devices and medical drugs. The article examines the current analytical construct of patent infringement as it relates to medical drug approval and device approval; each of which has its own regulatory requirements. This article proposes a new construct in § 271(e)(1) litigation that reverses the traditional construct. The traditional construct examines infringement first, then FDA approval laws. The new construct examines FDA law first, then analyzes any infringement issues. Therefore, this article breaks with past

⁴ Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982). This Act merged the Court of Customs and Patent Appeals (CCPA) and the Court of Claims into the U.S. Court of Appeals for the Federal Circuit (CAFC) effective October 1, 1982. I also suggest that the CAFC was created to take patent suits out of the hands of notorious anti-patent courts who curiously invalidated every patent that was litigated before them. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AM. INTELL. PROP. L. ASS'N. Q.J. 185, 191-92 (1998); Vincent Tassinari, *Patent Compensation Under 35 U.S.C. § 284*, 5 U. GA. J. INTELL. PROP. L. 147-50 (1997).

⁵ In this article, the term 'defendant' denotes the potential infringer and the term 'plaintiff' denotes the patentee. Readers should note this distinction in reading declaratory judgment actions in which the defendant is the patentee.

⁶ As described below, patents may cover a variety of inventions which are not tangible products.

§ 271(e)(1) scholarship by analyzing FDA law and its hypothetical application to patent law.

As mentioned above, since medical devices and drugs are governed by different statutory sections, later parts of this article examine the interaction of the more unique aspects of drug law as it relates to patents. In particular, this article focuses on the fundamentals of the drug approval process and its interaction with patent law.

II. BACKGROUND TO § 271(e): A HYPOTHETICAL PRE-1984 CASE

To begin any analysis of the statute and its effect, it is always necessary to examine the reason Congress enacted the statute as part of the plain text analysis.⁷ To do this, one must examine a pre-1984 (the year Section 271(e) was enacted) hypothetical when patents were governed by a seventeen-year⁸ term limit.⁹ In days of yore, the grant of a patent covering a process, a machine, an article of manufacture, a composition of matter or any new and useful improvement thereof,¹⁰ was effective the day the patent issued.¹¹ On the issue date, the exclusionary rights attached and the enforcement rights vested in the patentee.¹² At this point, no other unauthorized entity may have made, used, sold, offered for sale or imported any subject matter

⁷ Shashank Upadhye, *Trademark Surveys: Identifying the Relevant Universe of Confused Consumers*, 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J., 549, 579 (1998) (arguing that courts must examine the plain text of the statute to determine the scope and content of the words of the statute, and the legislative history to determine the policy and purpose of the statute); see also Vincent Tassinari, *The Statutory Term Analysis (STA) Method*, 1998 Det. Col. L. Rev. 977 (1998).

⁸ 35 U.S.C. § 154(c) (1994 & Supp. IV 1998).

⁹ 35 U.S.C. § 154(a)(2) (1994) (extending the term of the patent is to 20 years from the date of filing).

Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c) of this title, from the date on which the earliest such application was filed.

Id.

¹⁰ 35 U.S.C. § 101 (1994) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

¹¹ See *supra* note 9 and accompanying text; see also 35 U.S.C. § 271 (1994 & Supp. IV 1998).

¹² 35 U.S.C. § 271(a) (1994 & Supp. IV 1998) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.").

covered by the patent.¹³ Any unauthorized activity was infringement under § 271(a).¹⁴ However in this hypothetical, the grant of a patent on medical devices and drugs was also tied to other regulatory regimes, such as the Food and Drug Administration (FDA).

Therein lies the rub! In this hypothetical, imagine that a manufacturer invents a new drug¹⁵ or medical device¹⁶ and wishes to

¹³ See *supra* note 12; see also 35 U.S.C. § 271(g) (1994 & Supp. IV 1998)

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.

Id.

¹⁴ See *supra* note 12.

¹⁵ (1) The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) of this paragraph. A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term 'counterfeit drugs' means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

21 U.S.C. § 321(g) (1994).

¹⁶ The term 'device' (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c) and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

commercialize the product immediately. There is absolutely no requirement that the manufacturer seek patent protection. The manufacturer may proceed directly to the consuming public and its failure to pursue patent protection means that any competitor may freely copy the product. However, in this hypothetical, the product is regulated by the Federal Food, Drug, and Cosmetic Act (FDCA),¹⁷ which is administered by the FDA.¹⁸ The FDCA requires that the manufacturer comply with certain statutes, regulations and guidelines in order to receive FDA regulatory approval to market the product. Absent such approval, the marketing of unauthorized products in interstate commerce¹⁹ is illegal.²⁰ Therefore, a predicate to marketing a patented medical device or drug in interstate commerce is FDA approval. However, gaining FDA approval is not a trivial affair. Rather, it is a time consuming, costly and highly regulated procedure.

Therefore, one collision of FDA and patent laws becomes apparent. Generally, a patentee normally has a right to market the product immediately and gain an exclusive advantage for the entire patent term. If the invention is an FDA regulated product, however, the patentee is prejudiced as the proper FDA regulatory approval invades into the patentee's exclusive patent term. This is because the patent is often filed first, then the FDA approval process is sought. This sequence is problematic.

The flip side of this issue is another collision of laws. Returning to the hypothetical above, any competitor desiring to market a generic²¹ drug or device must await the grant of FDA approval. However, predicate to this approval is a showing to the FDA by the

21 U.S.C. § 321(h) (1994).

¹⁷ 21 U.S.C. § 301 (1994 & Supp. IV 1998).

¹⁸ 21 U.S.C. § 393(a) (1994) ("There is established in the Department of Health and Human Services the Food and Drug Administration . . .").

¹⁹ 21 U.S.C. § 321(b) (1994) ("The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.").

²⁰ See 21 U.S.C. § 331 (1994 & Supp. IV 1998) (prohibiting the interstate marketing of unapproved drug or device); see 21 U.S.C. § 351 (1994 & Supp. IV 1998) (presumptive determination of adulteration of unapproved device or drug); see 21 U.S.C. § 352 (1994 & Supp. IV 1998) (presumptive determination of misbranded device or drug); see 21 U.S.C. § 355(a) (1994) (prohibiting the introduction of any new drug into interstate commerce unless the drug application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug).

²¹ A generic drug/device refers to a drug that is not the first drug to be patented or approved for use by the FDA in a field. Generic drugs and devices are often called 'me-too' drugs/devices. A pioneer drug is also known as an 'innovator drug product' or a 'Reference Listed Drug' (RLD) to indicate that the drug is listed in the FDA Orange Book (discussed *infra*).

competitor that its drug or device is more or less the same as the pioneer drug or device.²² This feat requires extensive data submission. However, the competitor is foreclosed from gathering this data because the pioneer device or drug is covered by a patent²³ and it stands to reason that the pioneer patent holder will not permit any making, use or sale of the patented invention by the competitor until the patent expires.²⁴ Again, the collision of laws becomes evident. Here, the competitor must wait seventeen-years for the patent to expire before the competitor can even begin to make the product for use in the necessary clinical trials or experiments. Then the competitor would submit this information to the FDA to gain FDA approval, which could take years. Meanwhile, the patent on the product expired, but nobody except the patent holder is permitted to market the drug. Thus, the FDA approval process created a *de facto* patent term extension until the first of the generic makers can enter the field. Therefore, the FDA entanglements prevent competitors from exercising their legal right to enter the market to capitalize on the patent's expiration.

A. *Roche v. Bolar: Congressional Acceptance of a Judicial Invitation*

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,²⁵ the newly created Federal Circuit Court of Appeals invited Congress to correct what was perceived as the collision of laws described above. In *Roche*, the patentee, Roche, sued to enjoin Bolar, the generic manufacturer, from taking the necessary statutory steps to gain FDA regulatory approval during the life of Roche's patent.²⁶ Bolar desired to enter the market at the exact expiry date of the patent since it realized that a generic drug manufacturer's commercial success depended on how quickly the generic drug entered the market; that is, the first to market generally garnered the most market share.²⁷

²² Discussed *infra*.

²³ See *supra* note 12.

²⁴ One way to avoid this problem is for the pioneer company to create a wholly owned subsidiary that will manufacture generic equivalents under a different brand name. The pioneer company licenses the subsidiary to make, use, and sell the invention and gain FDA approval. Once the approval is received, this subsidiary will be the first generic manufacturer on the market and will be able to capitalize on the initial market share once the patent expires. Realistically, the generic maker can be in nationwide commerce the day after the patent expires.

²⁵ *Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984).

²⁶ *Id.* at 860 ("Roche argued that the use of a patented drug for federally mandated premarket tests is a use in violation of the patent laws.").

²⁷ *Id.*

Despite the fact that the term of the patent was set to expire within six months, Bolar nonetheless stated that it intended to immediately test its generic equivalent to earn FDA approval.²⁸

The Federal Circuit entertained and rejected Bolar's first argument that its use of the patented drug fell within the judicially created experimental use exception²⁹ if the exception was liberally applied.³⁰ The court rejected the argument since Bolar's use did not fall within the narrow requirement that the experimental use relate to the fulfillment of curiosity, self-gratification, amusement and other aspects related to strict non-commercial use.³¹

Not to be undone, Bolar then sailed forward with the catch-all public policy argument.³² Bolar argued that since the FDA approval

Because a generic drug's commercial success is related to how quickly it is brought to market after the patent expires, and because approval for an equivalent of an established drug can take more than 2 years, Bolar, not waiting for the '053 patent to expire, immediately began its effort to obtain federal approval to market its generic version of Dalmane.

Id.

²⁸ *Id.* ("When Bolar stated during discovery, on August 30, 1983, that it intended immediately to begin testing its generic drug for FDA approval."). The district court framed the issue to determine "the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last six months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable." *Id.* at 861.

²⁹ For a comparison of the experimental use exception to obviate a 35 U.S.C. § 102(b) bar versus the experimental use exemption described herein, see Eyal Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 NW. U. L. REV. 667 (1997). Briefly, experimental use under § 102(b) occurs where the patentee uses the invention in public to see if it works for its intended purpose, or for further research. See *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989). Experimental use under § 271(e) is a misnomer since the conduct complained of is for overcoming an infringement allegation, not to overcome claim validity problems.

³⁰ In *Whittemore v. Cutter*, Justice Story sought to justify a trial judge's instruction to a jury that an infringer must have an intent to use the patented invention for profit, stating: It could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or the purpose of ascertaining the sufficiency of the machine to produce its described effects.

Roche, 733 F.2d at 862 (citation omitted).

³¹ Bolar concedes as it must, that its intended use of [the patented drug] does not fall within the 'traditional limits' of the experimental use exception as established in these cases or those of other circuits Despite Bolar's argument that its tests are 'true scientific inquiries' to which a literal interpretation of the experimental use logically should extend, we hold the experimental use exception to be truly narrow and we will not expand it under the present circumstances.

Id. at 863.

³² *Id.* ("Bolar argues that even if no established doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to use prohibition.").

process took years, it gave the patentee the *de facto* extension of the patent whilst the generic manufacturer commenced the activities to gain the FDA approval.³³ The court sank that argument by stating that it was the role of Congress to maximize the public welfare through legislation and decided that the courts were not the proper forum to debate this public policy.³⁴ Therefore, the court, in an unusual restraint of judicial activism,³⁵ invited Congress to correct the perceived ills of the patent laws and the FDA laws.

In response to the *Roche* case,³⁶ Congress soon thereafter enacted the Drug Price Competition and Patent Term Restoration Act of 1984, affectionately known as the Hatch-Waxman Act (HWA)³⁷ to legislatively overrule the *Roche* case.³⁸ In so doing, Congress intended to expedite the marketing of drugs and devices into the marketplace as soon as the patent expired.³⁹ Pursuant to § 271(e)(1) of the HWA, a medical device or drug manufacturer now could

³³ *Id.* at 864 (“Bolar argues that the patent laws are intended to grant inventors only a limited 17 year property right to their inventions so that the public can enjoy the benefits of competition as soon as possible, consistent with the need to encourage invention.”).

³⁴ *Id.* (stating that Congress was aware of the public policy arguments made by Bolar and Roche and the court will not rewrite the patent laws to effectuate the public policy espoused).

³⁵ Judicial activism occurs when the judiciary as an institution believes it to be a “superior source of policy on the subject Congress dealt with.” *United States v. Lopez*, 514 U.S. 549 (1995) (Souter, J., dissenting). Judicial activism is shunned and often the politics of a case determine whether a judge or judges will exercise the mandate of not legislating new laws, rather just interpreting the existing ones. See *New Jersey v. T.L.O.*, 469 U.S. 325, 375 (1985) (Stevens, J., concurring and dissenting):

In characteristic disregard of the doctrine of judicial restraint, the Court avoided that result in this case by ordering reargument and directing the parties to address a constitutional question that the parties, with good reason, had not asked the Court to decide. Because judicial activism undermines the Court's power to perform its central mission in a legitimate way, I dissented from the reargument order.

See Tassinari, *supra* note 7, for a candid discourse on judicial activism in statutory interpretation.

³⁶ *Roche*, 733 F.2d 858 (Fed. Cir. 1984).

³⁷ Hatch-Waxman Act of 1984, Pub. L. 98-417, 98 Stat. 1985 (1984) (modifying sections of the patent act: 35 U.S.C. §§ 271(e), 155, 156, and 21 U.S.C. § 355(j)); see also *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 5 F. Supp. 2d 399, 400 (N.D. W.Va. 1998) (involving issues of the patent term restoration—gaining extra time to the patent term—due to FDA involvement); see generally *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546-47 (Fed. Cir. 1996). See also *Bristol-Myers Squibb Co. v. Royce Labs. Inc.*, 69 F.3d 1130 (Fed. Cir. 1995).

³⁸ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Abtox, Inc. v. Exitron, Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997); *Telectronics Pacing Sys. Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992); *Am. Standard Inc. v. Pfizer Inc.*, 722 F. Supp. 86, 102-103 (D. Del. 1989).

³⁹ *Telectronics Pacing Sys.*, 982 F.2d at 1525 (Fed. Cir. 1992); *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000).

“infringe” another’s patent “solely for uses reasonably related to the development and submission of information under a federal law which [sic] regulates the make, use, or sale of drugs or veterinary biological products.”⁴⁰ Therefore, while some careless *dicta* in cases state that § 271(e) is a defense to infringement, it is not.⁴¹ Rather, it is an exemption from infringement in that the putatively infringing conduct is, in fact, classified as non-infringement.⁴² This is not unlike hearsay in which a statement is classified as non-hearsay or is classified as hearsay within an admissible exception.⁴³ In addition, the HWA also provided for unique statutes designed to facilitate generic drug entry into the market by permitting the generic manufacturer to challenge the validity of the pioneer patent.⁴⁴ In summary, the HWA through § 271(e)(1) permits infringement so that generic manufacturers can develop the testing data necessary and enter the market, with FDA approval in hand, upon the pioneer patent expiry.

B. “Reasonably Related” to FDA Approval: A Narrow or Broad Interpretation

Like any newly promulgated patent statute, statutory interpretation litigation followed thereafter. One of the first issues encountered in § 271(e)(1) patent litigation concerned the word “solely” and whether it modified the word “uses” or the phrase “reasonably related” in the statute. As the district court in *Elan Transdermal Ltd. v. Cygnus Therapeutics Systems*⁴⁵ noted, there were two interpretations of the word “solely” in § 271(e)(1). Elan (patentee) sued Cygnus regarding patented transdermal patches and argued that it was infringing Elan’s patent. Cygnus was preparing for FDA approval.⁴⁶ At first, Cygnus argued that its patch was an entirely different product than Elan’s and was not infringing. Cygnus argued in the alternative that even if it was infringing, then it was covered by the § 271(e)(1) exemption.⁴⁷ In response thereto, Elan argued, *inter alia*, that the exemption did not apply because the

⁴⁰ 35 U.S.C. § 271(e)(1) (1994 & Supp. IV 1998).

⁴¹ *See id.*

⁴² *Id.*

⁴³ *See* FED. R. EVID. 801(d) (classifying conduct as non-hearsay and Rules 803 and 804 that classify conduct as hearsay but find it admissible under certain exceptions).

⁴⁴ 35 U.S.C. §§ 271(e)(2)-(4) (1994 & Supp. IV 1998).

⁴⁵ *Elan Transdermal Ltd. v. Cygnus Therapeutics Sys.*, 24 U.S.P.Q.2d 1926 (N.D. Cal. 1992).

⁴⁶ *Elan*, 24 U.S.P.Q.2d at 1927.

⁴⁷ *Id.* at 1928.

infringement was not “solely” for purposes of FDA approval.⁴⁸ The court noted that the plain language of § 271(e)(1) showed an apparent dichotomy in whether the word “solely” modify “uses” or “reasonably related.”⁴⁹

A first interpretation came from *Scripps Clinic & Research Foundation v. Genentech, Inc.*,⁵⁰ which focused on the word “solely.” The court found the word “solely” to be limiting § 271(e)(1) and thus found the exemption did not apply. A second interpretation by *Intermedics, Inc. v. Ventritex, Inc.*,⁵¹ focused on the word “reasonably related.” The court applied a liberal interpretation to § 271(e)(1) and found the activity within the scope of the exemption. The *Intermedics* court inquired into whether those acts of making, using or selling the patented device would constitute infringement but for the exemption.⁵² Furthermore, the court noted that a party that engages in otherwise infringing acts for *purposes* other than FDA approval does *not* lose the benefits of this exemption. Thus, the analysis must be limited solely to those *uses* that would otherwise constitute infringement of the patent.⁵³

In other words, in examining the phrase “reasonably related” of the statute, the inquiry was phrased as: “[w]ould it have been reasonable, objectively, for a party in a defendant’s situation to believe that there was a decent prospect that the ‘use’ in question would contribute (relatively directly) to the generation” of relevant information for the FDA.⁵⁴ The court noted that even if the activities serve other *purposes*, it is irrelevant since the plain language of the statute has the word “uses” and not “purposes.” Accordingly, if any commercial purpose was also detectable in the infringing use, then stripping protection of the exemption would negate the Congressional intent in allowing uses to generate FDA approval.⁵⁵ In other words, the court stated summarily, that if the otherwise infringing *uses* were *objectively* reasonably related to gathering information for submission

⁴⁸ *Id.*

⁴⁹ *Id.* at 1931-32.

⁵⁰ *Scripps Clinic & Research Found. v. Genentech, Inc.* 666 F. Supp. 1379 (N.D. Cal. 1987), *modified on other grounds* 678 F. Supp. 1429 (N.D. Cal. 1988), *aff’d in part, rev’d in part, vacated in part, remanded on other grounds*, 927 F.2d 1565 (Fed. Cir. 1991).

⁵¹ *Intermedics, Inc. v. Ventritex, Inc.* 775 F. Supp. 1269 (N.D. Cal. 1991), *aff’d without opinion*, 991 F.2d 808 (Fed. Cir. 1993).

⁵² *Intermedics*, 775 F. Supp. at 1277.

⁵³ *Elan*, 24 U.S.P.Q.2d at 1931 (emphasis added).

⁵⁴ *Intermedics*, 775 F. Supp. at 1280; *Elan*, 24 U.S.P.Q.2d at 1931.

⁵⁵ *Intermedics*, 775 F. Supp. at 1280; *Elan*, 24 U.S.P.Q.2d at 1931-32.

to the FDA, then the defendant is protected by the § 271(e)(1) exemption.⁵⁶ The interpretation used in *Elan* is liberal enough to encompass infringing activity that generates information even if that information is not in the final submission.

III. REVERSING THE PARADIGM OF § 271(e)(1) SCHOLARSHIP

Since the nature of a § 271(e)(1) suit is patent infringement, it is tempting to suggest that the analytical construct in a § 271(e)(1) case is: (1) to determine if there is an infringement of the patent by the accused device; and (2) if so, then whether the infringement is exempted due to § 271(e)(1)'s safe harbor.⁵⁷ Therefore, step (1) would follow the traditional course of infringement involving the two sub-steps: (i) determining the scope of the claims; and (ii) then determining whether the accused device falls under the scope of the properly construed claims.⁵⁸ The infringement determination would necessarily lead to *Markman* claim construction proceedings,⁵⁹ which may include a hearing and briefing, a full trial on the infringement issue proving either direct or equivalency infringement,⁶⁰ any appeals to the Federal Circuit on claim construction and jury verdicts review. In other words, a full trial on the infringement issues is necessary. This would naturally create issue and claim preclusion on all decided issues in the case,⁶¹ especially on claim construction⁶² and prosecution history estoppel.⁶³ After all that is completed, the issue of whether

⁵⁶ *Elan*, 24 U.S.P.Q.2d at 1931-32.

⁵⁷ See *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 206-12 (D.N.J. 1994).

⁵⁸ *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1315 (Fed. Cir. 1999).

⁵⁹ *Thomson v. Quixote Corp.*, 166 F.3d 1172, 1173-74 (Fed. Cir. 1999); *EMI Group N. Am., Inc. v. Intel Corp.*, 157 F.3d 887, 889-92 (Fed. Cir. 1998).

⁶⁰ Even if an accused product differs enough from an asserted claim to preclude literal infringement, that product may infringe under the doctrine of equivalents if there is equivalence between those elements of the accused product and the claimed limitations of the patented invention that are not literally infringed. Infringement lies under the doctrine only if an equivalent or a literal correspondence of every limitation of the claim is found in the accused device. One test used to determine 'insubstantiality' is whether the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation.

Zelinski, 185 F.3d at 1316-17 (citations omitted).

⁶¹ *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1453-54 (Fed. Cir. 1988).

⁶² *Ramp Research & Dev. Inc. v. Structural Panels, Inc.*, 977 F. Supp. 1169, 1177-78 (S.D. Fla. 1997).

⁶³ *TM Patents, L.P. v. Int'l Bus. Machs. Corp.*, 72 F. Supp. 2d 370, 375-76 (S.D.N.Y. 1999) (finding that claim construction in first trial even though settled prior to a final judgment still created collateral estoppel in the claim construction in the second trial). It is argued that it is improper to unfairly penalize a patentee with a binding claim construction from a previously

step (2)'s § 271(e) safe harbor exemption applies. Therefore, the requirement of a full trial of infringement would necessarily lead to two distinct results. The first result is that the accused device does not infringe and therefore it is irrelevant whether § 271(e)(1) applies. The second result is that there is infringement and now the issue is whether § 271(e)(1) applies. If there is infringement and § 271(e)(1) does not save the defendant, the plaintiff wins and the defendant loses. If there is infringement, but § 271(e)(1) saves the defendant, then the plaintiff loses and the defendant wins. Under the present regime of § 271(e)(1) scholarship, if there is no infringement in the first place, then later potential defendants would never learn of whether any particular conduct qualifies under § 271(e)(1) because that issue is moot by the finding of non-infringement. Therefore, a potential defendant can never be quite sure that particular conduct is permissible. It is only when a finding of infringement occurs in the second scenario that the court examines the conduct to determine if § 271(e)(1) exempts the infringement. If the court determines that § 271(e)(1) applies, then the defendant is found to be non-infringing but the plaintiff is bound by *res judicata* and *collateral estoppel* on all issues decided.

Therefore, the author posits a new analytical construct in § 271(e)(1) scholarship. The author suggests the new analytical construct to evaluate the applicability of § 271(e)(1) be called a *medical exemption proceeding*. That way, if the court determines the exemption applies, then it is irrelevant whether any infringement occurs or not. That is because if § 271(e)(1) applies, the particular conduct is safe harbored. Accordingly, the plaintiff is not prejudiced

settled case. First, the claim construction is not appealable as an interlocutory order. There must be a final judgment to appeal to the Federal Circuit. See *Schering Corp. v. Amgen Inc.*, 35 F. Supp. 2d 375, 377 (D. Del. 1999). Therefore, a party injured by claim construction could be interested in settling versus pursuing litigation and then appeal; a process that could take years. Second, there are many reasons to settle, most of which do not include an adverse claim construction. For example, a particular claim construction may facilitate summary judgment, may expose the patent claims to new prior art based invalidity arguments, may indicate a severe prolongation of the litigation; all to with which the injured party may not agree, but the business/economic decisions are not worth further pursuit. Third, since claim construction can occur prior to jury instruction submission, an adverse claim construction may initiate motions for directed verdicts that could dispose of the case prior to a jury verdict. In such a case, a party may never know the merits of the jury verdict since the parties settled prior to any judge ruling on directed verdict motions. So even though a patentee may have had a full and fair opportunity to litigate the claim, it does not mean that the party accepts that construction knowing it can be easily overturned on appeal since the standard of review for claim construction is *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). A party's propensity to settle prior to a final judgment can be based on a plurality of unrelated factors, such as plain business sense.

by the finality of *res judicata* and *collateral estoppel* on issues and potential defendants benefit because a court has decided the applicability of § 271(e)(1) to certain alleged conduct. A medical exemption proceeding also avoids the costly and time consuming litigation that often mires a district court's administration of the case. A medical exemption proceeding preserves the ability of the plaintiff to sue for infringement and get a final resolution on the alleged conduct. In other words, a court finding that § 271(e)(1) applies will moot the infringement question. The author suggests that deciding the applicability of § 271(e)(1) *ab initio*, since it is a question of law,⁶⁴ is infinitely easier to administer than proceeding with full blown infringement trials and the concomitant difficulties. Public policy favors the medical exemption hearing as it reduces the tax on the burgeoning court docket, yet comports with all notions of justice for the parties.

Hypothetically, assume a second generic manufacturer monitors § 271(e)(1) litigation in which the plaintiff sues a first generic manufacturer. The second manufacturer is less concerned about the first company's product and whether it infringes as it may not be interested in ever marketing that particular device. Rather, the second company is more concerned about obtaining a ruling on exempted conduct so that it too may engage in the same type of conduct with impunity. In the traditional construct, depending on how the infringement issue is resolved, this second company may never get an adjudication on the conduct. With the medical exemption hearing, the infringement issues take second chair until the conduct is adjudicated. Thus, the only issue is whether the activity is reasonably related to gaining FDA approval of the device. This is simply answered by understanding the nature of FDA law and what the FDA requires in the regulatory approval process.

It must be remembered that § 271(e)(1) is a safe harbor exemption to infringement, not an exception to infringement. This is an important distinction. If § 271(e)(1) is classified as an exception, a district court judge may be troubled in deciding defenses before liability adjudication. In other aspects, this would be akin to deciding

⁶⁴ *Scripps Clinic & Research Found. v. Baxter Travenol Labs. Inc.*, 7 U.S.P.Q.2d 1562, 1565 (D. Del. 1988). The author also suggests that since the applicability of § 271(e) is a question of law, this includes any subsidiary questions of fact. See claim construction under *Cybor*, 138 F.3d at 1456 (“[W]e review claim construction *de novo* on appeal including any allegedly fact-based questions relating to claim construction. Accordingly, we today disavow any language in previous opinions of this court that holds, purports to hold, states, or suggests anything to the contrary . . .”).

patent validity first before any infringement issue. However, under the proposed medical exemption proceeding, since the plain text of § 271(e)(1) states that the conduct “shall not be an act of infringement,” a district court is absolutely permitted to hold the easier medical exemption proceeding first to determine the applicability of § 271(e)(1), prior to any difficult infringement proceeding.

Therefore, if the primary purpose of the safe harbor exemption is to shield various infringing uses from liability for the purpose of gaining FDA regulatory approval, then it is critical to understand the FDA approval process, the type of information sought, the contents of an application and the methods of generating that information. To this end, the following parts introduce a primer in medical device and medical drug FDA laws.

IV. FUNDAMENTALS OF MEDICAL DEVICE APPROVAL UNDER THE FDCA REGIME.

As mentioned above, without FDA approval, the marketing of a medical device in interstate commerce is illegal.⁶⁵ Since the thrust of this article is to determine when activities are reasonably related to gaining FDA approval, it is important to understand the device laws to determine what the FDA requires to succeed in obtaining approval. Therefore, one must examine what the FDA requires a medical device applicant to include in the FDA approval application. There are three major FDA medical device application regimes: the PMA, the 510(k) and the PDP, discussed *in seriatim* below.

To obtain this approval, the manufacturer must show that its device is safe and effective. This is normally done by submitting a Pre-Market Approval (PMA) application in which the device manufacturer generally must submit clinical data demonstrating the safety and efficacy of the device.

A. The PMA Process

The PMA process is used for truly new devices that were not marketed prior to the 1976 Amendments to the FDCA and are not substantially equivalent to a device already on the market.⁶⁶ As part

⁶⁵ 21 U.S.C. § 331 (1994 & Supp. IV 1998) (prohibiting the interstate marketing of unapproved devices); *see generally* 21 U.S.C. § 321(b) (1994) (definition of interstate commerce).

⁶⁶ *See* 21 C.F.R. § 814.1 (2000); contrast the PMA with the 510(k) pre-market notification requirements discussed *infra*.

of the FDCA via the Medical Device Amendments of 1976,⁶⁷ involving medical devices, the Act created various Classes to classify the underlying medical device, such as:

* Class I devices,⁶⁸ which are devices⁶⁹ whose safety and efficacy could be reasonably assured by 'general controls'⁷⁰ as set out in the different sections of the FDCA⁷¹;

* Class II devices⁷² pose greater risks than Class I devices and were subject to performance standards⁷³ in addition to the residual general controls;

* Class III⁷⁴ includes devices⁷⁵ (1) whose safety and efficacy could not be reasonably assured by any combination of general controls and performance standards and (2) whose purported purpose was to aid in supporting or sustaining human life or preventing its impairment, or whose availability presented a potential unreasonable risk of illness or injury.⁷⁶

Any truly new device is automatically identified as a Class III device.⁷⁷ Unless, and until, the FDA reclassifies⁷⁸ this device into Class I or II,⁷⁹ the only way for the device to reach the market is

⁶⁷ 21 U.S.C. §§ 360c-360k (1994 & Supp. IV 1998) (classifying devices intended for human use); Medical Device Amendments Act of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

⁶⁸ 21 U.S.C. § 360c(a)(1)(A) (1994); *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996).

⁶⁹ Examples of Class I devices include: breath alcohol tests (21 C.F.R. § 862.3050 (2000)) and AC powered operating tables (21 C.F.R. § 878.4960 (2000)). Some exempted Class I devices include: color vision testers (21 C.F.R. § 886.1170 (2000)); hot and cold water bottles (21 C.F.R. § 880.6085 (2000)); and manual or power toothbrushes (21 C.F.R. §§ 872.6855, 872.6865 (2000)).

⁷⁰ 21 U.S.C. § 360c(a)(1)(A) (1994); *see generally* 21 C.F.R. § 860 (2000).

⁷¹ Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-395 (1994 & Supp. IV 1998).

⁷² 21 U.S.C. § 360c(a)(1)(B) (1994); *Abtox*, 122 F.3d at 1028; *Medtronic*, 518 U.S. at 477. Examples of Class II devices include: oxygen masks (21 C.F.R. § 868.5580 (2000)); paper chart recorders (21 C.F.R. § 870.2810 (2000)); and artificial eyes (21 C.F.R. § 886.3200 (2000)).

⁷³ 21 U.S.C. § 360c(a)(1)(B) (1994).

⁷⁴ 21 U.S.C. § 360c(a)(1)(C) (1994); *Abtox*, 122 F.3d at 1028; *Medtronic*, 518 U.S. at 477.

⁷⁵ Examples of Class III devices include: implanted cerebellar stimulators (21 C.F.R. § 882.5820 (2000)); replacement heart valves (21 C.F.R. § 870.3925 (2000)); and extended wear contact lenses (21 C.F.R. § 886.5925 (2000)).

⁷⁶ *Contact Lens Mfrs. Ass'n. v. FDA*, 766 F.2d 592, 594 (D.C. Cir. 1985).

⁷⁷ 21 U.S.C. §§ 360c(f), 360c(f)(1)(A) (1994 & Supp. IV 1998); 21 C.F.R. § 860.134 (2000).

⁷⁸ After classification in Class I, any person adversely affected by the Class I classification can petition the courts to order a higher classification. 21 U.S.C. §§ 351(f)(2)(B), 360g(a)(1) (1994) (for a 30 month grace period for compliance). A Class II or III classification can be objected to in the FDA or later in the courts. 21 C.F.R. §§ 10.33, 10.45 (2000).

⁷⁹ Class I and II devices are subject to an abbreviated process. 21 U.S.C. § 360(k) (1994). The approval process for Class II and III devices are not the same. *Abtox*, 122 F.3d at 1028;

through the PMA process.⁸⁰ In addition, there are three categories of Class III devices that require PMA approval:

* Those Class III devices that are truly new and not substantially equivalent to any predicate device that was on the market prior to 1976 Amendments. These devices are automatically classified as Class III⁸¹ unless FDA reclassifies them into Class I or II. Thus, the only way for these devices to enter market is through the PMA process.

* The second category requiring a PMA is pre-1976 Amendments Class III device for which the FDA now requires a PMA submission. A device is a pre-Amendment device if it was on the market before the 1976 Amendments effective date or was introduced after 1976 but was found by the FDA to be substantially equivalent to a pre-1976 Class III device.

* The third category subject to PMA is transitional devices. The 1976 Amendments automatically reclassified those devices, that had been classified as drugs, as Class III devices. For example, since pre-1976 devices required no pre-market clearances, the FDA regulated some devices as drugs, *e.g.*, bone cement, silicone implants, injectable TEFLON[®], contact lenses and surgical sutures.

1. Parts of the PMA Application

Of the more arduous FDA applications, PMAs require more information.⁸² As the applicant must show safety and efficacy of the device, the application should be very detailed regarding the clinical and non-clinical studies performed. The PMA generally includes more information than a 510(k)⁸³ would have contained therein. The applicant must state it has a reasonable assurance of safety and efficacy of the device. The PMA may include non-clinical data such as: microbiological, toxicology, immunology, bio-compatibility, stress, wear, shelf life and other lab-animal testing, plus compliance with all Good Laboratory Procedures. The PMA may include data such as: study protocols, number of investigators, number of test subjects, criteria for selecting subjects and investigators, study population, demographics, length of study, safety and effectiveness,

Medtronic, 518 U.S. at 478.

⁸⁰ 21 U.S.C. §§ 360c(f)(1)(A), 360e (1994 & Supp. IV 1998); 21 C.F.R. § 860.134 (2000).

⁸¹ 21 U.S.C. § 360c(f) (1994 & Supp. IV 1998).

⁸² See 21 C.F.R. § 814.20 (2000).

⁸³ Briefly, a 510(k) is a separate FDA medical device application. It is akin to an abbreviated PMA but is not as comprehensive as the PMA; *see infra*.

adverse reactions, tabulations of data, patient discontinuation, patient complaints, device failures and replacement devices, repairs and informed consent regulations compliance.⁸⁴ Since clinical procedures involve a primary investigator, the FDA generally requires the use of many investigators. If only one investigator was used, the applicant needs to submit a special statement explaining why the PMA clinical studies used only one investigator.⁸⁵

Medical devices requiring a PMA generally also require an environmental impact assessment⁸⁶ pursuant to the National Environmental Policy Act.⁸⁷ But exceptions apply, *e.g.*, where the device is based on a predicate device and the FDA is convinced that the approval of the PMA would not cause release of toxins in the environment. Therefore, a patent infringer defending a § 271(e)(1) infringement case on the grounds that its use is reasonably necessary for the environmental impact assessment in the PMA, must be sure that the use for environmental impact assessment is, in fact, required in the PMA. After all, a defendant cannot defend on the grounds of required environmental impact assessment if no assessment is needed.

While the PMA process is time consuming and generates voluminous information, the applicant can use data from other PMAs so as not to prove the same principle over and over again.⁸⁸ Therefore, a plaintiff may successfully negate the § 271(e) safe harbor exemption if the plaintiff can show that the data that would be generated from the infringement could have been found in the defendant's previous PMAs. The plaintiff may state, with a strong likelihood of success, that a reasonable defendant would not engage in costly and time consuming clinical studies and subject itself to an infringement charge merely to generate data that the defendant already possessed. However, this argument may have less force if the defendant does not have other PMAs in hand. Generally, PMAs are held in secret until a final action, such as the grant or denial, is made on the PMA, or unless the PMA is disclosed already.⁸⁹ If the FDA grants or denies the PMA, the FDA will then publish the PMA to the public.⁹⁰

⁸⁴ 21 C.F.R. § 814.20(b)(3)(v)(B) (2000).

⁸⁵ 21 C.F.R. § 814.20(b)(7) (2000).

⁸⁶ 21 C.F.R. § 814.20(b)(11) (2000).

⁸⁷ National Environmental Policy Act of 1976, 42 U.S.C. § 4321 (1994); *see also* 21 C.F.R. §§ 25.1, 25.20(n), 25.34(d), (e) (2000).

⁸⁸ 21 U.S.C. § 360j(h)(3) (1994).

⁸⁹ 21 C.F.R. § 814.9(b) (2000).

⁹⁰ 21 C.F.R. § 814.9(e) (2000).

Another common argument for a plaintiff to make is that the defendant is using the patented device in foreign countries in foreign clinical trials. First, it is undisputed that use of a U.S. patented medical device in foreign countries does not violate the U.S. patent laws since infringement is territorial.⁹¹ This means it is not infringement to make, use, or sell a product in a foreign country if it is only patented in the United States. A U.S. patentee who desires foreign patent protection must apply for patents in each desired country. Accordingly, § 271(a) does not reach extra-territorially. The only protection a U.S. manufacturer has against foreign uses of the medical device is to obtain domestic patent protection in those foreign nations. However, it is also undisputed that foreign clinical trials do occur and will often use the medical device in question.⁹²

Clinicians conduct tests in foreign nations for two reasons: (a) U.S. regulatory requirements have become more strict, thereby causing clinicians to look elsewhere; (b) foreign data is used to support foreign applications for approval. Superficially, it appears that if U.S. regulatory requirements are stricter than foreign countries, then the foreign clinical trial cannot be reasonably necessary to gaining U.S. federal regulatory approval; otherwise the clinician would do the test here in the United States. The assumption is that the applicant is engaging in conduct in foreign countries that is not allowed in the United States. and if it is not allowed, then it cannot be related to gaining approval in the United States. This is not persuasive since foreign derived data can be used for the FDA in the PMA.⁹³ In fact, the FDA tried to eliminate foreign derived data, but the court struck down the regulation in *Fmali Herb, Inc. v. Heckler*.⁹⁴ A contemporary view of foreign derived data indicates that foreign derived data must comply with ethical standards.⁹⁵ Studies started on or after November 19, 1985, must constitute valid scientific evidence as that term is defined in the regulations, and the investigator must conduct studies in conformance with the Declaration of Helsinki⁹⁶ or be in conformance with laws of the foreign country with the applicant explaining how those laws differ from Declaration rules and that

⁹¹ *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1366 (Fed. Cir. 1998).

⁹² 21 C.F.R. § 814.15(a) (2000).

⁹³ 21 C.F.R. § 814.15 (2000).

⁹⁴ *Fmali Herb, Inc. v. Heckler*, 715 F.2d 1385 (9th Cir. 1983).

⁹⁵ 21 C.F.R. § 814.15 (2000).

⁹⁶ *Helsinki Declaration*, <http://ohsr.od.nih.gov/helsinki.php3> (last visited Oct. 29, 2000). The Helsinki Declaration basically a code of ethics that request clinical trial investigators to comply with ethical cannons, such as informed consent, no deleterious product testing, no torture, etc.

foreign rules offer more humane protection.

As to the mechanics of the FDA filing process, the FDA reviews a PMA application for formal requirements, such as obvious defects, within 45 days.⁹⁷ If the PMA application is rejected for formal requirement violations,⁹⁸ then the applicant can cure the defects and refile the PMA or may challenge the FDA decision.⁹⁹

Since a defendant argues that its use of the patented device is necessary for gaining regulatory approval, a plaintiff must understand the contents of a PMA to attack the defendant's arguments. By understanding the PMA content required, the plaintiff can refute a defendant's arguments by showing that the alleged content is not necessary for PMA submission and thus the safe harbor exemption of § 271(e) does not apply. A PMA requires that the device be shown to be safe and effective. Safety and efficacy are considered: (1) with respect to the persons for whose use it is intended; (2) with respect to the conditions of use prescribed in the labeling; (3) and weighing any possible benefit against the probable risk of injury or illness.¹⁰⁰ A device is safe when it can be reasonably and assuredly:

determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.¹⁰¹

Thus clinical data must convince the FDA to make the risk/benefit determinations. Valid scientific evidence originates from many sources, such as well-controlled, partially controlled, non-controlled objective studies, plus from well-documented case histories by qualified experts and from documented significant human experiences.¹⁰²

If the FDA decides to approve or disapprove the PMA, the FDA decision can be: (1) an *order granting* the PMA; (2) a *letter approving* the PMA; (3) a *letter denying* the PMA or (4) *order*

⁹⁷ 21 C.F.R. § 814.42 (2000).

⁹⁸ 21 C.F.R. § 814.42(c) (2000).

⁹⁹ 21 C.F.R. § 814.42(d)(2) (2000).

¹⁰⁰ 21 C.F.R. § 860.7(b) (2000).

¹⁰¹ 21 C.F.R. § 860.7(d)(1) (2000).

¹⁰² 21 C.F.R. § 860.7(c)(2) (2000).

denying the PMA.¹⁰³ *Orders* are final agency actions, whereas *letters* require further information. This is akin in patent office practice to receiving an Office Action in which the patent applicant must do something versus receiving a Notice Of Allowance in which the patent application is approved and will issue as a registered patent.

The FDA sends a *Not Approved Letter* if the FDA is preliminarily rejecting the PMA, but will give the applicant a chance to correct the defects. However, the FDA will issue a *Not Approved Order* if the FDA is rejecting the PMA because: (1) the PMA contained false information about a material fact; (2) the labeling does not comply with FDA requirements; (3) the applicant forbids the FDA entry to inspect the facility for compliance with Good Manufacturing Practices (GMP); (4) some central or critical non-clinical data did not comply with Good Laboratory Practices or (5) the clinical studies were not in compliance with either the Helsinki Declaration, Institutional Review Board (IRB) policies or somehow violated informed consent laws.¹⁰⁴ If the FDA denies the PMA, an applicant may seek judicial review of the PMA process.¹⁰⁵ The FDA may revoke the PMA if, upon later review, the FDA finds violations of (1)-(5) above.¹⁰⁶

Merely because a PMA is provisionally rejected though does not mean that a defendant-infringer is now liable for infringement. The FDA may permit the applicant to correct defects by modifying the PMA. There are several types of modifications available to an applicant. An applicant may amend the PMA¹⁰⁷ during active review. This can be a major amendment in which the PMA contains significant new data from prior unreported studies, updates or the like or a minor amendment in which the amendment asks the FDA to consider new, but insignificant, information. This would be akin to patent office practice in which the patent applicant may submit evidence of patentability, such as Rule 132 affidavits,¹⁰⁸ that further clarify the patentability versus raising new matter. Therefore, if the FDA permits the applicant to correct the defects in the PMA, then any infringing activity reasonably related to obtaining that amendment data is likely to be within the safe harbor exemption.

¹⁰³ 21 C.F.R. § 814.45 (2000).

¹⁰⁴ 21 C.F.R. § 814.45 (2000).

¹⁰⁵ 21 U.S.C. § 360e (1994 & Supp. IV 1998).

¹⁰⁶ 21 C.F.R. § 814.46 (2000).

¹⁰⁷ 21 C.F.R. § 814.37 (2000).

¹⁰⁸ 37 C.F.R. § 132 (2000).

The other way to modify a PMA is to supplement it. Supplements add to the PMA once the PMA review period is completed.¹⁰⁹ It is generally used when the PMA applicant wants to modify the safety and efficacy of the device. Since a PMA is approved based on the representations made in the PMA, a change in representation will normally require a re-evaluation, which may include filing supplements for changes in safety and efficacy; new indications of use of the device; changes in labeling; use of a different facility to make, process or package the device; changes in manufacturing facilities, methods or quality control procedures; changes in sterilization procedures; changes in performance or design specifications, circuits, components, ingredients, principles of operation or physical layout of the device.¹¹⁰

In this regard, since the test for the medical device safe harbor exemption is whether the complained of activity was reasonably related to gaining FDA approval, the author contends that if the defendant submitted false information or denied entry to FDA inspectors to inspect the manufacturing facilities, then that should be a *per se* violation of the "reasonably related" rule since intentional fraud or intentional withholding of information in the PMA can never be reasonable, even though it may be related to gaining FDA approval. Accordingly, a defendant who includes this intentional falsity should be precluded from seeking refuge behind the § 271(e) safe harbor exemption.

One interesting factor in patent infringement concerns GMP compliance.¹¹¹ Refusing to permit the FDA inspectors entry into a manufacturing facility is grounds for denying a PMA. Therefore, a defendant must permit entry of FDA inspectors, otherwise any infringing activity will not be shielded under the safe harbor exemption. Accordingly, a defendant may argue that use of other patented inventions to produce the infringing device in suit are also permissible if the use of the other patented devices are reasonably related to gaining FDA approval of the device in question. This is because to get approval of the device in question, it may be necessary for the defendant to infringe another's patent to comply with GMP.

By way of illustration, suppose that patent X (the patent in suit) covers a catheter, which is clearly a medical device. The defendant is trying to gain approval on the generic version of the catheter. The

¹⁰⁹ 21 C.F.R. § 814.39 (2000).

¹¹⁰ See 21 C.F.R. §§ 814.37, 814.39 (2000).

¹¹¹ See 21 C.F.R. § 820.1 (2000).

simple case is that the defendant is infringing patent X on the catheter because the making, using or selling of the catheter is reasonably related to gaining FDA approval for the generic catheter. However, one aspect of FDA approval is compliance with GMP. Suppose now the defendant, in order to comply with GMP for catheter manufacture, must infringe patent Y because patent Y is a patent on catheter plastic extrusion processes. That is, to make the catheter comply with GMP, the GMP standard requires plastic extrusion using process Y. It is quite plausible, therefore, that compliance with GMP may require infringing someone else's patent. The same may be true that a defendant must infringe patent Z because patent Z is the only way to make a component of the catheter under GMP standards. Accordingly, infringing patent X, patent Y, and patent Z is necessary to gain FDA approval of the generic catheter covered just by patent X.

This begs the question: How far down the chain of infringement may a defendant go in order to get FDA approval of the device in question? Stated another way, does § 271(e)(1) only protect infringement of a patent that is the sole subject of the intended FDA application? Can a defendant infringe many totally unrelated patents if the infringement of each patent is somehow reasonably related to gaining FDA approval of a device in question? This, the author suggests, is a function of how liberal § 271(e)'s "reasonably related" language will be construed.

To show how extensive and long the chain of infringement might become, it is necessary to understand what is the scope of GMP. GMPs regulate many aspects of the device, such as the manufacturing processes used; facilities used; controls used; packaging; inventorying and storage.¹¹² More specifically, GMP requirements include the following systems:

- * Quality Assurance System¹¹³ that monitors maintenance schedules and records, any complaint files, distribution records and personnel training and handling reports.

- * Pre-Production Quality Assurance¹¹⁴ that evaluates device design before manufacturing and confirms the manufacturing processes that the resulting product is an approvable device.

¹¹² 21 C.F.R. § 820.1(c) (2000).

¹¹³ 21 C.F.R. §§ 820.20, 820.25 (2000).

¹¹⁴ 21 C.F.R. § 820.100 (2000).

* Building and Cleanliness¹¹⁵ that ensures that the device is not contaminated and maintains facility parameters such as temperature, humidity, air quality control, ventilation and hygiene.¹¹⁶

* Equipment Care and Maintenance¹¹⁷ to ensure upkeep with equipment and maintain calibration of measuring devices.¹¹⁸

* Device Master Records¹¹⁹ that include design specifications and manufacturing records that are required for certain devices based on its classification.¹²⁰

* Components Compliance¹²¹ that assures that components are in compliance with the intended use and of complying quality.

* Production control systems are used to generate a Device History Record¹²² that tracks the manufacturing process to determine how defects are handled, reprocessing of non-conforming devices¹²³ and sterilization procedures.¹²⁴

* Finished Device Evaluation¹²⁵ that examines finished devices to finalize the device and monitor defective or re-processed devices.¹²⁶

* Labeling controls to maintain compliance¹²⁷ with labeling and prevent misbranding.¹²⁸

¹¹⁵ 21 C.F.R. § 820.40 (2000).

¹¹⁶ 21 C.F.R. § 820.56 (2000).

¹¹⁷ 21 C.F.R. § 820.60 (2000).

¹¹⁸ 21 C.F.R. § 820.61 (2000).

¹¹⁹ 21 C.F.R. § 820.3(i) (2000).

¹²⁰ 21 C.F.R. § 820.181 (2000).

¹²¹ 21 C.F.R. § 820.20 (2000).

¹²² 21 C.F.R. § 820.184 (2000).

¹²³ 21 C.F.R. § 820.115 (2000).

¹²⁴ 21 C.F.R. § 801.150(e) (2000).

¹²⁵ 21 C.F.R. § 820.160 (2000).

¹²⁶ 21 C.F.R. § 820.160 (2000).

¹²⁷ 21 C.F.R. § 820.120 (2000).

¹²⁸ 21 U.S.C. § 352 (1994 & Supp. IV 1998). A device is misbranded under § 352 if it contains false or misleading labeling. A device is misbranded if its labeling is false or misleading in any particular; it is in package form and its label fails to contain the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; any required wording is not prominently displayed as compared with other wording on the device or is not clearly stated; its label does not bear adequate directions for use, including warnings against use in certain pathological conditions, by children where its use may be dangerous in health, against unsafe dosage or methods or duration of administration or application; it is dangerous to health when used in the

* Packaging to enclose the device¹²⁹ with consideration paid to methods of packaging, types of packaging, storage of devices, sterility processing, packaging material compatibility and manner of shipment. Furthermore, materials ultimately used in packaging are also subject to GMP controls as these materials must be stored prior to use.¹³⁰

* Distribution controls to ensure that devices first made are the ones first sent out.¹³¹

* Complaint and Failure Investigations to ensure proper documentation of device complaints or failures.¹³²

* Quality Assurance Audits are not generally requested by the FDA, but may be requested if the applicant sues the FDA.¹³³

2. Summary of PMA Device Law

As can be seen, the PMA process is very complex and time consuming. There are many stringent controls needed to bring a device to market. However, because of the numerous requirements, a defendant has many defenses under § 271(e)(1) so long as the defendant can characterize the alleged conduct as furthering a PMA requirement.¹³⁴ However, not all devices are approved under the

dosage or manner or with the frequency or duration prescribed, recommended or suggested in the labeling; it does not comply with the color additives provisions listed under § 706 of the Act. It is also misbranded if: the device's established name (if it has one), its name in an official compendium or any common or usual name is not prominently printed in type at least half as large as that used for any proprietary name; if the establishment is not registered with FDA per § 510, has not device listed per § 510(j) or obtained applicable pre-market notification clearance per § 510(k); if the device is subject to a performance standard and it does not bear the labeling prescribed in that standard; if there is a failure to comply with any requirement prescribed under the FDCA § 518 on notification and other remedies or failure to furnish any materials or information requested by or under § 519 on reports and records or under § 522; if there is any representation that created an impression of official approval because of the possession by the firm of an FDA registration number.

¹²⁹ 21 C.F.R. § 820.130 (2000).

¹³⁰ 21 C.F.R. § 820.20 (2000).

¹³¹ 21 C.F.R. § 820.150 (2000).

¹³² 21 C.F.R. § 820.198 (2000).

¹³³ 43 Fed. Reg. 31508, 31516 (July 21, 1978).

¹³⁴ See Thomas Poche, Note, *The Clinical Trial Exemption From Patent Infringement: Judicial Interpretation of § 271(e)(1)*, 74 B.U. L. Rev. 903 (1994) (arguing that judicial interpretation of the exemption is "too broad"). See also Ned Israelson, *Making, Using, & Selling Without Infringing: An Examination of 35 U.S.C. § 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AM. INTELL. PROP. L. ASS'N. Q. J. 457 (1988-89) (arguing that § 271(e) should be interpreted to effectuate the stated Congressional intent, which may mean a narrow interpretation).

PMA process. Devices may also be approved under the 510(k) process.

B. The 510(k) Pre-Market Notification Process: An Abbreviated Device Application

Not all medical devices require a full blown PMA for the FDA. An abbreviated process is available under a separate medical device section, namely the 510(k) application.¹³⁵ The 510(k) does not require all the clinical data to be generated from scratch if the device is the same as an already approved device. Rather, the 510(k) process, which is also known as the Pre-Market Notification process, asks the FDA to decide if the generic device is substantially equivalent to a predicate device.¹³⁶ A predicate device can be: (1) a similar device of any Class that was on the market before May 28, 1976¹³⁷; (2) a similar device legally marketed after May 28, 1976, that has been placed in Class I or II or (3) any similar device that has already been found by the FDA to be substantially equivalent to a device described in (1) or (2).¹³⁸ Thus, a predicate device cannot be a post-1976 Class III (*e.g.*, a Class III device that has itself gone through a PMA process) device. To prove substantial equivalence, a generic device manufacturer must demonstrate that the new device is substantially equivalent to a predicate device.¹³⁹ Since the predicate device must be a lawful device, showing substantial equivalence to an unlawful predicate device will not suffice.

Substantial equivalence does not require identical devices. A device is not substantially equivalent merely because its intended use is the same as the predicate device. According to the FDA's Office of Device Evaluation, it developed a three-pronged test that was later codified into the Safe Medical Devices Act of 1990 (SMDA). Prong-one examines whether the two devices have the same intended use. This refers to the purposes for which the product is designed.¹⁴⁰ If they are not for the same intended use, then the devices are not substantial equivalents. Prong-two examines the technological characteristics of the compared devices. The SMDA defines different technological characteristics to mean "there is a significant change in

¹³⁵ 21 C.F.R. § 807.81 (2000).

¹³⁶ 21 C.F.R. § 807.92(b) (2000).

¹³⁷ 21 C.F.R. § 807.92(a)(3) (2000).

¹³⁸ 21 C.F.R. § 807.81 (2000).

¹³⁹ 21 C.F.R. § 807.100 (2000).

¹⁴⁰ BRADLEY THOMSON, FDA REGULATION OF MEDICAL DEVICES 81 (1995).

the materials, design, energy source, or other features of the device from those of the predicate device.”¹⁴¹ If they are technologically equivalent, then the FDA will likely adjudge them substantial equivalents. On the other hand, if they are not technologically equivalent, then under prong-three, the FDA will evaluate the devices’ safety and efficacy performance.

Ultimately, the question in § 271(e)(1) infringement is whether the activity is reasonably related to gaining FDA approval.¹⁴² Accordingly, one helpful tool in examining whether the activity is reasonably related is to examine the actual application and its content. The 510(k) application does not have a prescribed format. However, the 510(k) must comprise the following categories:

- * A detailed description of the device, including labeling, advertisements, photographs and engineering drawings, sufficient to describe the device, its intended use, directions for use, principles of operation, power source, composition and any other information necessary to understand the device¹⁴³;

- * A statement with accompanying data indicating how the device is substantially similar to and/or different from, other comparable products (e.g., predicate devices) that are already in commercial distribution; for devices that applicant wishes to protect with a patent, which must be novel under US patent law, the 510(k) submission should state that the device is substantially equivalent for purposes of the FDA’s regulations of medical devices or words to that effect¹⁴⁴;

- * For devices that come in patient contact, an identification of the composition of all materials that contact the patient should be provided, and any differences or similarities with the predicate device should be stated. For any material changes in a new device compared to the predicate device, bio-compatibility test data must be provided;

- * For devices containing computer software, extensive information on the potential hazards, software development, testing and other areas;

- * Any specific information requested by the FDA for a particular device; and

¹⁴¹ 21 U.S.C. § 360c(i)(1)(B) (1994).

¹⁴² *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 107 (D. Mass. 1998).

¹⁴³ 21 C.F.R. § 807.100(b)(2)(ii)(A) (2000).

¹⁴⁴ 21 C.F.R. § 807.100(b)(2)(ii)(B) (2000).

* Either a detailed summary of the safety and efficacy information or a statement by the maker certifying that if the 510(k) is approved, a duplicate copy will be provided to any person within 30 days of the request.

1. Substantial Equivalence Under Section 510(k) and Equivalency Infringement

Here, another inter-relationship between patent law and FDA law becomes apparent. Currently, patent law finds infringement if the device infringes the patent claims via the *doctrine of equivalents* (DOE). The law of what constitutes an equivalent is uncertain since the doctrine seems to encompass many tests. Under one test, the allegedly infringing product is equivalent under the doctrine if the elements of the product is an insubstantial change from that covered by the elements in the patent claims.¹⁴⁵ That is, a product is likely to infringe if there is not a substantial difference. Another test used is whether the components of the claim in the accused product performs substantially the same function, in substantially the same way, to achieve substantially the same result.¹⁴⁶ Therefore, assuming the predicate device is patented, if a defendant (infringer) must allege that its product is substantially equivalent to the predicate device in order to obtain 510(k) approval, then can the patent holder of the predicate device argue that the defendant admits its product is equivalent under the doctrine of equivalents? Also, since the 510(k) process requires a comparison of the products, then perhaps this is also an admission of at least equivalency infringement. It may be suggested that a defendant may be estopped from asserting otherwise. In addition, as far as burden of proof shifting exists, if the patent holder asserts a *prima facie* equivalency infringement case based on the 510(k) substantial equivalency admissions, then the burden should shift to the defendant to prove that its statements are not the basis of equivalency infringement. Thus, a defendant could be judicially estopped from asserting otherwise.

¹⁴⁵ EMI Group N. Am., Inc. v. Intel Corp., 157 F.3d 887, 896 (Fed. Cir. 1998) (“Thus the doctrine of equivalents is invoked to prevent a fraud on the patent when an accused infringer is stealing the benefit of the invention by making insubstantial changes that avoid the literal scope of the claims.”).

¹⁴⁶ Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed. Cir. 1998) (holding that whether an element of the accused device is equivalent to a claim limitation depends on “whether the substitute element matches the function, way, and result of the claimed element, or whether the substitute element plays a role substantially different from the claimed element.”). See also Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 38 (1997).

C. Product Development Protocol: A Third Regime of Medical Device Approval

Another FDA regulatory regime for medical device is the Product Development Protocol (PDP).¹⁴⁷ Under the PDP, this protocol permits small entities to earn FDA approval for new Class III devices¹⁴⁸ by aggregating the investigation and approval regimes into a single procedure. The PDP can lead to faster and cheaper approval than the petition for reclassification or PMA routes¹⁴⁹ and also provides for increased confidentiality of submitted data.¹⁵⁰ To comply with PDP requirements,¹⁵¹ a generic device manufacturer must initiate the PDP by submitting a PDP proposal to the FDA.¹⁵² The PDP application must include supporting data that demonstrates the methods, facilities and controls used to make, process, package and install the device.¹⁵³ Since the procedure is slightly abbreviated, the PDP proposal must include any other information that the FDA may require.¹⁵⁴ As labeling is an FDA requirement, the PDP should include a sample of the labeling¹⁵⁵ and the applicant must confirm that it will continue to use the labeling as submitted during the protocol.¹⁵⁶ Since the PDP does relate to medical devices, the PDP application should enumerate any pre-clinical and clinical experiments and enumerate the expected results.¹⁵⁷

In evaluating the sufficiency of the PDP, the FDA will consider whether the medical device is a proper candidate for PDP procedures.¹⁵⁸ The FDA has 120 days to approve the PDP.¹⁵⁹ If the FDA approves of the PDP, then the applicant will file a *Notice of Completion*.¹⁶⁰ The notice of completion must include the data generated and fully describe the components, ingredients, properties

¹⁴⁷ 21 U.S.C. § 360e(f) (1994 & Supp. IV 1998); see also THOMSON, *supra* note 140.

¹⁴⁸ H.R. REP. NO. 853, 94th Cong. 2d Sess. 32-33 (1976).

¹⁴⁹ See THOMSON, *supra* note 140.

¹⁵⁰ 21 U.S.C. § 360j(h)(3) (1994); see also THOMSON, *supra* note 140.

¹⁵¹ 21 U.S.C. § 360e(f)(3) (1994).

¹⁵² 21 U.S.C. § 360e(f)(2) (1994 & Supp. IV 1998).

¹⁵³ 21 U.S.C. § 360e(f)(3)(B)(iv) (1994).

¹⁵⁴ 21 U.S.C. § 360e(f)(3)(B)(i), (v), (vii) (1994).

¹⁵⁵ 21 U.S.C. § 360e(f)(3)(B)(vi) (1994).

¹⁵⁶ 21 U.S.C. § 360e(f)(3)(B)(viii) (1994).

¹⁵⁷ 21 U.S.C. § 360e(f)(3)(B)(ii)-(iii) (1994).

¹⁵⁸ 21 U.S.C. § 360e(f)(2) (1994 & Supp. IV 1998).

¹⁵⁹ 21 U.S.C. § 360e(f)(4) (1994). Compare these procedures with approving/disapproving criteria set out in an IDE application and the PMA procedures in § 360c(f), § 360c and § 360j(g).

¹⁶⁰ 21 U.S.C. § 360e(f)(5) (1994).

and principles of operation of the device.¹⁶¹

After filing the notice of completion, the FDA must, within 90 days, issue a final approval of the PDP demonstrating that all the safety and efficacy standards were met.¹⁶² When the FDA issues the final *Order of Approval*¹⁶³ and if the PDP is complete, then the final order replaces the approval given for PMAs.¹⁶⁴ If the PDP is incomplete, then the FDA can withhold the final order upon which the applicant can appeal.¹⁶⁵ As with a PMA though, even if the PDP is complete, the FDA can revoke¹⁶⁶ the approval, which entitles the applicant to appeal.¹⁶⁷ Naturally, the FDA can revoke the PDP at any time, even after approval.¹⁶⁸

Therefore, since the PDP is a permissible route for a generic device manufacturer to take in gaining FDA approval of the underlying device, it is reasonable that any applicant that follows PDP procedures to gain FDA approval should find refuge under the § 271(e)(1) safe harbor exemption.

V. WHAT CONDUCT IS "REASONABLY RELATED" TO GAINING FDA APPROVAL?

As mentioned throughout this article, the § 271(e)(1) litigation paradigm should be shifted to determine if particular conduct is exempted by analyzing FDA law first. This section discusses how courts have already evaluated whether certain conduct qualifies under § 271(e)(1) and how the courts could have decided the issue without resorting to traditional infringement analyses.

Since the preceding section discusses medical devices in part, the primary question should be whether § 271(e)(1) applies to medical devices. Recall that § 271(e)(1) states:

(e)(1) 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

¹⁶¹ 21 U.S.C. §§ 360e(f)(5)(B), 360e(c)(1) (1994).

¹⁶² 21 U.S.C. §§ 360e(f)(5)(A), 360e(f)(6)(B) (1994); *see also* 21 C.F.R. § 814.40 (2000).

¹⁶³ 21 U.S.C. § 360e(f)(6)(B) (1994).

¹⁶⁴ 21 U.S.C. § 360e(f)(1) (1994); *see also* 21 C.F.R. § 814.19 (2000).

¹⁶⁵ 21 U.S.C. § 360e(f)(6)(B) (1994).

¹⁶⁶ 21 U.S.C. § 360e(f)(7) (1994).

¹⁶⁷ 21 U.S.C. §§ 360e(f)(8), 360e(g)(1)(B) (1994).

¹⁶⁸ 21 U.S.C. § 360e(f)(6)(A) (1994).

veterinary biological products. (emphasis added)

At first instance, the plain text of the statute indicates that § 271(e)(1) applies to drugs only, as shown by the italicized word *drug* in the above statute. The plain text does not mention the word “devices” in the statute. As understood in the context of FDA law, drugs¹⁶⁹ and devices¹⁷⁰ are different. Therefore, it would be reasonable that § 271(e)(1) does not apply to devices.

However, in *Eli Lilly & Co. v. Medtronic, Inc.*,¹⁷¹ the Supreme Court held that § 271(e)(1) does apply to medical devices. Justice Scalia noted that the focus of § 271(e)(1) was on the words “patented inventions” and that patented inventions included medical devices.¹⁷² Justice Scalia also noted that, whilst § 271(e)(1) is far from elegantly drafted, there is statutory symmetry since including devices would serve the legislative intent and comport with the specific drug related sections of §§ 271(e)(2)-(4).¹⁷³

As demonstrated above, medical devices can be classified into categories. The *Medtronic* decision only related to the applicability of § 271(e)(1) to medical devices in general. This begged the next question involving § 271(e)(1) and medical devices: Whether all medical devices could find refuge in § 271(e)(1)?¹⁷⁴ Several courts since 1990 have arrived at conflicting rulings involving Class I and II devices. In *Baxter Diagnostics, Inc. v. AVL Scientific Corp.*,¹⁷⁵ the district court held that since only Class III medical devices had to endure the prolonged regulatory approval process and were entitled to patent term extension, and Class I and II devices did not, Congress must have intended to exclude Class I and II devices from the

¹⁶⁹ 21 U.S.C. § 360e(f)(6)(A) (1994).

¹⁷⁰ See *supra* note 15.

¹⁷¹ *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989), *denied*, 879 F.2d 849 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

¹⁷² *Eli Lilly & Co. v. Medtronic, Inc.* 496 U.S. 661 669 (1990).

¹⁷³ *Id.* at 670-75.

¹⁷⁴ On an interesting aside, the case of *Gore v. Bard*, 977 F.2d 558 (Fed. Cir. 1992) is quirky. Gore sued Bard in February 1984 for infringement of a medical device settled out of court wherein Bard agreed that it would not infringe the patent for any reason. Congress then overruled *Roche v. Bolar* and basically permitted infringement under the HWA. However, when the Supreme Court decided *Medtronic*, this permitted infringement under the HWA for medical devices. Bard then petitioned the court to modify the consent agreement of 1984, under federal rules of civil procedure 60(b), to permit Bard to legally infringe under the HWA and *Medtronic*. The Federal Circuit affirmed the refusal to permit Bard to modify the consent agreement as the new change in laws did not amount to an extreme and unexpected hardship. *Gore*, 977 F.2d at 563.

¹⁷⁵ *Baxter Diagnostics, Inc. v. AVL Scientific Corp.*, 798 F. Supp. 612 (C.D. Cal. 1992), *modified in part*, 43 U.S.P.Q.2d (C.D. Cal. 1996).

purview of § 271(e)(1). Later, in *Chartex Int'l PLC v. MD Personal Products Corp.*,¹⁷⁶ the Federal Circuit held that Class I and II devices were protected under the § 271(e)(1) exemption. The Federal Circuit recently resolved this question definitively in *Abtox, Inc. v. Exitron Corp.*¹⁷⁷

In *Abtox*, Exitron hired MDT to conduct tests on a device called a plasma sterilizer¹⁷⁸ but the tests were limited to collecting test data necessary for a Class II medical device FDA application.¹⁷⁹ Abtox alleged that the tests were intended to promote the devices to others and to induce MDT to purchase rights in the device.¹⁸⁰ At the time of the suit, MDT had not applied for any FDA approval nor marketed the device.¹⁸¹ The district court ruled that MDT's use of the invention did not constitute infringement in pursuing regulatory approval.¹⁸²

The issue before the Federal Circuit was whether § 271(e)(1) covers Class II medical devices. This novel question involved statutory construction and, thus, was a question of law.¹⁸³ The Federal Circuit began by examining the *Medtronic* Supreme Court case. In *Medtronic*,¹⁸⁴ the Supreme Court held that § 271(e)(1) applies to medical devices. Recall that the FDCA¹⁸⁵ proposes three classes of medical devices: Class I, II, and III. For Class III devices, new devices are subject to the rigorous pre-market approval (PMA) process.¹⁸⁶ However, Class I and II devices are subject to an abbreviated process.¹⁸⁷ The approval process for Class II and Class III are not the same.¹⁸⁸

Abtox relied on the argument that *Medtronic* only dealt with Class III devices.¹⁸⁹ Thus, the safe harbor provisions do not exempt

¹⁷⁶ *Chartex Int'l PLC v. MD Personal Prods. Corp.*, 5 F.3d 1505 (Fed. Cir. 1993) (unpublished opinion).

¹⁷⁷ *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997).

¹⁷⁸ Often medical devices are reused and have to be cleaned and sterilized. A plasma sterilizer bombards a used medical device with highly excited and energized gas ions thereby destroying any microbes on its surface and rendering the device sterile.

¹⁷⁹ *Abtox*, 122 F.3d at 1027.

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Abtox Inc. v. Exitron Corp.*, 888 F. Supp. 6 (D. Mass. 1995).

¹⁸³ *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027-28 (Fed. Cir. 1997).

¹⁸⁴ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

¹⁸⁵ Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301-395 (1994 & Supp. IV 1998).

¹⁸⁶ 21 U.S.C. § 360e (1994 & Supp. IV 1998).

¹⁸⁷ 21 U.S.C. § 360(k) (1994).

¹⁸⁸ *Abtox*, 122 F.3d at 1028; *Medtronic v. Lohr*, 518 U.S. 470, 478 (1996).

¹⁸⁹ *Abtox*, 122 F.3d at 1028.

Exitron's tests on Class II devices.¹⁹⁰ However, the Court dismissed this argument by relying on the statutory scheme of § 271(e)(1) and its interplay with the HWA.¹⁹¹

In *Medtronic*, the court examined the nature of § 271(e)(1) and how it was to legislatively overrule *Roche*.¹⁹² The Supreme Court determined that the term "federal law" was one indication that § 271(e)(1) was to apply to medical devices, irrespective of the device's Class designation.¹⁹³ Furthermore, the Court looked to other chapters of the HWA,¹⁹⁴ notably the patent term restoration provisions,¹⁹⁵ that extended the term of the patent whilst the patent was caught up in lengthy FDA regulatory mechanisms.¹⁹⁶ In fact, the restoration chapter indicated that certain medical devices generally were entitled to patent term extension. As such, when combining the federal law portion with the explicit provisions of medical devices entitled to restoration, the Supreme Court determined that § 271(e)(1) must include all classes of medical devices. To parallel and reconcile two separate provisions of a statute is known as *the doctrine of statutory symmetry*.¹⁹⁷

However, under the above reasoning, Abtox argued that since the restoration chapter excludes Class II devices expressly, then it follows that Class II devices should have been excluded from § 271(e)(1).¹⁹⁸

¹⁹⁰ 35 U.S.C. § 271(e)(1) (1994 & Supp. IV 1998).

¹⁹¹ *Abtox*, 122 F.3d at 1029-30 ("Therefore, the Supreme Court disposed of the argument, made here by Abtox, that § 271(e)(1) is limited to Class III devices. Section 271(e)(1) contains no such limitation.").

¹⁹² *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Abtox*, 122 F.3d at 1028.

¹⁹³ *Medtronic*, 496 U.S. at 666; *Abtox*, 122 F.3d at 1028 ("The Supreme Court, however, interpreted the phrase 'federal law' to refer to 'an entire statutory scheme of regulation' not merely to single sections or subsections related to drugs or veterinary biological products.").

¹⁹⁴ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585, also known as the Hatch-Waxman Act, implemented as, *inter alia*, 35 U.S.C. §§ 271(e), 155, 156; and 21 U.S.C. § 355(j). See *Pharmacia & Upjohn Co. v. Mylan Pharms. Inc.*, 5 F. Supp. 2d 399, 400 (N.D. W.Va. 1998).

¹⁹⁵ 35 U.S.C. §§ 155, 156 (1994 & Supp. IV 1998); see also *Merck & Co. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996) (regarding patent term restoration and when it takes effect).

¹⁹⁶ *Abtox*, 122 F.3d at 1028-29.

¹⁹⁷ *Nordberg Inc. v. Telsmith, Inc.*, 881 F. Supp. 1252, 1287 (E.D. Wis. 1995); *Buell v. Beckstrom*, 22 U.S.P.Q.2d 1128, 1132 (BPAI 1992), 1992 WL 88046.

¹⁹⁸ Class II devices, however, are not eligible for patent term extensions. Specifically, section 156 defined the method of calculating the regulatory review period for a corresponding term extension. The section limits the regulatory review period for medical devices to those devices that require review under section 515 of the FDCA [21 U.S.C. § 360e]. In turn, 21 U.S.C. § 360e [FDCA § 515] applies only to Class III devices. Title 35 thus supplies no extension for Class II devices, such as the plasma sterilizer at issue in the instant case.

As such, Exitron's use of a Class II device cannot find refuge in the safety of § 271(e)(1). However, the court determined that to comport with statutory symmetry, the broad acceptance of the Supreme Court's *Medtronic* must be followed here.¹⁹⁹ To this end, § 271(e)(1) protects Class II medical devices, even though it appears that the *Medtronic* rationale is in conflict with statutory symmetry.

Since § 271(e)(1) applies to the device at issue, Abtox then argued that Exitron's uses did not comply with the section.²⁰⁰ Here the court held that § 271(e)(1) requires only that the otherwise infringing act be performed "solely for uses reasonably related to" FDA approval.²⁰¹ According to the court, the underlying purposes or attendant consequences of the activity (*e.g.*, testing that subsequently led to the sale of the patent from Exitron to MDT), are irrelevant as long as the use was reasonably related to FDA approval.²⁰² That is, the plain text permitted data use for more than FDA approval.²⁰³ Therefore, the court found that Exitron's uses qualified for exemption under § 271(e)(1).²⁰⁴

From a practical standpoint, a patentee will likely wait until the device is approved prior to commencing any expensive patent litigation to determine if the testing qualified under § 271(e)(1).²⁰⁵ Since all classes of medical devices find refuge in § 271(e)(1), it is now appropriate to examine what activities qualify for exemption.

Many patent infringement cases arising under § 271(e)(1) concern the issue of whether a generic device manufacturer may sell the infringing device yet still find refuge behind the safe harbor

Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1029 (Fed. Cir. 1997) (citation omitted).

¹⁹⁹ *Id.* at 1029 ("Therefore, under the broad holding of *Eli Lilly*, all classes of medical devices fall within the plain meaning of section 271(e)(1).").

²⁰⁰ *Id.* at 1027-28.

²⁰¹ *Id.* at 1029-30.

²⁰² *Id.* at 1030.

²⁰³ *Id.* at 1030; Teletronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.3d 1520, 1524-25 (Fed. Cir. 1992).

²⁰⁴ Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1030 (Fed. Cir. 1997) ("Even drawing all factual inferences in favor of Abtox, the activities of MDT were either non-infringing or reasonably related to seeking FDA approval.").

²⁰⁵ On an interesting aside, one question remaining is whether the plaintiff-patentee must already have FDA approval for its patented device in order that § 271(e) applies to a defendant. In *Richard Wolf Medical Instruments v. Dory*, 723 F. Supp. 37 (N.D. Ill. 1989), the court held that a defendant may "infringe" and still be within the § 271(e) exemption even if the patentee does not seek out, or already have received, FDA approval on its own device covered by the patent. This is sensible since a patentee is not required to make, use, or sell its device under the patent. Accordingly, a patentee that never makes its device nor wishes to pursue FDA approval can still sue a defendant-infringer to see if its activities constitute infringement or is exempted.

exemption. The plaintiff's theory is that a defendant should not be able to profit from the infringement and still claim the legal defense under § 271(e)(1). Whether a generic manufacturer can sell the device is answered yet again in the FDA laws. Recall that a sponsor or investigator cannot commercialize the device without FDA approval. But recognizing that some devices are expensive to manufacture and that it would seriously increase the costs of the FDA approval process if devices were distributed for free, the FDA rules permit the interstate sale of a device under certain circumstances. Under the FDA rules, a generic manufacturer, sponsor or investigator cannot commercialize the device to gain a profit. In other words, the manufacturer may only recover the costs of manufacture, research, development and handling.²⁰⁶ It is self-evident that a great many costs may be compartmentalized into these categories such that a defendant infringer may reasonably recover significant costs associated with the infringement. Other conduct litigated under § 271(e)(1) includes the following cases.

A. Non-Infringing Activities

1. *Intermedics, Inc. v. Ventritex, Inc.*²⁰⁷

The plaintiff accused the defendant of engaging in the following activities: (1) using data gathered from the testing of the device to obtain import approval from the German government; (2) authorizing the publication of articles describing the features of the device; (3) relying on the device to generate interest (earn a reputation) and income (capital); (4) demonstrating the device at various trade shows and medical conferences²⁰⁸ and (5) obtaining foreign patent rights on the device.²⁰⁹ Since none of these activities constitute infringement under § 271(a), they are non-infringing and the applicability of § 271(e)(1) was moot.²¹⁰

²⁰⁶ 21 C.F.R. § 812.7 (2000).

²⁰⁷ *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd. without opinion*, 991 F.2d 808 (Fed. Cir. 1993).

²⁰⁸ Of course, if the demonstration is an offer to sell, then this is direct infringement under § 271(a). See *HollyAnne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1308 (Fed. Cir. 1999) ("In its first attempt to define the contours of an 'offer to sell,' this court held that there had been an 'offer to sell' where the defendant manufacturer had communicated to prospective buyers both a description of the product and a price at which it can be purchased.").

²⁰⁹ *Intermedics*, 775 F. Supp. at 1281; see also *Chartex Int'l PLC v. M.D. Personal Prods. Corp.*, 1993 U.S. App. LEXIS 20560, at *10-11 (overseas dealings).

²¹⁰ *Intermedics*, 775 F. Supp. at 1281; see also *Chartex Int'l*, 1993 U.S. App. LEXIS 20560, at *8-9 (trade show demonstrations).

2. *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*²¹¹

The Federal Circuit affirmed that demonstrating the device to physicians in an effort to select them to participate in the clinical trials was exempt.²¹² Disseminating the test data to non-medical people is not infringement and moreover, did not strip a defendant of its § 271(e)(1) exemption.²¹³

3. *Elan Transdermal Ltd. v. Cygnus Therapeutics Systems*²¹⁴

The court held that circulating test data and results to corral potential licensees was not infringement.²¹⁵

4. *Amgen, Inc. v. Hoechst Marion Roussel, Inc. (HMR)*²¹⁶

Amgen sued HMR for infringement of Amgen's patent on erythropoietin (EPO).²¹⁷ The court noted that the Federal Circuit has

²¹¹ *Telectronics Pacing Sys. Inc. v. Ventritex, Inc.*, 19 U.S.P.Q.2d 1960 (N.D. Cal. 1991), *aff'd*, 982 F.2d 1520 (Fed. Cir. 1992).

²¹² *Telectronics Pacing Sys. Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523 (Fed. Cir. 1992).

²¹³ *Id.* at 1524; *see also Chartex Int'l*, 1993 U.S. App. LEXIS 20560, at *7-8; *see also Intermedics*, 775 F. Supp. at 1278.

²¹⁴ *Elan Transdermal Ltd. v. Cygnus Therapeutics Sys.*, 24 U.S.P.Q.2d 1926 (N.D. Cal. 1992).

²¹⁵ *Id.* at 1932-33; *see also Infinitex, Inc. v. Vitrophae, Inc.*, 842 F. Supp. 332, 336 (N.D. Ill. 1994) (conceding that the activities such as licensing to others, contracting with suppliers, purchasing collateral machinery, and preparing FDA applications, are exempt). This case also advances another interesting issue regarding declaratory judgment (DJ) actions in § 271(e) proceedings. To sue for DJ, an infringer must show reasonable apprehension of being sued for infringement. To defend a DJ action, the patentee must show that the infringer has not made substantial preparations to infringe, or must show that patentee has no intention of suing for infringement. The litigation tactic is that a potential infringer can drag a patentee into the forum of its choosing. *See Cardinal Chem. Co. v. Morton Int'l. Inc.*, 508 U.S. 83, 95-96 (1993) (stating that prior to the Declaratory Judgment Act, 28 U.S.C. § 2201, the patentee would continuously threaten and harass an infringer with the infringer waiting for that fateful day in which the suit would finally begin.). This becomes relevant in § 271(e) actions where the patentee can argue that if alleged infringer's activities are within the § 271(e)(1) safe harbor provisions, then the infringer is not committing infringement and cannot possess reasonable apprehension of suit and the DJ action must be dismissed. *See Farmaceutisk Laboratorium Ferring v. Solvay Pharms. Inc.*, 25 U.S.P.Q.2d 1344 (N.D. Ga. 1992); *see also Zenith Labs. Inc. v. Bristol-Myers Squibb Co.*, 24 U.S.P.Q. 2d 1641 (D.N.J. 1991); (DJ actions by infringers against patentees). *But see Intermedics*, 775 F. Supp. at 1269; *Telectronics Pacing Sys.*, 982 F.2d at 1520 (DJ actions brought by the patentee).

²¹⁶ *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998).

²¹⁷ Erythropoietin (EPO) is a hormone formed in the kidneys to stimulate red blood cell production. EPO is used in transfusions or other surgeries to rapidly replenish red blood cells

approved certain activities as qualifying for § 271(e)(1) refuge such as demonstrating the invention to recruit clinical investigators²¹⁸; hiring an outside firm to test the invention, even if the partial purpose or motive was to motivate the firm to purchase rights in the invention.²¹⁹ The court also noted that some other courts adopted a narrower construction in which the uses must be for FDA purposes and no other. Sales or uses that had multiple uses of which only some were for FDA purposes would fall outside the safe harbor provisions of § 271(e)(1).²²⁰ Thus, the use must be reasonably related to, but not exclusively related for the purpose of, gaining FDA approval.²²¹ Amgen argued that six activities were outside the § 271(e)(1) exemption:

Export to Japan. Amgen argued that HMR used process #1 to make its drug in the U.S. and sought its FDA approval on the drug produced by process #1. But HMR exported the drug to Japan to evaluate the manufacturing of the drug using another process (process #2). HMR did not include the description of process #2 in its U.S. FDA application. The court held that since process #2 would need its own separate FDA approval,²²² this process would generate data useful for a regulatory submission based either on process #1 or a later submission based on process #2. In this case it did not matter that HMR was not going to include process #2 data in its initial FDA submission. Therefore, the exemption applied and shielded HMR's allegedly infringing conduct.

Rabbit Pyrogen Studies. The FDA requires that the drug be relatively pure and includes testing the pyrogenicity of the drug.²²³ Two testing protocols exist to study pyrogenicity: (a) one *in vitro* test and (b) one *in vivo* rabbit test. HMR used the rabbit data to support the *in vitro* testing data, but did not intend to submit the rabbit testing data in the FDA submission. Thus, it was only ancillary support to the *in vitro* tests. The court held that this was permissible under the exemption so long as a use was calculated to

lost during excessive bleeding.

²¹⁸ *Telectronics Pacing Sys.*, 982 F.2d at 1523.

²¹⁹ *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997).

²²⁰ *Hoechst Marion Roussel*, 3 F. Supp. 2d at 107; *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987); *Biogen, Inc. v. Schering AG*, 954 F. Supp. 391, 396 (D. Mass. 1996) (stating that large scale production and market preparation stripped the defendant of any safe harbor provisions).

²²¹ *Hoechst Marion Roussel*, 3 F. Supp. 2d at 107.

²²² *Id.* at 108; 21 C.F.R. § 601.12(b) (2000).

²²³ 21 C.F.R. § 610.13 (2000).

lead to relevant information for submission.²²⁴ Therefore, even if the data from the rabbit studies was acceptable on its own, this was not enough to strip the exemption from the HMR.²²⁵

Consistency Batches. In addition to clinical testing batches, HMR also made three large scale production batches of commercial size. FDA requires three batches to be made to ensure that the large scale production would yield consistent results. Even though HMR was not satisfied with the large scale production and thus did not intend to submit these results in FDA submissions, this was activity reasonably related to regulatory approval. Again, the data was objectively likely to generate useful information even if the results were later discarded or abandoned due to dissatisfaction with the intended commercial success.²²⁶ Furthermore, merely inventorying the drugs after the commercial scale production was not infringement under § 271(a) and thus did not strip any exemption status under § 271(e)(1).

*Characteristics of GA-EPO.*²²⁷ The defendant conducted experiments to characterize the drug to compare the synthetic drug with naturally occurring hormone. The defendant alleged that this type of characterization was necessary pursuant to FDA guidelines for approval.²²⁸ Amgen argued that the defendant's actions were to compare the defendant's products against naturally occurring hormones. However, the proper comparison should have been against Amgen's patented products. As such, Amgen asserted that the comparison should have been to assess the patent position of the defendant and had no FDA regulatory merit.²²⁹ The district court ruled that the ancillary use was immaterial since the other uses included the regulatory submissions to the FDA and were therefore exempt.²³⁰

Viral Clearance Tests in Europe. The defendant shipped a drug to Europe for viral testing, the results of which were submitted to the FDA. Amgen argued that this was impermissible since European standards were more stringent than FDA's and thus immaterial.

²²⁴ *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 109 (D. Mass. 1998); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1284-85 (N.D. Cal. 1991).

²²⁵ *Hoechst Marion Roussel*, 3 F. Supp. 2d at 110.

²²⁶ *Id.*

²²⁷ Gene Activated Erythropoietin (GA-EPO) is HMR's tradename for the synthetic version of erythropoietin. See note 217 *supra*.

²²⁸ *Hoechst Marion Roussel*, 3 F. Supp. 2d at 110-11; see also 21 C.F.R. §§ 610.18(e), 312.23(a)(7) (2000).

²²⁹ *Hoechst Marion Roussel*, 3 F. Supp. 2d at 111.

²³⁰ *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 111 (D. Mass. 1998).

The court ruled that even though it applied more stringent standards, it was reasonably exempt, citing the *Intermedics* case that held it did not matter that reasonable people would have concluded that FDA approval could be secured even without the information in question.²³¹

Radio-Labeling. Amgen complained that the defendant once tried to conduct radio-labelling studies that were particular only to Japanese regulatory requirements. The defendant agreed that that was its intent, but never executed those plans and abandoned them.²³² The court ruled that unexecuted plans do not constitute infringement under § 271(a) and thus cannot be infringement under § 271(e)(1).²³³

In essence, Amgen argued that the defendant engaged in a world-wide conspiracy to gain regulatory approval in the United States, Japan and Europe and this was not what Congress intended in enacting § 271(e)(1). The district court stated that this assertion would read into the statute that disclosure of information to non-U.S. FDA personnel somehow repealed the exemption. The court further stated that this is not the law since any activities reasonably related to gaining FDA approval were permissible.²³⁴

B. *Infringing Activities Yet Exempted Under § 271(e)(1)*

1. *Intermedics, Inc. v. Ventritex, Inc.*

The plaintiff accused the defendant of: (1) manufacturing the device in the United States; (2) selling the device to hospitals in the United States; (3) selling the device to international distributors and (4) testing the device, particularly in Germany. The court held that while the defendant was infringing in all cases, the defendant was also exempted because: (a) the manufacture of the device was infringing but was used to obtain FDA approval²³⁵; (b) the sale of devices to hospitals were for their use in collecting clinical data and that no sales of the devices occurred to non-clinical participants. Even though sales continued after the PMA was filed, this was defensible since the applicant had no way of knowing whether the PMA data was

²³¹ *Id.*

²³² *Id.*

²³³ *Id.*

²³⁴ 35 U.S.C. § 271(e) (1994 & Supp. IV 1998); *Hoechst Marion Roussel*, 3 F Supp. 2d at 111; *Telectronics Pacing Sys. Inc. v. Ventritex, Inc.*, 982 F.2d 1523, 1524 (Fed. Cir. 1992).

²³⁵ *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1282 (N.D. Cal. 1991).

sufficient or whether further clinical data would be needed²³⁶; (c) the sales to international distributors who subsequently resold the devices to authorized, but foreign, clinical doctors whose responsibilities included collecting information²³⁷ and (d) the testing in Germany was to collect data and that submission to the FDA of data derived from foreign testing sites was allowed, especially since the German doctors were preeminent doctors in the field of cardiology.²³⁸

However, in *Ortho Pharm. Corp. v. Smith*,²³⁹ the Federal Circuit upheld a district court injunction that enjoined the defendant from using the product to obtain foreign pre-market approval, promotional, and commercial activities in the U.S.²⁴⁰ The Federal Circuit refused to entertain the issues on exempted activities because there was no prior determination of infringement under § 271(a).²⁴¹

2. *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*²⁴²

In this case, Telectronics sued Ventritex for infringement of a patented defibrillator. The only making, using or selling activity that Telectronics specifically alleged as unrelated to FDA approval was Ventritex's demonstration of its defibrillator to some non-physicians

²³⁶ *Id.* at 1282. *But see* *Eli Lilly & Co. v. Premo Pharm. Labs. Inc.*, 843 F.2d 1378, 1382 (Fed. Cir. 1988) wherein the court held that once the FDA application was approved, the approval did not give the defendant the right to continue infringement. *Compare* *Merck & Co. v. Biocraft Labs. Inc.*, 874 F.2d 804, 806 (Fed. Cir. 1989), *and* *Zenith Labs. Inc. v. Bristol-Myers Squibb Co.*, 24 U.S.P.Q. 2d 1641 (D.N.J. 1991) (holding that filing of FDA application extinguishes section 271(e) safety refuge), *with* *Intermedics*, 775 F. Supp. at 1289 (holding that PMA application does not extinguish rights).

²³⁷ *Intermedics*, 775 F. Supp. at 1282-83.

²³⁸ *Id.* at 1284.

²³⁹ *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936 (Fed. Cir. 1992).

²⁴⁰ *Ortho Pharm.*, 959 F.2d at 945-46. *See also* *Amgen, Inc. v. Elanex Pharms. Inc.*, No. C93-1483D, 1996 WL 84590, at *4 (W.D. Wash. 1996) wherein the court preliminarily denied § 271(e) safe harbor to the defendant because the defendant never sought out pre-clinical or clinical trials, never filed for FDA approval, never submitted any information to the FDA, and admitted that many of its U.S. activities were in support of its European marketing efforts.

²⁴¹ *Ortho Pharm.*, 959 F.2d at 945-46. *See also* *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 206-12 (D.N.J. 1994) (holding that the manufacturing of a patented product and its shipment to foreign countries to obtain foreign regulatory approval is not a defense under § 271(e) since foreign approval is not reasonably related to gaining FDA approval). *See also* *Biogen, Inc. v. Schering AG*, 954 F. Supp. 391 (D. Mass. 1996) (holding that stock-piling products was non-exempt and that foreign regulatory approval is not related to U.S. FDA approval). In this case, Biogen sent samples to foreign agencies to obtain foreign regulatory approval and knew it was no longer exempt. *Id.* at 396. Biogen also spent twenty four million in stockpiling drug to prepare for commercialization as soon as FDA approval occurred and was thus outside the scope of the exemption. *Id.* at 396-97. *But see* *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 110 (D. Mass. 1998) (permitting stock-piling).

²⁴² *Telectronics Pacing Sys. Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

at medical conferences.²⁴³ Ventritex argued that its demonstrations were set up for the purpose of obtaining clinical investigators.²⁴⁴ Such demonstrations constituted an exempt use reasonably related to FDA approval because the device sponsors were responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing.²⁴⁵ The fact that some non-physicians may have seen the device at the conference is merely incidental and of minimal import since only the physicians can implant the device.²⁴⁶

In addition, all of the other Ventritex activities that Teletronics complained of—presenting clinical trial data at a cardiology conference, reporting clinical trial progress to investors, analysts and journalists and describing clinical trial results in a private fund-raising memorandum—fall under the category of dissemination of the data for FDA approval.²⁴⁷ The statute does not identify dissemination of this information as a potentially infringing activity.²⁴⁸ Teletronics conceded that this disclosure of the clinical trial data cannot, in and of itself, constitute an infringing activity.²⁴⁹ To adopt Teletronics' interpretation, the court would have to read into this statute an unspoken requirement that the disclosure of information obtained during clinical trials to persons other than FDA officials, although not an act of infringement, somehow repeals the exemption.²⁵⁰ The court did not read this into the statute.²⁵¹

3. *Chartex Int'l PLC v. M.D. Personal Products Corp.*²⁵²

The Federal Circuit noted that Dr. Lash had used the device (a female condom) in sexual intercourse to test its fitness for FDA feasibility studies. The device failed. Other doctors used the device but were not employed by the defendant and the plaintiff did not join these others. Therefore, the defendant did not induce infringement

²⁴³ *Id.* at 1521-22.

²⁴⁴ *Id.*

²⁴⁵ See 21 C.F.R. § 812.40 (2000).

²⁴⁶ *Teletronics Pacing Sys.*, 982 F.2d at 1521-22.

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ *Id.*

²⁵² *Chartex Int'l PLC v. M.D. Personal Prods. Corp.*, 1993 U.S. App. LEXIS 20560 (Fed. Cir. 1993).

under § 271(b).²⁵³

4. *American Standard, Inc. v. Pfizer, Inc.*²⁵⁴

American Standard owned a patent on improved bone implant prostheses for improved fixation into the endogenous bone. In this case, the court determined that the defendant's use was also for commercial use. The court viewed § 271(e)(1) in its historical context. It was promulgated to overturn *Roche*.²⁵⁵ The Federal Circuit made it clear in *Medtronic* that the exemption from patent infringement for investigational devices under § 271(e)(1) is limited to medical devices used "solely for purposes reasonably related to the submission of information to the FDA."²⁵⁶ In the present case, the defendant marketed the product for commercial use also. Interestingly, the court stated that where the identical products are intended for both investigational and commercial use, it necessarily means that the investigational use warranting safe harbor cannot be solely for investigational uses.²⁵⁷ Even though the defendant labeled the infringing product warning consumers to only use the product with non-claimed products, this did not save the defendant since the patentee of a product is entitled to all applications to which his product may fit and the defendant's product could be used with or without the other products. Therefore, the safe harbor provisions did not apply.²⁵⁸ Commercial activity also stripped the defendant of § 271(e)(1) immunity in *Eli Lilly & Co. v. AH Robbins Co.*,²⁵⁹ in which the defendant believed that the patent was invalid. Accordingly it made and sold infringing products for the purposes of commercial gain. The court held that since this activity was purely for business reasons, the exemption did not apply.²⁶⁰

C. *Summary of § 271(e)(1) and its Application to Devices and Drugs*

As discussed, § 271(e)(1) provides a safe harbor exemption to a defendant who infringes a medical device or drug patent if the

²⁵³ 35 U.S.C. § 271(b) (1994) ("Whoever actively induces infringement of a patent shall be liable as an infringer."). See *Chartex Int'l*, 1993 U.S. App. LEXIS 20560 at *11.

²⁵⁴ *Am. Standard Inc. v. Pfizer Inc.*, 722 F. Supp. 86 (D. Del. 1989).

²⁵⁵ *Id.* at 103.

²⁵⁶ *Id.* (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989)).

²⁵⁷ *Id.*

²⁵⁸ *Id.*

²⁵⁹ *Eli Lilly & Co. v. A.H. Robbins Co.*, 228 U.S.P.Q. 757 (E.D. Va. 1985).

²⁶⁰ *Id.* at 760.

infringement is reasonably related to gaining FDA approval. It should be noted that all medical device infringement exemptions are within the ambit of § 271(e)(1) as no other provision of the HWA applies to medical devices. However, in addition to § 271(e)(1), there are sections of the HWA that only apply to drugs. Accordingly, the following sections only apply to drugs since drugs have their own unique approval process.

VI. GENERIC DRUG PATENT INFRINGEMENT UNDER THE HWA

While the preceding discussion focused, for the most part, on medical devices, drug approval also plays a significant role in patent laws since the HWA purported to introduce low cost generic drugs into the market.²⁶¹ As mentioned above, the marketing of an unapproved drug²⁶² in interstate commerce is illegal.²⁶³ However, since the focus of this part is on generic drugs, this presumes that a pioneer drug already exists. Recall that § 271(e)(1) categorically creates a safe harbor exemption for activities reasonably related to gaining FDA approval. However, in the drug context, this immunity is removed if the generic drug applicant goes farther than merely obtaining information. The generic drug applicant loses immunity under section § 271(e)(1) if the applicant then proceeds with a generic drug approval application to the FDA. Once the generic drug manufacturer submits an application for approval to the FDA, a new series of statutes under sections 35 U.S.C. § 271(e)(2) and 21 U.S.C. § 355(j) apply. Section 271(e)(2) states:

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent; or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. § 151-158) for a drug or veterinary biological product which is not primarily manufactured using

²⁶¹ Teva Pharms., USA, Inc. v. FDA, 182 F.3d 1003, 1004 (D.C. Cir. 1999).

²⁶² An unapproved new drug is defined as any drug that has a composition that is not recognized by qualified experts as safe and effective for use under the conditions prescribed, recommended or suggested under its labeling or is any drug that as a result of some investigation is recognized as safe and effective but except for the investigation, it has not been used to a material extent for the material time. 21 U.S.C. § 321(p)(1)-(2) (1994).

²⁶³ 21 U.S.C. § 355 (1994 & Supp. IV 1998). An adulterated drug, as defined by 21 U.S.C. § 331, cannot be marketed in interstate commerce. 21 U.S.C. § 331(a)-(c), (g), (k) (1994). Similarly, a misbranded drug, as defined by 21 U.S.C. §§ 331, 352(a)-(g), cannot be marketed. *Id.*

recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.²⁶⁴

Before undertaking an analysis of § 271(e)(2) and § 355(j), it is necessary to understand some fundamentals of the drug approval process.

A. Fundamentals of Drug Law

In order to market a new drug, the applicant must establish that the new drug is safe and effective.²⁶⁵ To establish that a drug is safe and effective, an applicant must undergo significant, time consuming, and costly testing²⁶⁶ and reporting, which generally results in an application called a New Drug Application (NDA).²⁶⁷ One study indicated that it takes about twelve to nineteen years for a patentee to recover a reasonable profit and the capital input costs.²⁶⁸ However, like device law, there is an abbreviated procedure that drug approval applicants may use in the FDA process. In the case of a generic manufacturer, the HWA created an abbreviated application, called an Abbreviated New Drug Application (ANDA). As the discussion above indicated, any infringement of a patent is exempted via § 271(e)(1). However, ANDA procedures set forth in § 271(e)(2)-(4) are unique creatures to drug law as they were implemented by the HWA specifically.

In submitting an ANDA, the generic drug manufacturer must show that its drug is bio-equivalent,²⁶⁹ that is, the drug must be shown

²⁶⁴ FDCA sections are quoted as enacted and not cited to the United States Code. A reference to the FDCA section number presupposes the reader understands that the FDCA is found in 21 U.S.C. Ch.9. Accordingly, § 505 of the FDCA corresponds to 21 U.S.C. § 355.

²⁶⁵ 21 U.S.C. § 355(b) (1994 & Supp. IV 1998).

²⁶⁶ *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994).

²⁶⁷ *Serono Labs. Inc. v. Shalala*, 974 F. Supp. 29, 30 (D.D.C. 1997).

²⁶⁸ Henry G. Grabowski & John M. Vernon, *A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development*, 3 *Managerial & Decision Econ.* 36 (1982).

²⁶⁹ 21 U.S.C. §§ 355(j)(8), 355 (j)(7)(B) (1994 & Supp. IV 1998). See *Foster*, 29 F.3d 165, 169 n.3.

Bio[-]equivalence means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug

to be a pharmaceutical equivalent²⁷⁰ to the pioneer patented drug.²⁷¹ The ANDA applicant basically relies on the prior existing information in order to meet the safety and efficacy requirements.²⁷² In other words, the generic drug manufacturer need not engage in its own clinical testing programs.²⁷³ The applicant must show that the rate and extent of absorption of the generic version is not substantially different from the rate and extent of absorption of the pioneer drug.²⁷⁴ The generic drug applicant can show bio-equivalence by showing *in vitro* or *in vivo* studies or both.²⁷⁵ In addition, an applicant can show bio-equivalence by showing that the drug has the same bio-availability,²⁷⁶ which means that the rate and extent of absorption of the active ingredient in the generic drug becomes available at the drug action sites.²⁷⁷ If the ANDA applicant cannot show similar identity of the generic drug to the pioneer drug, the ANDA applicant can still file a *suitability petition* that denotes the basis upon which the product is still a pharmaceutical alternative.²⁷⁸

Initially, the ANDA is reviewed for compliance with procedural rules to generate a pre-filing assessment by the Regulatory Support Branch of the Office of Generic Drugs (RSB) at the FDA. If the

action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain controlled release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bio[-]equivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

²⁷⁰ 21 C.F.R. § 320.1(e) (2000).

²⁷¹ 21 C.F.R. § 320.1(c) (2000).

²⁷² 21 U.S.C. §§ 355(j)(2)(A)(iv), 355(j)(4)(F) (1994 & Supp. IV 1998).

²⁷³ 21 U.S.C. § 355(j)(7)(B) (1994 & Supp. IV 1998); *Glaxo, Inc. v. Heckler*, 623 F. Supp. 69, 72 (E.D.N.C. 1985).

²⁷⁴ *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546-47 (Fed. Cir. 1996).

²⁷⁵ 21 U.S.C. §§ 355(j)(2)(A)(ii-iv), 355(j)(4)(C-D) (1994 & Supp. IV 1998) (stating that a pharmaceutical equivalent must have the same route of administration, the same dosage form, the same active ingredient, and the same drug strength as the pioneer drug).

²⁷⁶ 21 U.S.C. § 355(j)(6)(A)(i)(III) (1994 & Supp. IV 1998).

²⁷⁷ 21 U.S.C. § 355(j)(7)(A) (1994 & Supp. IV 1998).

²⁷⁸ 21 U.S.C. § 355(j)(3)(F) (1994 & Supp. IV 1998); *see Schering Corp. v. Shalala*, 995 F.2d 1103, 1104 (D.C. Cir. 1993); 21 C.F.R. § 320.1(a) (2000). Non-systemically effective drugs (NSED) work by topical application and not by absorption into the bloodstream. Therefore, under the old rules, NSED's did not qualify for ANDA procedures if bioequivalency was the only measure. Accordingly, new rules permit ANDA procedures for NSEDs.

²⁷⁹ 21 U.S.C. § 355(j)(2)(C) (1994 & Supp. IV 1998); 21 C.F.R. § 320.1(d) (2000).

ANDA complies, then the ANDA will be forwarded for substantive examination. If the RSB determines that the ANDA fails on some procedural defect, it will send a *Refuse To File* letter documenting the defects and inviting the ANDA applicant to correct the defects; the defects must be corrected before being forwarded for substantive examination.

In essence, the ANDA must include the following information:

- (i) the use of the pioneer drug has been previously approved;
- (ii) the generic drug contains the same active ingredient(s)²⁷⁹ as the previously approved drug, or documents the differences in the pharmaceutical alternative suitability petition;
- (iii) the generic drug possesses the same route of administration, dosage form, and strength of the previously approved drug, or otherwise documents the differences;
- (iv) the new drug is bio[-]equivalent to or has the same therapeutic effect as the pioneer drug;
- (v) the new drug has the same labeling as the previously approved drug, or the differences are approved²⁸⁰ and
- (vi) it has complied with other statutory requirements, which include providing a full list of articles used as components, a full statement of composition, samples of the drug, labeling specimens and a description of manufacturing, processing and packaging.²⁸¹

²⁷⁹ 21 C.F.R. § 314.127(a)(8)(ii)(B) (2000); *see also* 54 Fed. Reg. 2872, 28902 (July 11, 1989). The FDA requires that the generic drug also contain the same inactive ingredients (excipients) as the pioneer drug since the FDA believes that changing the excipients may affect safety and efficacy.

²⁸⁰ Although, the generic manufacturer may alter the labeling to add or strengthen a contraindication, warning, precaution or adverse effects; or to delete false, misleading or unsupported indications with prior FDA approval. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994); 21 C.F.R. §§ 314.70(c)(2), 314.97 (2000).

²⁸¹ 21 U.S.C. § 355(j)(2) (1994 & Supp. IV 1998); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1005 (D.C. Cir. 1999); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 448 (D.N.J. 1998). *See also* 21 C.F.R. § 211 (2000) (documenting FDA's right to demand a plant inspection to ensure the applicant's compliance with current GMP).

The following table matches the regulatory requirements of generic and pioneer drugs.

TABLE 1

FDA Requirement	Pioneer Drug (NDA)	Generic Drug (ANDA)
Safety & Efficacy Data	Yes	No ²⁸²
Bio-Availability and Bio-Equivalency	Yes	Yes
Current GMP Evaluation Before Marketing	Yes	Yes
Pre-marketing formulation review, active and inactive ingredients	Yes	Yes
Active ingredient testing	Yes	Yes
Drug product testing	Yes	Yes
Label review	Yes	Yes
Prior approval for manufacturing changes	Yes	Yes
Required registration of product before marketing	Yes	Yes
Plant inspection before marketing	Yes	Yes
FDA drug quality monitoring after approval	Yes	Yes

If the applicant successfully demonstrates bio-equivalency, then the FDA will grant the ANDA and will publish the drug in the FDA's Orange Book, which then permits pharmacists to substitute the pioneer drug for the generic version.²⁸³ The Orange Book information includes any patent information, such as patent expiration dates.²⁸⁴ Without approval of the ANDA, the generic manufacturer may not market the generic version.²⁸⁵ The purpose of proving bio-equivalency ensures that the generic drug is just as safe and effective as the pioneer drug.²⁸⁶ Since the FDA is approving the ANDA based on an abbreviated process, without the traditional clinical trials and

²⁸² ANDA applicants do not undergo primary safety and efficacy testing as it relies on the pioneer drug testing data.

²⁸³ 21 U.S.C. § 355(j)(4) (1994 & Supp. IV 1998); *Serono Labs. Inc. v. Shalala*, 974 F. Supp. 29, 31 (D.D.C. 1997); *See also* U.S. FOOD AND DRUG ADMINISTRATION, *Center for Drug Evaluation and Research*, <http://www.fda.gov/cder/orange/adp.htm> (last visited Oct. 29, 2000).

²⁸⁴ 21 U.S.C. §§ 355(b)(1), 355(j)(7)(A)(iii) (1994 & Supp. IV 1998); *Ben Venue Labs.*, 10 F. Supp. 2d at 447.

²⁸⁵ *TorPharm Inc. v. Novopharm, Ltd.*, 48 U.S.P.Q.2d 1471, 1472 (E.D.N.C. 1998).

²⁸⁶ *Schering Corp. v. FDA*, 51 F.3d 390, 396 (3rd Cir. 1995), *cert. denied*, 516 U.S. 907 (1995).

results, the FDA has great latitude in determining bio-equivalence.²⁸⁷

B. ANDAs and the Patent Laws

As mentioned above, the HWA created a legal regime for ANDA procedures as it relates to patent laws under § 271(e)(2) and 21 U.S.C. § 355(j). In addition to the bio-equivalency information necessary, the ANDA must also contain one of four certifications relating to the patent status of the pioneer drug. These certifications are known as Paragraph I, II, III or IV certifications wherein the ANDA applicant certifies:²⁸⁸

- (I) that the patent information has not been filed;
- (II) that the patent has expired;
- (III) the date on which such patent will expire; or
- (IV) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

Paragraphs I and II denote that either no patent information is listed in the Orange Book (Paragraph I) or that any patent related to the ANDA drug is expired (Paragraph II). Therefore, a certification under these two paragraphs indicate that the ANDA approval will not implicate any patent rights and the ANDA applicant will be free to market the generic version upon FDA approval of the ANDA.

An ANDA containing a Paragraph III certification is certifying that despite the existence of a patent, the applicant is submitting the ANDA now, so that the ANDA can be approved upon patent expiration. However, a Paragraph IV certification requests the FDA to approve the ANDA immediately prior to the patent expiration. The FDA will do so because the ANDA applicant is certifying that the patent is either invalid or that the ANDA drug will not infringe the patent.²⁸⁹ Accordingly, the ANDA applicant is inviting the FDA to approve the ANDA prior to the patent expiration. A Paragraph IV certification is an invitation to the patentee to engage in the patent litigation to determine the patent and ANDA status.²⁹⁰ Obviously, if

²⁸⁷ 21 U.S.C. § 355(j)(2)(A) (1994 & Supp. IV 1998); *Schering*, 51 F.3d at 398.

²⁸⁸ 21 U.S.C. § 355(j)(2)(A) (1994 & Supp. IV 1998).

²⁸⁹ 21 U.S.C. § 355(j)(2)(B)(ii) (1994).

²⁹⁰ A Paragraph IV certification evokes interesting constitutional law questions. For example, since the process involves both equitable (application of the HWA, imposition of injunctions) and legal (infringement and invalidity) questions, Coggio suggests that a jury trial is necessary in traditional infringement questions but have a diminished role in HWA cases. See Brian

the ANDA applicant proves the patent invalid or proves that its ANDA drug will not infringe the patent, the approval of the ANDA will permit the generic manufacturer to enter the market forthwith.²⁹¹ On the other hand, if the patentee proves the patent is valid or that the ANDA drug will infringe, then the ANDA applicant loses and must await patent expiry for ANDA approval.

In order to encourage generic drug manufacturers to come forth and sue to invalidate patents and bring low-cost equivalents to the market, the first generic manufacturer to file a Paragraph IV certification will be given a 180-day exclusivity period in which no other ANDAs on that same generic drug will be approved.²⁹² That 180-day clock starts either when the generic manufacturer begins outright commercial marketing of its drug (the commercial marketing trigger) or when there is a court decision finding that the pioneer drug patent is either not infringed or is invalid (the court-decision trigger).²⁹³ This 180-day period, therefore, gives the ANDA applicant six months of non-competitive marketing of the generic drug.

However, filing a Paragraph IV certification is not without its attendant consequences.²⁹⁴ Since the Paragraph IV certification is an invitation to sue, the patentee, who must be notified of the ANDA filing, will get notice of the facts and legal theories of the ANDA applicant's allegations of non-infringement or patent invalidity.²⁹⁵ From the date the patentee receives notice of the Paragraph IV certification, the patentee will have forty-five days to launch suit

Coggio & Sandra A. Bresnick, *The Right to a Jury Trial in Actions Under the HWA*, 79 J. PAT. & TRADEMARK OFFICE SOC'Y 765 (Nov. 1997); see also Brian Coggio & Sandra Bresnick, *The Diminishing Role of Juries in Intellectual Property Litigation*, 5 METROPOLITAN CORPORATE COUNSEL 15 (1997).

²⁹¹ See, e.g., *Merck & Co. v. Biocraft Labs. Inc.*, 874 F.2d 804 (Fed. Cir. 1989) (filing of an ANDA and proved that the Merck patent was invalid as being obvious).

²⁹² See Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(4)(D)(i)-(v) (1994); *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987).

²⁹³ 21 U.S.C. §§ 355(j)(5)(B)(iv)(I)-(II) (1994 & Supp. IV 1998); see also *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000).

²⁹⁴ See, e.g., *Marrion Merrell Dow, Inc. v. Hoechst Roussel Pharms. Inc.*, 32 U.S.P.Q.2d 1156, 1158 (D.N.J. 1994) (holding that a patentee may continue to sue for infringement even though the ANDA did not refer to the patents in suit), but see *Abbott Labs. v. Zenith Labs. Inc.*, 35 U.S.P.Q.2d 1161, 1169 (N.D. Ill. 1995) (comparing actual notice to the patentees as being dispositive to whether a suit by the patentee can be maintained). Since Abbott's patent had not yet issued by the time the FDA approved the ANDA, Zenith could not certify against the patent as it had not yet issued. This is a distinction with a difference. An ANDA applicant that fails to certify against a patent that already exists must correct the ANDA to include the certification concerning the patent. 21 C.F.R. § 314.94(a)(12)(vi) (2000).

²⁹⁵ 21 U.S.C. § 355(j)(2)(B)(ii) (1994); *Ben Venue Labs., Inc. v. Novartis Pharms. Corp.*, 10 F. Supp. 2d 446, 448 (D.N.J. 1998).

against the generic applicant.²⁹⁶ If the patentee files suit in the forty-five day window, then the FDA is forbidden from approving the ANDA for a thirty-month period.²⁹⁷ This permits the infringement suit to proceed without having the generic drug on the market and eroding sales of the pioneer drug.²⁹⁸ If the court renders a decision of patent validity or infringement (the ANDA applicant loses the suit) within the thirty-month period, then the ANDA will not be approved until patent expiry. On the other hand, if the ANDA applicant proves the patent invalid or proves non-infringement (the ANDA applicant wins the suit) within the thirty-month period, then the FDA will approve the ANDA effective as of the court judgment date.²⁹⁹ Even though the generic drug must be bio-equivalent to the pioneer drug, it is not necessary that the generic drug literally infringe the patent claims in order for infringement to be shown. As with any infringement analysis, infringement may be shown in ANDA cases using the DOE.³⁰⁰ For example, in *Pharmacia Upjohn Co. v. Mylan*

²⁹⁶ 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. IV 1998); *Ben Venue Labs.*, 10 F. Supp. 2d at 448.

²⁹⁷ 21 U.S.C. § 355(j)(2)(A)(iv) (1994); *Zeneca Ltd. v. Mylan Pharms. Inc.*, 173 F.3d 829 (Fed. Cir. 1999) (arguing that jurisdiction is proper in Maryland district court since alleged infringer, Mylan, sent its Paragraph IV certification to the FDA which is located in Rockville, MD and filing of a Paragraph IV certification is a statutory act of infringement); *Eli Lilly v. Medtronic*, 496 U.S. 661, 675-77 (1990); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568-69 (Fed. Cir. 1997). One reason that Zeneca might prefer to sue in Maryland is that Maryland courts operate faster in patent cases. In affirming the Maryland court's order to transfer the case back to Pennsylvania, the Federal Circuit held that the filing of an ANDA containing a Paragraph IV certification cannot be the sole basis for exercising jurisdiction in Maryland merely because the FDA is located in Maryland. *Zeneca*, 173 F.3d at 831.

²⁹⁸ See *Infinitech, Inc. v. Vitrophase, Inc.*, 842 F. Supp. 332, 337 (N.D. Ill. 1994); *Intermedics, Inc. v. Ventritex, Inc.* 775 F. Supp. 1269, 1276-77 (N.D. Cal. 1991); *Teletronics Pacing Sys. Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1522-23 (Fed. Cir. 1992); *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1401-02 (Fed. Cir. 1995); *BP Chem. Ld. v. Union Carbide Corp.*, 4 F.3d 975, 977-78 (Fed. Cir. 1993) (holding that an ANDA applicant may sue for patent invalidity, non-infringement, or for a ruling that its activities fall under the safety of § 271(e)(1)). Under § 271(e)(1), a patentee cannot sue now for future infringement when the "infringement" moves out of the safe harbor exemption. Therefore, an infringer may want to sue now and waive its exemption to determine if its activities fall under § 271(e)(1)). See also *Ben Venue Labs.*, 10 F. Supp. 2d at 449 (citing to 21 U.S.C. § 355(j)(5)(B)(iii)(III) (Supp. IV 1998), stating that during the 45 day window, the infringer is forbidden from bringing a Declaratory Judgment Action against the patentee).

²⁹⁹ 21 U.S.C. § 355(j)(5)(B)(iii)(I) (Supp. IV 1998); *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000) (holding that collateral estoppel and res judicata are also implicated in ANDA actions); *Imperial Chem. Indus. v. Barr Labs.*, 795 F. Supp. 619 (S.D.N.Y. 1992), *vacated without opinion*, 991 F.2d 811 (Fed. Cir. 1993) (making the patent valid and enforceable); *Zeneca Ltd. v. Novopharm Ltd.*, 45 U.S.P.Q.2d 1055, 1057 (Fed. Cir. 1997) (rejecting Novopharm's argument that the patent was invalid due to the prior adjudication).

³⁰⁰ See, e.g., *Merck & Co. v. Mylan Pharms., Inc.*, 19 F. Supp. 2d 334 (1998), *aff'd* 190 F.3d 1335 (Fed. Cir. 1999), *later proc.* 79 F. Supp. 2d 552 (E.D. Pa. 2000) (affirming non-infringement under the doctrine of equivalents and prosecution history estoppel).

Pharmaceuticals, Inc.,³⁰¹ Mylan submitted an ANDA and Pharmacia Upjohn conceded that Mylan's drug did not literally infringe the patent and sued under the doctrine of equivalents.³⁰² In the interim, in another proceeding, another court determined that the patent was invalid. Pharmacia Upjohn then filed for a judgment as a matter of law to reverse the invalidity decision. The court in Mylan noted that despite the question of patent invalidity, the present court determined that prosecution history barred application of the doctrine and ruled that Mylan's drug did not infringe, either literally or equivalently. Accordingly, the Paragraph IV certification was correct in that Mylan's drug did not infringe the patent.

As mentioned above, one aspect of the Paragraph IV certification process is the 180-day exclusivity period granted to the first filer.³⁰³ One outstanding issue regarding the 180-day exclusivity period is the impact on second filers when a first ANDA filer has not been sued for patent infringement and successfully defended the suit. One of the first cases to address this issue was *Inwood Laboratories, Inc. v. Young*.³⁰⁴

In this case, the plaintiff was the generic manufacturer of propranolol HCl³⁰⁵ and the first ANDA applicant. Inwood sued the FDA to require the FDA to delay approvals of subsequent ANDAs by 180 days.³⁰⁶ The parties agreed that the purpose of HWA was to facilitate entry of generic drugs into the market as soon as the patent on the pioneer drug expired by permitting the generic drug manufacturer to rely on the FDA's prior determinations of safety and efficacy.³⁰⁷ In implementing the Amendments, a new procedure permitted the filing of an ANDA and presumptively, the ANDA became effective once the pioneer patent expired.³⁰⁸

³⁰¹ *Pharmacia & Upjohn Co. v. Mylan Pharms. Inc.*, 5 F. Supp. 2d 399 (N.D. W.Va. 1998), *see also* *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998); *see also* *Pharmacia & Upjohn Co. v. Mova Pharm. Corp.*, 899 F. Supp. 46 (D.P.R. 1995).

³⁰² *Pharmacia & Upjohn Co. v. Mylan Pharms. Inc.*, 5 F. Supp. 2d at 399.

³⁰³ *See* 21 U.S.C. § 355(j)(5) (1994 & Supp IV 1998) for 180 exclusivity period. *See also* *Torpharm Inc. v. Novopharm Ltd.*, 181 F.R.D. 308, 310 (E.D.N.C. 1998) granting company 180 day exclusivity period to ensure that FDA would not grant final approval to any other company's ANDA until first company's 180 days is over.

³⁰⁴ *Inwood Labs. Inc. v. Young*, 723 F. Supp. 1523 (D.D.C. 1989), *appeal dismissed, vacated as moot*, 43 F.3d 712 (D.C. Cir. 1989).

³⁰⁵ Propranolol HCL is the hydrochloride form of propranolol, which is a beta adrenergic blocking agent. It is used to treat abnormal heart rhythms and angina pectoris. <http://www.damicon.fi/sd/sd-propranolol-hydrochloride.html> (last visited Oct. 10 2000).

³⁰⁶ 21 U.S.C. § 355(j)(5)(B)(iv) (Supp. IV 1998); *Inwood Labs.*, 723 F. Supp. at 1524.

³⁰⁷ *Inwood Labs.*, at 1524-25.

³⁰⁸ *Id.* at 1524-25.

However, by filing one of four certifications in the ANDA, a generic applicant can accelerate its approval and obtain approval prior to the original pioneer patent expiry date.³⁰⁹ If the ANDA contains a paragraph IV certification, then the ANDA applicant must notify the patentee of the ANDA application.³¹⁰ Upon receipt of the notification, the patentee must file suit for infringement within forty-five days, which if the suit is filed, operates to suspend the ANDA approval date for thirty months or the court determines that no infringement exists (or the patent is invalid), whichever occurs earlier.³¹¹ Otherwise, if the patentee fails to sue in that time, it acts as quasi-permission to the FDA to proceed and as such, the FDA will approve the ANDA immediately on the forty-sixth day.³¹²

One issue that will undoubtedly be one of first impression will be when the ANDA applicant fails to properly notify the patentee. The issue would then be whether the forty-five day clock starts when the applicant filed the ANDA or when the patentee received the notice. The author suggests that the plain language of the forty-five day notice provision indicates that the forty-five day clock starts when the patentee receives the notice.³¹³

In addition to providing the ANDA applicant with an accelerated approval process, the HWA permits the FDA to grant a 180-day period of exclusivity to the ANDA applicant that submitted a paragraph IV certification.³¹⁴ In the present case, the parties agreed that Inwood submitted an ANDA containing a paragraph IV

³⁰⁹ Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii) (1994).

³¹⁰ 21 U.S.C. § 355(j)(2)(B) (1994 & Supp. IV 1997).

³¹¹ 21 U.S.C. § 355(j)(5)(B)(iii) (1994).

³¹² *Id.*

³¹³ If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received.

21 U.S.C. § 355(j)(5)(B)(iii) (Supp. IV 1998).

³¹⁴ If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (1994 & Supp. IV 1998).

certification; duly notified the patentee that Inwood was the first ANDA applicant and that the patentee failed to sue within the 45-day window.³¹⁵ To this end, the FDA approved the ANDA immediately and two weeks later, the ANDA applicant notified the FDA that it started commercial marketing and, as such, the ANDA applicant claimed the 180-day exclusivity period.³¹⁶ The FDA rejected the claim for exclusivity on the grounds that the patentee failed to sue for infringement and thus the period does not start until then.³¹⁷ The FDA's position was that the filing of a suit under § 355(j)(4)(B)(iii) must be read into § 355(j)(4)(B)(iv) as a precondition for exclusivity. Since the patentee failed to sue, Inwood was not entitled to the exclusivity period.³¹⁸

The court rejected the FDA's position since only Subpart II requires a suit. Subpart I makes no mention of a suit. Instead, Subpart I preconditions exclusivity on the ANDA applicant being the first to market commercially.³¹⁹ Under the FDA's construction, the applicability of the exclusivity period would then be hostage of the patent holder, who may decide to sue or not. In a bizarre result, the patent holder may choose to sue the second, third or subsequent ANDA applicant and would result in no generic applicant obtaining the exclusivity period.³²⁰ In addition, the first applicant would bear the brunt of filing the first ANDA but not be sued, however, a subsequent applicant could bear the burden of defending in the infringement suit if the patentee decided to sue the subsequent applicant.³²¹ The FDA then argued that no exclusivity period would occur in the event the first applicant was not sued, and the first applicant failed to commercially market the drug. As such, according to the FDA, this would frustrate other competitors.³²² However, the court ruled that economic incentives exist that the first applicant will likely begin commercial marketing soon after approval as evidenced by the applicant in this case.³²³

³¹⁵ *Inwood Labs. Inc. v. Young*, 723 F. Supp. 1523, 1525 (D.D.C. 1989).

³¹⁶ 21 U.S.C. § 355(j)(5)(B)(iv)(II) (Supp. IV 1998); *Inwood Labs.*, 723 F. Supp. at 1525.

³¹⁷ 21 U.S.C. § 355(j)(5)(B)(iii) (1994 & Supp. IV 1998); *Inwood Labs.*, 723 F. Supp. at 1525.

³¹⁸ *Inwood Labs.*, 723 F. Supp. at 1525.

³¹⁹ *Id.* at 1526.

³²⁰ This would be because the first applicant is not entitled to any exclusivity because he was not sued by the patentee. Subsequent applicants would not get any exclusivity because they were not the first applicant to apply.

³²¹ *Inwood Labs.*, 723 F. Supp. at 1526-27.

³²² *Id.* at 1527.

³²³ *Id.*

The 180-day exclusivity period to protect the patentee and the first ANDA applicant is further underscored in the recent case of *Purepac Pharmaceuticals Co. v. Friedman*,³²⁴ which illustrates the history of the successful defense prong of the 180-day exclusivity period.

Recall that the HWA conferred upon the first generic ANDA applicant a 180-day exclusivity period during which it would be free from competition from later generic applicants who also filed for generic drug approval.³²⁵ Accordingly, the FDA promulgated a regulation to implement the statute. However, in *Mova Pharmaceutical Corp. v. Shalala*,³²⁶ the court enjoined the FDA from

³²⁴ *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201 (D.C. Cir. 1998).

³²⁵ *Id.* at 1206.

³²⁶ *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1062-63 (D.C. Cir. 1998). In *Mova*, Pharmacia Upjohn is the patentee on micronized glyburide, a drug for diabetes. Mova was the first to file an ANDA to market a generic version, but before its approval, Upjohn sued for patent infringement. In the meantime, Mylan submitted an ANDA to market generic version and the FDA granted Mylan's ANDA. Mova, as the first ANDA applicant learned of Mylan's approval and then sued to compel the FDA to suspend the effective date of Mylan's approval until 180 days after the earlier of the dates that Mova won its suit or began to market its product. Mova argued that since it was the first to file the generic version application, then 21 U.S.C. § 355(j)(5)(B)(iv) applied. [Note: that at the time of the district court suit, Mova sued under then 21 U.S.C. § 355(j)(4)(B)(iv), which was later amended and renumbered by the Food and Drug Modernization Act of 1997, Pub. L. 105-115, 111 Stat. 2296 (1997)]. The Act granted a 180 day period of market exclusivity running from the time Mova won its suit or began marketing its product, and the FDA was barred from granting another manufacturer's application until the end of the 180-day period. The FDA argued that it had the agency authority to approve Mylan's application since at the time of Mylan's submission, Mova had not yet 'successfully defended' and prevailed in its *Upjohn v. Mova* suit. Mova argued that the regulation in the C.F.R. was inconsistent with the § 355 of the statute. The trial court ruled in favor of Mova and enjoined FDA from approving Mylan application until resolution of the *Upjohn v. Mova* suit. The court noted that in implementing § 355(j)(B)(5)(iv) and the two triggers, the FDA added in regulations that the first and a paragraph IV applicant must have "successfully defended against a suit for infringement" before the 180-day exclusivity period begins to run. 21 C.F.R. § 314.107(c)(1) (2000). On appeal, the FDA argued that the policy reason of the 'successful defense' provision is to further Congressional intent and reduce bizarre results. Particularly, the FDA argued that two situations occur that create bizarre results: (1) the case where the first ANDA applicant is never sued by the patent holder; or (2) the case in which the first ANDA applicant loses its patent suit. In particular, in (1) where the first ANDA applicant is not sued then the court-decision trigger could never occur. Later ANDA applicants cannot market their products until the first applicant decides to market its product, thus triggering the commercial marketing trigger. Theoretically, the first applicant could wait it out and block other ANDA applicants from entering the market. This could occur where the first applicant colludes with the patentee to eliminate generic competition, or if the first applicant is unable to comply with FDA requirements and thus the first applicant is unable to market. Concerning issue (2) where the first ANDA applicant loses the suit, then the applicant could never satisfy the court decision trigger nor the commercial marketing trigger since there is no favorable court decision and the loss means that the applicant cannot make, use or sell to begin the commercial market trigger. Thus, no generic company could enter the market until the patent expired.

enforcing the then-regulation.³²⁷ In response to the injunction, the FDA revised its regulation on the 180-day exclusivity period. The present case discusses the new regulation and the validity of the revised regulation.

In July 1998 the FDA preliminarily granted Purepac's generic drug application for an anti-thrombosis medicine. However, Purepac was a secondary applicant as another applicant, Torpharm (a division of Apotex), had a prior application pending. Thus, under the prior regulation, Torpharm had a 180-day exclusivity period once the FDA had approved Torpharm's application. Given this pendency period, Purepac sued, challenging the validity of the post-*Mova* revision and claiming that Torpharm was not entitled to the 180-day exclusivity period because it had not yet been sued for patent infringement.³²⁸

Since the patentee did not sue for infringement against Torpharm or Purepac, the issue before the court concerned the 180-day exclusivity period.³²⁹ Since the patentee failed to sue, Torpharm had not successfully defended under the regulation, which meant that the first generic applicant was entitled to the 180-day period only after it successfully defended a patent infringement suit. In *Mova*, the court held this regulation invalid as being inconsistent with the statutory text and structure.³³⁰ Under the old regulation, to qualify for the 180-day exclusivity period, the first generic applicant would have had to have been unsuccessfully sued for infringement, that is, it must have successfully defended against an infringement suit.³³¹ Under this construction, the pre-*Mova* regulation would eliminate the commercial marketing trigger also since the regulation was phrased in the conjunctive in that the regulation called for both a paragraph IV certification *and* a successful defense, both before the 180-day exclusivity period would attach, despite the regulation calling for a commercial marketing trigger. Thus the *Mova* court struck out the successful defense part of the regulation.³³²

After *Mova*, the FDA issued a new interim guidance that eliminated the successful defense prong of the regulation while the FDA conducted the normal rulemaking procedures to implement

³²⁷ *Mova Pharm.*, 140 F.3d at 1076-77.

³²⁸ *Purepac Pharm.*, 162 F.3d at 1202.

³²⁹ 21 U.S.C. § 355(j)(5)(B)(iv) (Supp. IV 1998); *Purepac Pharm.*, 162 F.3d at 1203.

³³⁰ *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1203 (D.C. Cir. 1998); *Mova Pharm.*, 140 F.3d at 1076; *see also* *Granutec, Inc. v. Shalala*, 46 U.S.P.Q.2d 1398, 1998 U.S. App. LEXIS 6685, at *19 (4th Cir. 1998).

³³¹ *Purepac Pharm.*, 162 F.3d at 1202; 59 Fed. Reg. 50338, 50367 (1994).

³³² *Purepac Pharm.*, 162 F.3d at 1202-3; *Mova Pharm.*, 140 F.3d at 1069.

§ 355(j)(5)(B)(iv) using the law of post-*Mova*.³³³ Meanwhile this suit was pending and in November 1998, the FDA issued a new rule that eliminated the successful defense provision.³³⁴

Purepac argued that Torpharm was not entitled to a 180-day exclusivity period since Torpharm had not been sued for infringement, irrespective of whether Torpharm successfully defended or not. That is, Purepac argued that the *Mova* court only struck down the successful defense provision but did not strike down the entire applicant-must-be-sued provision also. This meant to Purepac that the patentee must still sue Torpharm, plain and simple, before Torpharm was entitled to any 180-day exclusivity. So, according to Purepac, the FDA must still insist that Torpharm be sued, but cannot insist that Torpharm successfully defend.³³⁵

The court stated that the new FDA regulation does not require the first generic applicant to be sued in order to benefit from market exclusivity.³³⁶ The statute states on its face that the 180-day exclusivity period for the first generic applicant starts upon two factors, whichever is earlier: commercial marketing by the first applicant³³⁷ or a court order in favor of the first generic applicant.³³⁸ The first factor does not require a lawsuit whereas the second factor obviously requires a lawsuit since a court order is predicated on a court decision.³³⁹

Purepac argued that without the benefit of a mandatory lawsuit, if the first generic applicant is never sued, then it is quite possible that

³³³ *Purepac Pharm.*, 162 F.3d at 1203.

³³⁴ *Id.* at 1202; 21 C.F.R. § 314.107(c)(1) (2000); 63 Fed. Reg. 59,710, 59,712 (1998).

³³⁵ *Purepac Pharm.*, 162 F.3d at 1203.

³³⁶ *Id.* at 1204.

³³⁷ One interesting issue not yet resolved is whether the commercial marketing trigger is activated if the first ANDA Paragraph IV applicant and the patentee settle the infringement case prior to any final decision. A problem arises for subsequent ANDA applicants if the settlement agreement requires the patentee to pay the first ANDA applicant to not enter the market (and hence not start the commercial marketing trigger). The problem is that since the first ANDA applicant is entitled to an exclusivity period, but will not start since no trigger is activated, this acts to delay entry of all subsequent ANDA applicants indefinitely. A settlement agreement like this may arise where the patent is likely invalid so the patentee pays the first ANDA applicant to not pursue the invalidity in exchange for keeping the patent alive. One solution is for the FDA, for the purpose of activating a 180-day trigger, to interpret the term "commercial marketing" to apply to ANDA applicants who settle Paragraph IV lawsuits in exchange for payments by the patentee. Arguably, the ANDA applicant who receives payment is also receiving some commercial valuable consideration.

³³⁸ *Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1204 (D.C. Cir. 1998); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998).

³³⁹ 21 U.S.C. § 355(j)(5)(B)(iv) (1994 & Supp. IV 1998); *Purepac Pharm.*, 162 F.3d at 1204.

neither of the two triggers will occur to start the 180-day exclusivity period. That is, if there is no commercial marketing, then the 180-day period does not start. If there is no lawsuit, then there can be no judicial decision with respect to factor (b). Thus, without the triggering of the 180-day period, later generic applicants would be barred from bringing the products to the market.³⁴⁰

In response, the court stated that *Mova* had already addressed this issue. The court reiterated that Congress may have intended that the first generic applicant enjoy this exclusivity period whether or not the generic applicant is sued or not. Furthermore, the FDA has indicated that it will send letters to the first generic applicant that the FDA expects it to commence commercial marketing upon approval, despite the fact that the first generic applicant had not been sued.³⁴¹ Therefore, the FDA's withholding of Purepac's approval (since Purepac is a later applicant) pending Torpharm's commercial marketing was not irrational, but was consistent with § 355(j)(B)(5)(iv), and was consistent with *Mova*.³⁴²

In the aftermath of Purepac, the question for ANDA applicants arose on how to trigger a court decision to start the 180-day clock. That question was partially answered in *Teva Pharmaceuticals, USA, Inc. v. FDA*,³⁴³ where the issue was whether the dismissal of a district court action due to a lack of subject matter jurisdiction was a "court decision" to start the 180-day clock. Both Teva and Purepac filed ANDAs on a generic version of TICLID[®] for stroke victims. Both companies were subsequent ANDA applicants as a prior first ANDA had been filed.³⁴⁴ Teva then sued Syntex, the patentee, in a declaratory judgment action under the Act. Syntex determined that Teva's proposed product would not infringe the Syntex patent and accordingly informed Teva that Syntex would not sue.³⁴⁵ Cleverly, Syntex alleged that since it would not sue, then Teva lacked the reasonable apprehension of a potential lawsuit necessary to support the declaratory judgment action. Accordingly, Syntex argued, the case should be dismissed for lack of subject matter jurisdiction to which the district court agreed.³⁴⁶ Teva requested that the FDA consider the district court's dismissal as a court decision and

³⁴⁰ *Purepac Pharm.*, 162 F.3d at 1204.

³⁴¹ *Id.* at 1204; *Mova Pharm.*, 140 F.3d at 1071 n.11.

³⁴² *Purepac Pharm.*, 162 F.3d at 1204-05.

³⁴³ *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999).

³⁴⁴ *Teva Pharms.*, 182 F.3d at 1006.

³⁴⁵ *Id.* at 1006.

³⁴⁶ *Id.*

requested that the FDA start the 180-day clock. The FDA declined to consider this as a court decision prompting Teva to sue the FDA demanding that the FDA approve Teva's ANDA in 180 days. The district court refused Teva's requests for injunctive relief and Teva appealed.³⁴⁷

The appellate court, however, reversed. The appellate court held that in order to justify its interpretation and have the appropriate *Chevron* deference³⁴⁸ the FDA must set forth its reasoning. The court stated that the plain text of the statute requires a "decision of a court holding the patent . . . invalid or not infringed."³⁴⁹ Court decisions include a final judgment after a full trial, summary judgment or partial summary judgment, or even a dismissal for failure to state a cause of action.³⁵⁰ Since dismissal of a declaratory judgment action for lack of a case or controversy predicated on the patentee's negation of the intent to sue, it has a preclusive estoppel effect.³⁵¹ One problem with this interpretation is that the term "holding" as used in the statute could be construed in two ways. A first interpretation is that "holding" means a true holding of a court that creates a binding precedent. A second interpretation is that "holding" does not mean the creation of binding precedent, such as mere dicta or a court finding of fact or conclusion or law. Furthermore, a certification that a patent is unenforceable—which is different from certifying a patent as non-infringed or invalid—is also grounds for a proper Paragraph IV certification.³⁵² Accordingly, a court decision for the purposes of starting the 180-day clock will also include a finding of patent unenforceability.³⁵³ In summary, the appellate court reversed and

³⁴⁷ *Id.* at 1006-07.

³⁴⁸ Administrative agency decisions are entitled to a certain deference by reviewing courts pursuant to *Chevron USA, Inc. v. Natural Resource Def. Counsel, Inc.*, 467 U.S. 837, 842-44 (1984). In patent cases, the Federal Circuit reviews decisions of the Patent & Trademark Office under Administrative Procedures Act standards of reviews. *Dickinson v. Zurko*, 527 U.S. 150 (1999).

³⁴⁹ *Teva*, 182 F.3d at 1005.

³⁵⁰ *Id.*

³⁵¹ *Id.* (citing *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059 (Fed. Cir. 1995)).

³⁵² *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418 (Fed. Cir. 1989); Food and Drug Act, 21 C.F.R. § 314.94(a)(12)(i)(A)(4) (2000).

³⁵³ *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1006 (D.C. Cir. 1999). A patent can be unenforceable due to inequitable conduct or Walker Process antitrust violations. *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411 (Fed. Cir. 1987). It is important to differentiate between patent invalidity (which extinguishes the patent such that it cannot be enforced at all because it no longer exists); patent unenforceability (a patent still exists but cannot be enforced against any defendant); or non-infringement (which only applies to a particular defendant).

remanded for the district court and the FDA to come up with concrete findings as to whether the dismissal is a court decision under the statute.³⁵⁴ Therefore, the appellate court determined that preliminarily, a dismissal order is one type of court decision under the statute.

The next issue in the court decision saga concerns whether a district court decision of invalidity or non-infringement can trigger the 180-day clock or whether the patentee is entitled to await a decision on appeal from the Federal Circuit.

Currently, this issue is at the district court level in *Mylan Pharmaceuticals, Inc. v. Shalala*.³⁵⁵ Mylan submitted an ANDA on a generic drug.³⁵⁶ Previously, the FDA determined that it would not start the 180-day clock until the underlying patent infringement was affirmed by the Federal Circuit.³⁵⁷ However, in this case, since the prior adjudication ruled that the underlying patent was invalid and that Mylan was a second ANDA applicant, Mylan argued that its ANDA should be effective immediately since the 180-day clock started when the district court ruled the patent invalid in the prior proceeding. Mylan argued that despite the Federal Circuit appeal upholding the patent invalidity, the earlier district court decision started the clock. Since it was more than 180 days from the district court decision of invalidity when Mylan filed its ANDA, the FDA should have approved it immediately.

In the present case, the district court began its analysis giving deference to the FDA's interpretation of § 355(j)(5)(B)(iv), wherein the FDA will start the 180-day clock once the Federal Circuit affirms the invalidity or non-infringement rulings.³⁵⁸ The district court found

³⁵⁴ *Teva*, 182 F.3d at 1008.

³⁵⁵ *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 36 (D.D.C. 2000).

³⁵⁶ In this particular case, Abbott Laboratories was the patentee and Geneva Pharmaceuticals was the first generic manufacturer to file an ANDA containing a Paragraph IV certification. Abbott sued Geneva on four different patent suits, each of which was dismissed. Geneva technically should have had its ANDA approved immediately. Later, the FDA listed another Abbott patent that prompted Geneva to file another Paragraph IV ANDA. Abbott then sued Geneva and triggered the thirty month ANDA approval delay period. The district court agreed with Geneva that the Abbott patent was invalid; a decision that was appealed and affirmed by the Federal Circuit. See *Mylan Pharms.*, 81 F. Supp. 2d at 34-35; see generally *Abbott Labs. v. Geneva Pharms. Inc.*, 182 F.3d 1315 (Fed. Cir. 1999) (holding that Geneva was entitled to the 180 day exclusivity period). See *Abbott Labs. v. Mylan Pharms. Inc.*, 37 F. Supp. 2d 1076 (N.D. Ill. 1999), *aff'd*, 1999 WL 970186 (Fed. Cir. 1999) (collaterally estopping Abbott on the invalidity issue since Mylan was not the first ANDA applicant, Mylan's victory in the patent suit did not result in approval to immediately market the generic version).

³⁵⁷ *Mylan Pharms. Inc.*, 81 F. Supp. 2d at 34. See also 21 C.F.R. § 314.107(e) (2000).

³⁵⁸ 21 C.F.R. § 314.107(e) (2000).

that the plain language of the statute indicates that an “appealed district court decision finding the patent at issue to be invalid or not infringed unambiguously qualifies as a decision of a court” under the statute.³⁵⁹ Accordingly, by considering a district court opinion as a court decision, the HWA policy of getting generic drugs on the market sooner is promoted.³⁶⁰ Therefore, the district court held that the FDA incorrectly interpreted the statute as requiring an appeal resolution before starting the 180-day clock.³⁶¹ Considering the district court’s opinion, a ‘court decision’ is the better view. First, the plain text of the statute states that a court decision triggers the clock. Accordingly, and without reasonable dispute, a district court rendering such a decision should start the clock. While this may cause concern for the parties, Congress as promulgator of the statute is the correct body to clarify whether a court decision in question is an appellate court decision.

C. *For What Can the Patentee Sue?*

In addition to the issue of the 180-day clock, the next question that should be asked is for what can the patentee sue? Recall that the ANDA applicant certifies in its ANDA what it will be attempting to commercialize. However, can the patentee still sue for infringement of its patent on something that is beyond the scope of the ANDA? This situation occurred in *Bayer A.G. v. Elan Pharmaceutical Research Corp.*³⁶²

In *Bayer*, Elan submitted an ANDA that it certified under Paragraph IV that its product did not infringe Bayer’s patent because its drug was above a certain claimed range of bio-availability.³⁶³ In this case, the drug would fall within the claimed range over an extended time and eventually constitute an infringement. Thus, Bayer attempted to sue based on what might happen rather than what Elan actually submitted in its ANDA.

The Federal Circuit affirmed dismissal of the case and stated that the primary inquiry under 35 U.S.C. § 271(e)(2)(A) is on the product to be sold as defined in the ANDA.³⁶⁴ The court noted that Elan was

³⁵⁹ *Mylan Pharms. Inc.*, 81 F. Supp. 2d at 37.

³⁶⁰ *Id.* at 41.

³⁶¹ *Id.* at 47.

³⁶² *Bayer A.G. v. Elan Pharm. Research Corp.*, 64 F. Supp.2d 1295 (N.D. Ga. 1999), *aff’d*, 212 F.3d 1241 (Fed. Cir. 2000).

³⁶³ *Bayer A.G. v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1246 (Fed. Cir. 2000).

³⁶⁴ *Id.* at 1247; *see also* *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

bound by the statements made in the ANDA and thus the infringement question was directly resolved by the plain text of the ANDA submission. In particular, the ANDA stated that its drug was outside the claimed range and was not infringing.³⁶⁵ Accordingly, Elan had to market that product as defined in its ANDA, otherwise it would be subject to penalties.³⁶⁶ If Elan later changed its ANDA to fall within the claimed range, then Bayer could sue for infringement based on the new ANDA.³⁶⁷

As an aside, it is worth noting that although the panoply of penalties exist to punish Elan if Elan markets a drug outside the scope of its ANDA, nothing precludes Bayer from suing for run of the mill infringement if Elan markets a drug that falls within the scope of the claims. Recall that the ANDA defines an artificial act of infringement in which the patentee sues based on what the ANDA applicant *will* sell. However, if the patentee fails on this issue (as did Bayer), this does not preclude the patentee from suing for infringement based on what the ANDA applicant *actually* sells. The existence of the penalties against the ANDA applicant does not extinguish the patentee's right to sue. Furthermore, if the patentee fails in the Hatch-Waxman infringement suit, the patentee is not estopped from suing based on what the ANDA applicant actually sells since the issues previously litigated, while facially similar, are not the same for the purposes of issue and claim preclusion.³⁶⁸

D. Remedies for Drug Infringement Under the HWA

As for remedies in § 271(e) cases, it appears that there is a facial contradiction between certain sections. Pursuant to 35 U.S.C. § 271(e)(2), the simple act of submitting a Paragraph IV certification in the ANDA constitutes an act of infringement, even though the infringing acts necessary to prepare the ANDA are deemed to be non-infringing under § 271(e)(1). The apparent contradiction between

³⁶⁵ *Bayer A.G.*, 212 F.3d at 1247.

³⁶⁶ *Id.* at 1248. Food, Drug and Cosmetic Act, 21 U.S.C. § 333(b)(2) (1994) (civil penalties); 21 U.S.C. § 355(e) (1994) (withdrawal of drug approval); 21 U.S.C. § 355(d) (1994 & Supp. IV 1998) (injunctions for selling unapproved drugs); 21 U.S.C. § 333(a) (1994) (criminal penalties); 21 U.S.C. § 334(a)(1) (1994) (seizure of the unapproved drug); 21 U.S.C. § 335a (1994) (debarment of the company or its officials from further participation in the ANDA process); 18 U.S.C. § 1001(a) (1994) (fraud and false statements to the government); 18 U.S.C. § 371 (1994) (conspiracy to defraud the United States); and 18 U.S.C. § 1501 (1994) (obstruction of proceedings before a federal agency).

³⁶⁷ *Bayer A.G.*, 212 F.3d at 1249.

³⁶⁸ See generally *Foster v. Halco Mfg. Co.*, 947 F.2d 469 (Fed. Cir. 1991); *W.L. Gore & Assocs. Inc. v. C.R. Bard, Inc.*, 977 F.2d 558 (Fed. Cir. 1992).

§ 271(e)(1) and § 271(e)(2) are resolved through § 271(e)(3) and § 271(e)(4).³⁶⁹ Section 271(e)(3) provides that no injunctive relief may be granted for the acts a manufacturer undertakes solely in preparation for seeking FDA approval. This makes sense as this activity is expressly permitted in § 271(e)(1). Where the manufacturer goes beyond mere preparation, the remedies under § 271(e)(4) are available.³⁷⁰ Money damages under § 271(e)(4)(C) or injunctive relief under § 271(e)(4)(B) are only available if there was actual infringement (*e.g.*, erroneous Paragraph IV certification regarding the inapplicability or invalidity of the patent) and there has been, or will be, actual *commercial* manufacture, sale or use of the patented drug.³⁷¹

E. Willful Patent Infringement as a Remedy for Paragraph IV Certifications

In addition to the above remedies, suppose for example, the patentee wins and proves that the patent is valid and infringed despite the Paragraph IV certification. Is there willful infringement of the patent? This issue arose in *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.*³⁷² that concerned the patent on the anti-acid drug, famotidine, sold under the brand name PEPCID[®]. Yamanouchi, the plaintiff pioneer drug patentee, sued Schein and its subsidiary Danbury (the generic manufacturers) for infringement. Schein hired a patent attorney to comb through many different pioneer drug patents to see which ones arguably were invalid and subject to attack.³⁷³ The attorney contacted Schein with an opinion of invalidity of Yamanouchi's famotidine patent and Schein then filed an ANDA containing a Paragraph IV certification and sent notification to Yamanouchi thereafter. Yamanouchi filed suit seeking, *inter alia*, a judgment that Schein had willfully infringed the patent by filing a Paragraph IV certification in its ANDA and attorney fees and costs as allowed under 35 U.S.C. § 285.

The district court began its analysis of the certification. A Paragraph IV certification speaks to the pioneer patent's invalidity

³⁶⁹ *Upjohn Co. v. Mova Pharm. Corp.*, 899 F. Supp. 46, 49 (D.P.R. 1995).

³⁷⁰ *Id.* at 49.

³⁷¹ *Id.*

³⁷² *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 21 F. Supp. 2d 366 (S.D.N.Y. 1998), *aff'd*, 2000 U.S. App. LEXIS 27455 (Fed. Cir. 2000).

³⁷³ *Id.* at 369; *see also* *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 31 (D.D.C. 2000) ("in order to encourage generic drug manufacturers to incur the potentially substantial litigation costs associated with challenging pioneer drug maker's patents . . .").

and if the certification is successful, then the generic maker may market the drug prior to the pioneer patent expiration.³⁷⁴ When the generic maker certifies under Paragraph IV in its ANDA, the certification is deemed statutorily to be infringement.³⁷⁵ The patentee has forty-five days to sue for infringement otherwise the ANDA becomes effective immediately allowing for FDA approval and commercial exploitation of the generic drug prior to the patented drug's patent expiration date.³⁷⁶ If the patentee timely brings suit, then the FDA must suspend approval of the ANDA until either the court rules that the patent is invalid or, if the patent is adjudicated valid, then suspended until the patent expires.³⁷⁷

If the court finds the patent to be valid and the generic maker has not yet made, used, or sold the product, then the patentee's remedies are limited to: (1) a court order directing the FDA to not approve the ANDA until the patent expires; (2) injunctive relief against the defendant and (3) an award of the patentee's attorney's fees for defending the suit.³⁷⁸

The HWA specifically contemplates the issue of willful infringement in the submission of an ANDA. The generic applicant, in filing an ANDA containing a Paragraph IV certification, represents that "in the opinion of the applicant and to the best of its knowledge" that the patent covering the pioneer drug is invalid; such certification must be done in good faith objectively.³⁷⁹

In this case, Schein's patent attorney made some patently defective analyses in his invalidity report.³⁸⁰ In addition, the attorney was to be compensated for each invalid patent that Schein ultimately produced and sold.³⁸¹ In his invalidity report, the attorney stated that the famotidine patent challenge was less likely to win over a patent challenge to nizatidine, yet Schein elected to pursue the famotidine patent invalidity challenge.³⁸² The invalidity report, which was predicated on obviousness, failed to examine the unexpected results

³⁷⁴ 35 U.S.C. § 271(e) (1994 & Supp. IV 1998); 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994); *Yamanouchi*, 21 F. Supp. 2d at 368.

³⁷⁵ 21 U.S.C. § 355(j)(2)(B) (1994); *see also* 35 U.S.C. § 271(e)(2)(A) (1994).

³⁷⁶ 21 U.S.C. § 355(j)(5)(B)(iii) (Supp. IV 1998).

³⁷⁷ *Id.*

³⁷⁸ 35 U.S.C. § 271(e)(4) (1994 & Supp. IV 1998); *Bristol-Myers Squibb Co. v. Royce Labs. Inc.*, 69 F.3d 1130, 1132 (Fed. Cir. 1995).

³⁷⁹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994); *Yamanouchi*, 21 F. Supp. 2d at 368.

³⁸⁰ *Yamanouchi*, 21 F. Supp. 2d at 375.

³⁸¹ *Id.* at 369.

³⁸² *Id.* at 375-76.

of famotidine and its superior properties; two elements of the obviousness test.³⁸³ Furthermore, in attempting to vitiate the claim of willful infringement, Schein only produced selective non-infringement reports and kept others hidden behind the veil of privilege.³⁸⁴ Schein's trial witnesses could not, at the time of trial, testify that at the time of the patenting, the famotidine structure was not safe, not effective, nor non-toxic, which its safety and efficacy, were found to contribute to its success.³⁸⁵

In summary, the trial judge determined by clear and convincing evidence that Schein willfully infringed the patent and deserved attorney fees and costs based on:

- * Schein's patent attorney's overt failure to consider other art;
- * The patent attorney's examination predicated only on structure;
- * The invalidity report's failure to discuss the other indicia of non-obviousness such as commercial success and superior results;
- * The normal protocol of seeking independent counsel's advice was not followed since the patent attorney here had a stake in the outcome as a financial incentive to provide positive reports;
- * That other attorney client reports regarding the ANDA certification were withheld under the guise of privilege; and
- * In the totality of circumstances, no reasonable person should have relied on the reports to assert in good faith that the patent was invalid for being obvious over the prior art.³⁸⁶

The Federal Circuit affirmed on similar grounds. The court agreed with the district court that Schein had no basis for asserting patent invalidity. Accordingly, the court held that "a paragraph IV filing requires a certification, in the opinion of the applicant and to the best of his knowledge, [that] each patent . . . for which the applicant is

³⁸³ *Id.* at 376-78.

³⁸⁴ *Id.* See also Shashank Upadhye, *Understanding Willfulness in Patent Infringement: An Analysis of the "Advice of Counsel" Defense*, 8 TEX. INTELL. PROP. L. J. 39, 51-52 (1999) (arguing that invalidity or non-infringement opinions must be critically executed and must be competent). See also *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopedics Co.*, 976 F.2d 1559, 1580 (Fed. Cir. 1992) ("[A]n opinion of counsel does not guarantee against a finding of willfulness."); *Avia Group Int'l Inc. v. L.A. Gear Cal. Inc.*, 853 F.2d 1557, 1566 (Fed. Cir. 1988) (stating that failure to secure counsel's advice is but a factor in the willfulness analysis, but is not dispositive of the issue); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1579-80 (Fed. Cir. 1986).

³⁸⁵ *Yamanouchi*, 21 F. Supp. 2d at 374.

³⁸⁶ *Id.* at 377-78.

seeking approval . . . is invalid.”³⁸⁷ Thus, simply losing the Paragraph IV ANDA fight does not *ipso facto* require an award of willfulness. Rather the totality of the circumstances must warrant a finding that the case is exceptional for willfulness.³⁸⁸

One other issue involved in willful infringement is potential fraud in filing FDA applications. As mentioned above, one premise behind § 271(e)(1)’s safe harbor is to protect reasonable pre-filing conduct from infringement. However, since the culmination of the conduct results in a FDA filing, it would be unreasonable if the applicant materially misled the FDA by submitting falsities in the application. Accordingly, the author submits that falsities in the FDA filing is grounds for stripping the § 271(e)(1) exemption. In addition, it should be grounds for punishing the applicant through a finding of willful infringement. For example, in the drug context, in *Barr Laboratories, Inc. v. Quantum Pharmics, Inc.*³⁸⁹ Barr sued Quantum when it learned that Quantum had filed false ANDAs with the FDA in order to copy Barr’s drugs. If an ANDA applicant filed false and misleading statements to the FDA, then a patentee should have the remedy of willful infringement since the filing of the ANDA, presumably with a Paragraph IV certification, precipitated a suit by the patentee in an effort to vindicate its rights. The patentee is then forced into a decision to sue quickly (within the forty-five day window) or risks having the FDA approve the ANDA thereby eroding into the patentee’s sales. If the patentee does sue, then it is engaged in the usual costly and time consuming traditional patent infringement suit all due to falsities in the ANDA. The author suggests that this conduct is willful infringement since it is objectively unreasonable to force a patentee’s hand like this.

Therefore, since willful infringement is a predicate to an award of treble damages, fees and costs, the court awarded such fees and costs.³⁹⁰

VII. CONCLUSION

In conclusion, it is shown throughout this article that patent law is not insulated from the FDA legal regimes. It is suggested that the statutory framework in 1984 created unique and interesting issues

³⁸⁷ *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, No. 99-1521, 2000 U.S. App. LEXIS 27455, at *19 (Fed. Cir. 2000).

³⁸⁸ *Id.* at *19-20.

³⁸⁹ *Barr Labs., Inc. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111 (E.D.N.Y. 1993).

³⁹⁰ *Yamanouchi*, 21 F. Supp. 2d at 378.

regarding the interaction of patents with medical devices and drugs. Accordingly, it is suggested that to implement the statutory constructs, changes must be made in § 271(e)(1) lawsuits. In addition, it is shown that generic drugs, as the overwhelming beneficiary of the HWA statutes, are subject to unique issues involving the interaction of patent law with medical drugs. Accordingly, it is suggested that given the highly technical framework of the HWA, a better understanding of the patent law issues involves a better understanding of the FDA laws.