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Litigating the Drug Price Competition and Patent Term Restoration Act of 1984

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I.

Introduction

The Drug Price Competition and Patent Term Restoration Act of 1984,[1] also known as the Hatch-Waxman Act in honor of its sponsors Senator Orrin Hatch and Representative Henry Waxman, was enacted in an attempt to reconcile two seemingly contradictory policy goals. The Act represented a compromise between the interests of generic drug manufacturers and the competing interests of the "pioneer" drug manufacturers who research and develop novel drug prod-

[1] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

ucts.[2] Thus, the Act was designed to improve the availability of inexpensive generic drugs, while maintaining sufficient incentives for investment in new drug development.[3]

The Act addressed several perceived distortions in the patent term that were peculiar to the drug context.[4] First, pioneer drug manufacturers lost the benefit of a large portion of each drug patent's term because so much of the term expired during the lengthy process of regulatory review by the U.S. Food and Drug Administration (FDA), before the manufacturer could market its drug. Without the benefit of a full patent term, pioneer drug manufacturers might not have sufficient incentives to make the huge investment required to develop new drug products. On the other hand, in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[5] the U.S. Court of Appeals for the Federal Circuit held that activities undertaken by generic manufacturers seeking FDA approval for generic drugs, because of their ultimately commercial goals, infringed pioneer drug patents. Thus, pioneer drug manufacturers could retain market exclusivity for their drugs beyond the duration of the drugs' patent terms because generic manufacturers could not even start developing and seeking approval for competing generic products until after the pioneer patent expired.

To compensate for the time lost from the patent term during pioneer drug approval, the Hatch-Waxman Act created 35 U.S.C. §156, which grants pioneer drug patentees a limited patent term extension. The extension is based on the length of the regulatory review period and cannot exceed five years.[6] In reaction to *Bolar*, [7] the Hatch-Waxman Act created a "safe harbor" for generic drug manufacturers under 35 U.S.C. § 271(e)(1). This section provides that it is not

[2] *See* Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 271 (1985).

[3] *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, IDEA 389 (1999).

[4] *See* David J. Bloch, *If It's Regulated Like a Duck... Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act*, Food Drug L.J. 111, 113 (1999).

[5] 733 F.2d 858 (Fed. Cir. 1984).

[6] *See* 35 U.S.C. §§ 156(c), (g)(6) (1994).

[7] 733 F.2d 858 (Fed. Cir. 1984).

an act of infringement to make, use, or sell a patented product "solely for uses reasonably related to the development and submission of information" for FDA approval.

The Hatch-Waxman Act also set out procedures for the approval of generic drugs under abbreviated new drug applications (ANDAs), which may rely on data submitted in the pioneer drug applicant's new drug application (NDA).[8] The pioneer drug manufacturer's patent rights are protected by 21 U.S.C. § 355(j)(2)(A)(vii), which requires every ANDA applicant to submit a "certification" with respect to each patent that covers the corresponding pioneer drug. The certification must specify (I) that no patent information has been listed for the drug, (II) that the patent has expired, (III) the patent's expiration date, or (IV) that the patent is invalid or will not be infringed by the commercial manufacture and marketing of the ANDA applicant's drug.[9] A certification of type IV, a "paragraph IV certification," indicates that the generic manufacturer seeks approval to market its drug before the pioneer patent expires.

Because § 271(e)(1) creates a safe harbor for the activities of generic manufacturers seeking FDA approval, the Hatch-Waxman Act created a new infringement cause of action allowing patentees to challenge generic manufacturers who sought to market their drugs before the pioneer drug patent expired. § 271(e)(2) provides that it is an act of infringement to submit an ANDA for a patented drug if the purpose of the ANDA is to obtain marketing approval before the patent expires. Under § 355(j), an ANDA applicant who files a paragraph IV certification is required to notify the patentee, who then has forty-five days to sue for infringement.[10] FDA approval of the ANDA is then stayed for thirty months to allow the suit to be resolved.[11] In order to encourage ANDA applicants to challenge dubious pioneer drug patents, the Hatch-Waxman Act also created a 180-day market exclusivity period for the first generic manufacturer

[8] *See* 21 U.S.C. § 355(j) (1994).
[9] 21 U.S.C. § 355(j)(2)(A) (1994).
[10] *See* 21 U.S.C. §§ 355(j)(2)(B), (5)(B) (1994).
[11] *See* 21 U.S.C. § 355(j)(5)(B) (1994).

to file a paragraph IV certification for a given drug.[12]

The Hatch-Waxman Act creates a complex statutory framework, such that many problems and debates have arisen surrounding its implementation. This paper gives an overview of the issues that have been litigated under the Hatch-Waxman Act in the nearly sixteen years since its enactment.

II.

Litigation of the Patent Term Extension in 35 U.S.C. § 156

A.

Defining "Claims"

35 U.S.C. § 156 provides for the extension of patents that "claim" drug products, or methods of manufacturing or using those drug products, that have undergone FDA approval.[13] In *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*,[14] the U.S. Court of Appeals for the Federal Circuit addressed the meaning of the word "claims" in § 156. The court affirmed the U.S. Patent and Trademark Office's (PTO's) denial of Hoechst's application for patent term extension because the patent did not "claim" the active ingredient tacrine hy-

[12] *See* 21 U.S.C. § 355(j)(5)(B)(iv) (1994).

[13] 35 U.S.C. § 156 (1994) provides that:

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if...

(4) the product has been subject to a regulatory review period before its commercial marketing or use....

(f) For purposes of this section:

(1) The term "product" means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term "drug product" means the active ingredient of -

(A) a new drug, antibiotic drug, or human biological product... or

(B) a new animal drug or veterinary biological product... including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

To be eligible for term extension, the patented active ingredient must be present in the drug at the time of administration. *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224, 1227-28 (Fed.Cir.1990). 1-hydroxy-tacrine is neither a salt nor an ester of tacrine hydrochloride.

[14] 109 F.3d 756 (Fed. Cir. 1997).

drochloride used in an FDA-approved drug for Alzheimer's disease. [15] The patent disclosed and described in its claims only 1-hydroxy-tacrine, a metabolite of tacrine hydrochloride, and a method for using that compound to treat patients with memory loss. Thus, even though Hoechst's patent was infringed when patients ingested and metabolized tacrine hydrochloride, the patent did not actually "claim" that active ingredient, and therefore was not eligible for term extension under § 156.[16]

The court, in an opinion by Judge Clevenger, explained that the plain meaning of "claim" covers "the invention that an applicant believes is patentable" or "that portion of the specification that defines the patent owner's property rights in the invention."[17] The court distinguished between the concepts of claiming and infringement: "the claims define the patent owner's property rights whereas infringement is the act of trespassing upon those rights."[18] Judge Clevenger rejected the possibility that the plain language or legislative history of the statute supported Hoechst's argument that a patent "claims" anything that infringes it: if Congress intended to refer to infringement, it would have done so explicitly.[19] In a concurring opinion, Judge Newman argued that the legislative history clearly demonstrates that "claims," as used in § 156, refers to all subject matter protected by the patent.[20] However, she agreed that Hoechst was not entitled to a patent term extension because it was not a proper applicant: it had not participated in the regulatory approval process, and the marketing entity who did obtain FDA approval was not acting as its agent.[21]

B.

Defining "Drug Product"

[15] *Id.* at 757.
[16] *Id.*
[17] *Id.* at 759.
[18] *Id.*
[19] *Id.* at 759-60.
[20] *Id.* at 764.
[21] *Id.* at 762.

As a requirement for extending the term of a patent on an approved drug product, 35 U.S.C. § 156(a)(5)(A) demands that "the permission for the commercial marketing or use of the product after [the FDA] regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred." § 156(f) defines, in relevant part, "product" as "drug product," and "drug product" as "the active ingredient of a new drug... including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient."[22] In *Fisons PLC v. Quigg*,[23] the Federal Circuit addressed the PTO's position that, combining the definition of "product" in § 156(f) and the extension requirement in § 156(a)(5)(A), patent term extension is available only for the first commercial marketing or use of a given active ingredient. Fisons contended, in contrast, that "product" in § 156(a)(5)(A) refers to the specific drug product approved by FDA; thus, it was entitled to term extension for each of three patents that covered different first-approved uses or dosages of the same active ingredient, cromolyn sodium. None of the patents covered the first commercially marketed product containing cromolyn sodium, which was approved in 1973.[24]

The Federal Circuit rejected Fisons' interpretation as contrary to the plain meaning of the statute. The court dismissed Fisons' reliance on the last sentence of 35 U.S.C. § 156(a), which states that, "[t]he product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the 'approved product"': the sentence is "merely a drafting device adopted to simplify the language of subsequent provisions in the section," and does not apply to paragraph (5), which precedes it.[25] The court also refused to agree with Fisons that 35 U.S.C. § 156(c)(4), which states that "in no event shall more than one patent be extended for the same regulatory review period for any product," suggests that one patent may necessarily be extended for each regulatory review

[22] 35 U.S.C. § 156(f) (1994).
[23] 876 F.2d 99 (Fed. Cir. 1989).
[24] *Id.* at 100-101.
[25] *Id.* at 101.

period.[26] Analyzing the legislative history, the court found insufficient support for Fisons' views to overcome the plain meaning of the statute. Thus, it affirmed the PTO's denial of Fisons' patent term extension applications.[27]

In *Glaxo Operations UK Limited v. Quigg*,[28] the Federal Circuit addressed another PTO dismissal of an application for patent term extension. Glaxo received FDA approval for its antibiotic drug Ceftin, which contains the active ingredient cefuroxime axetil, in 1987. Cefuroxime axetil is an ester of the organic acid cefuroxime; it becomes therapeutically effective only upon oral administration. Two salts of cefuroxime, which become therapeutically active antibiotics only upon intramuscular or intravenous administration, received FDA approval in 1983 and 1986. They are marketed under the names Zinacef and Kefurox.[29] The PTO denied Glaxo's application for term extension for its cefuroxime axetil patent based on the prior FDA approval of the two cefuroxime salts. The PTO reasoned that Ceftin did not satisfy the requirement in 35 U.S.C. § 156(a)(5)(A) that "the permission for the commercial marketing or use of the product after [the FDA] regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred."[30]

Glaxo challenged the PTO's denial, citing the definition of "product" in 35 U.S.C. § 156(f)(2) as "the active ingredient of a new drug... including any salt or ester of the active ingredient...." The active ingredient in Ceftin is cefuroxime axetil. Neither Zinacef nor Kefurox is a salt or an ester of cefuroxime axetil. Thus, Glaxo argued that FDA's approval of Ceftin marked the "first permitted commercial marketing or use" of the patented "product," such that the requirement of § 156(a)(5)(A) was satisfied.[31] The PTO replied that Congress intended to define "product" broadly as any "new chemical entity" or "new active moiety." This definition would cover "all acid, salt, or ester forms of a single

[26] *Id.*
[27] *Id.* at 101-02.
[28] 894 F.2d 392 (Fed. Cir. 1990).
[29] *Id.* at 393.
[30] *Id.* at 394.
[31] *Id.*

therapeutically active substance even if the drug before being administered contained only other substances." Ceftin, Zinacef, and Kefurox are all metabolized to produce the same therapeutically active chemical entity. Thus, under the PTO's interpretation, Glaxo could not receive a patent term extension for its Ceftin patent because the "product," in the form of Zinacef and Kefurox, had been approved previously by FDA.[32]

The Federal Circuit found that the plain meaning of the statutory language "active ingredient of a new drug... including any salt or ester of the active ingredient"[33] supported Glaxo's interpretation. Furthermore, the legislative history gave no conclusive support for the PTO's broader interpretive gloss.[34] The PTO's position was entitled to no deference because it contradicted the plain, unambiguous statutory text.[35] Thus, the court approved the district court judgment holding that Glaxo's patent term extension application met the requirements of § 156(a).[36]

C.

Defining "Regulatory Review Process"

On May 31, 1985, FDA approved Unimed's drug Marinol, the active ingredient of which is a synthetic equivalent of marijuana. However, in its approval letter, FDA reminded Unimed that it could not market Marinol until the drug was rescheduled by the Drug Enforcement Agency (DEA) under the Controlled Substances Act.[37] On May 13, 1986, the DEA rescheduled Marinol. Within two weeks of DEA rescheduling, Unimed applied for a term extension for its Marinol patent. However, the PTO denied the application as untimely under 35 U.S.C. § 156(d)(1), which provides that an application for patent term extension "may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which

[32] *Id.*
[33] 35 U.S.C. § 156(f)(2) (1994).
[34] 894 F.2d 392, 395-96 (Fed. Cir. 1990).
[35] *Id.* at 398.
[36] *Id.* at 400.
[37] *See Unimed, Inc. v. Quigg*, 888 F.2d 826, 12 U.S.P.Q.2d 1644 (Fed. Cir. 1989).

the applicable regulatory review period occurred for commercial marketing or use."[38]

In *Unimed, Inc. v. Quigg*,[39] the Federal Circuit addressed Unimed's challenge to the PTO's denial of its application. The court began by examining 35 U.S.C. § 156(g)(1)(B), which defines the "regulatory review period" in § 156(d)(1) in terms of the combined duration of several stages of FDA approval under the Federal Food, Drug, and Cosmetic Act (FFDCA).[40] In view of this definition, the "provision of law under which the applicable regulatory review period occurred" in this case was § 505 of the FFDCA, which regulates FDA approval of new drugs. § 156(d)(1) made no reference to DEA action or 21 U.S.C. § 811(a), which regulates drug scheduling. Thus, the sixty-day period for submission of a timely application for patent term extension began on the date of FDA approval.[41]

FDA and courts generally agreed that the date of FDA approval was the date of the FDA approval letter, in this case May 31, 1985.[42] The Federal Circuit held that this did not change because FDA noted in its Marinol approval letter that marketing could not legally occur until after DEA rescheduling. FDA approval, which involved only safety and effectiveness, was complete as of the May 31, 1985 approval letter; DEA rescheduling was a separate obstacle to commercial marketing that was irrelevant for purposes of an application for patent term extension. Thus, the court affirmed the PTO's denial of Unimed's application for patent term extension because it was not filed within sixty days of FDA's approval of Marinol.[43]

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[38] *Id.*

[39] 888 F.2d 826, 12 U.S.P.Q.2d 1644 (Fed. Cir. 1989).

[40] § 156(g)(1)(B) (1988) provides that:

The regulatory review period for a human drug product is the sum of-

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 became effective for the approved human drug product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507, and

(ii) the period beginning on the date the application was initially submitted for the approved human drug product under section 351, subsection (b) of section 505, or section 507 and ending on the date such application was approved under such section.

[41] 12 U.S.P.Q.2d 1644, 1645-46 (Fed. Cir. 1989).

[42] *Id.* at 1646.

[43] *Id.* at 1646-47.

In *Westwood Pharmaceuticals, Inc. v. Quigg*,[44] Westwood challenged the denial of a term extension for the patent covering its approved drug Lac-Hydrin, which contained the active ingredient lactic acid and was intended for treatment of dry, itchy skin. In denying Westwood's application, the PTO reasoned that eight other lactic acid drugs had previously been approved by FDA, such that Lac-Hydrin was not "the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred," as required for patent term extension under 35 U.S.C. § 156(a)(5)(A).[45]

For new drugs, the "provision of law under which [the] regulatory review period occur[s]" is § 505 of the FFDCA, 21 U.S.C. § 355. This section has governed new drug approval since 1938; however, it was changed significantly in 1962, when new effectiveness requirements were added. Westwood argued that the 1962 amendments were so drastic that the old and new versions of § 505 constituted different "provisions of law" for purposes of § 156(a)(5)(A). Since the eight lactic acid drugs approved by FDA before Lac-Hydrin were all approved under the pre-1962 version of § 505, they did not preclude a patent term extension for Lac-Hydrin under § 156(a)(5)(A).[46]

In response, the PTO argued that § 505 of the FFDCA was a single provision of law, regardless of whether it had been amended over time. Even if the provision was significantly different before and after the 1962 amendments, products approved before 1962 are considered to be approved under the amended § 505. Thus, even if the "provision of law" for purposes of § 156(a)(5)(A) was limited to § 505 as amended in 1962, Lac-Hydrin did not constitute the "first permitted commercial marketing or use" of lactic acid under that provision.[47] The U.S. District Court for the District of Columbia found the PTO's interpretation consistent with statute's text and legislative history; thus, it deferred to the PTO's decision and affirmed the denial of Westwood's application for patent

[44] 13 U.S.P.Q.2d 2067 (D.D.C. 1989).
[45] *Id.* at 2068.
[46] *Id.* at 2068-69.
[47] *Id.* at 2069.

term extension.[48]

In *Hoechst AG v. Quigg*,[49] the Federal Circuit reviewed the PTO's denial of a patent term extension for Hoechst's drug Trental for failure to satisfy the requirement in 35 U.S.C. § 156(a)(4) that "the product has been subject to a regulatory review period before its commercial marketing or use." 35 U.S.C. § 156(g)(1)(A) defines the "regulatory review period" of a new drug as "the period described in subparagraph (B) to which the limitation described in paragraph (6) applies." 35 U.S.C. § 156(g)(1)(B) in turn sets out the duration of the regulatory review period: the sum of the testing phase and approval phase periods for the drug.[50] For Trental, the calculation under § 156(g)(1)(B), reduced as required under § 156(c), yields a patent extension term of 6.8 years. The dispute between Hoechst and the PTO involved the effect of the language "to which the limitation described in paragraph (6) applies."[51]

35 U.S.C. § 156(g)(6) provides the following limitations:

(A) If the patent involved was issued after the date of enactment of this section, the period of extension... may not exceed five years.
(B) If the patent involved was issued before the date of the enactment of the section and -
(i) no request for an exemption described in (1)(B)... was submitted... before such date for the approved product the period of extension... may not exceed five years....
(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension... may not exceed two years....

None of these limitation was applicable to Trental: (A) because the patent issued before the date of enactment, (B) because Hoechst applied for the relevant exemption before that date, and (C) because Trental was approved before that date.[52]

[48] *Id.* at 2069-70.
[49] 917 F.2d 522 (Fed. Cir. 1990).
[50] *See supra* note 40.
[51] 917 F.2d 522, 524 (Fed. Cir. 1990).
[52] *Id.* at 525.

The PTO argued that "to which the limitation described in paragraph (6) applies" was part of the definition of "regulatory review period." Thus, if none of the limitations in § 156 (g)(6) obtained, the applicant was entitled to no patent term extension. The PTO argued that its view was supported by the principle of construing statutes to avoid rendering any language superfluous, as well as legislative history demonstrating congressional intent to prevent any patent term extension greater than five years.[53] Hoechst replied that, according to the plain meaning of the statute, the limitations in paragraph (6) merely cap the length of the extensions for eligible patents; they are not part of the definition of "regulatory review period" for purposes of determining which patents are eligible for extension. In Hoechst's view, the lack of a limit on the duration of the term extension for a small category of drugs like Trental was simply due to Congressional oversight.[54]

The Federal Circuit reviewed the legislative history of § 156 and decided that Congress intended to define "regulatory review period" in §§ 156(g)(1)-(5), with § 156(g)(6) functioning only as a limitation on the duration of the term extension. The language "to which the limitation described in paragraph (6) applies is "merely an internal cross-reference."[55] Thus, Trental met all the statutory requirements for term extension under § 156. Congress almost definitely did not intend to grant Hoechst a patent term extension greater than 5 years; however, there was no reason to believe Congress meant to deny Hoechst any term extension, and the statutory formula unambiguously yields a 6.8 year extension for Trental. Thus, the court refused to contort the statute to attempt to remedy an anomalous result: it held that Hoechst was entitled to a 6.8 year term extension for its Trental patent.[56]

In *Astra v. Lehman*,[57] the Federal Circuit held that the Secretary of Health

[53] *Id.*
[54] *Id.*
[55] *Id.* at 527-28.
[56] *Id.* at 529.
[57] 71 F.3d 1578 (Fed. Cir. 1995).

and Human Services, or FDA as the Secretary's delegate, must determine the regulatory review period from which the patent term extension is calculated; the Commissioner of Patents has no authority to revise or put aside the Secretary's determination. Astra submitted an application for patent term extension for its anti-viral drug Foscavir. According to the statutory scheme in 35 U.S.C. § 156, the Commissioner of Patents requested that the Secretary of Health and Human Services determine the applicable regulatory review period required for calculating the term extension.[58] The Secretary determined the regulatory review period, based on the sum of the "testing" and "approval" phases of FDA review,[59] and published it in the Federal Register as required.[60] The Commissioner in turn used the Secretary's determination to calculate the patent term extension[61] as one half the testing phase plus the full approval phase.[62] Astra believed that the Secretary's determination placed too much time in the testing phase and not enough time in the approval phase, such that the overall calculated term extension was shorter than it should have been. However, Astra forewent its opportunity to challenge the Secretary's determination at the time of its publication[63]; instead, Astra sought later to have the Commissioner recalculate its term extension. The Commissioner denied Astra's petition for review, reasoning that he had no authority to reconsider the Secretary's determination.[64]

The court held that the clear, unambiguous statutory language supported the Commissioner's position.[65] 35 U.S.C. § 156(d)(2)(A) states that:

> (A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify...
> (ii) the Secretary of Health and Human Services... and shall submit to the Secretary... a copy of the application.... [T]he Secretary... shall review the dates contained in the application... and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall

[58] *Id.* at 1579.
[59] *See* 35 U.S.C. § 156(g)(1)(B) (1994), *supra* note 40.
[60] *See* 35 U.S.C. § 156(d)(2)(A) (1994).
[61] *See* 35 U.S.C. § 156(c) (1994).
[62] 71 F.3d 1578, 1579 (Fed. Cir. 1995).
[63] *See* 21 C.F.R. §§ 60.24, 60.26 (1994).
[64] 71 F.3d 1578, 1579-80.
[65] *Id.* at 1580.

publish in the Federal Register a notice of such determination.

Thus, the court found that the statute "plainly mandates the Secretary, not the Commissioner, to determine the regulatory review period."[66] This conclusion was not undermined by provision in 35 U.S.C. § 156(d)(1)(C) that an application for patent term extension must contain "information to enable the Commissioner and the Secretary of Health and Human Services... to determine the period of the extension under subsection (g)." Although the Commissioner and the Secretary determine the extension period jointly, the Secretary alone is responsible for determining the regulatory review period under § 156(d)(2)(A). Thus, after noting that the legislative history was consistent with the plain meaning of the statutory text, the court denied Astra's request for a recalculation of its patent term extension by the Commissioner.[67]

D.

Interaction with the URAA

Enacted in 1984, the Uruguay Round Agreements Act (URAA)[68] changed the term of a U.S. patent from seventeen years from the date of issue to twenty years from the date of filing.[69] For patents in force on June 8, 1995, the URAA's effective date, the term would be the greater of twenty years from filing or seventeen years from issue.[70] The URAA limits the remedies a patentee may assert against parties who, before June 8, 1995, had begun or made a substantial investment towards activities that became infringing only as a result of a term extension under the URAA.[71] Patentees may not assert the usual infringement remedies in 35 U.S.C. §§ 283-85 against such activities during the period of URAA extension (the "delta period"), and are instead entitled only to equitable

[66] *Id.*
[67] *Id.*
[68] Pub. L. No. 103-465, 108 Stat. 4983 (1994).
[69] *See* 35 U.S.C. § 154(a)(2) (1994).
[70] *See* 35 U.S.C. § 154(c)(2) (1994).
[71] *Id.*

remuneration.[72]

In *Merck & Co. v. Kessler*,[73] the Federal Circuit considered whether patents already in force on June 8, 1995 could combine extensions under the URAA with extensions under § 156. Each of the patents in suit was in force on June 8, 1995 and had received a two-year extension under § 156; some of the patents were still in force only because of that extension. The patents had been granted seventeen year terms at issuance, but these terms would be extended if the patentees took advantage of the alternative term of twenty years from filing under the URAA.[74] However, FDA refused to publish new expiration dates for these patents using the twenty-year term. Its refusal was based on a PTO "Final Determination,"[75] which stated that patents in force on June 8, 1995 could not combine a twenty-year term under the amended URAA with an extension under § 156.[76] PTO's position rested on the provision in 35 U.S.C. § 156(a) that a patent term "shall be extended in accordance with this section from the *original expiration date* of the patent" (emphasis added). The PTO reasoned that any patent issued before June 8, 1995 was granted for a term of seventeen years. Thus, the date seventeen years after the issue date was the "original expiration date" and an extension under § 156 could be added only to that date. The PTO also noted that in some cases, absent recalculation, combining the twenty-year term under the URAA with an extension already granted under § 156 would cause the total extended patent term to violate the fourteen-year post-approval extended term cap set out in 35 U.S.C. § 156(c)(3).[77]

The Federal Circuit rejected the PTO's interpretation of "original expiration date."[78] The court examined the legislative history of § 156 and determined that the phrase "original expiration date" was included to assure that no more than one § 156 term extension was granted to any patent to compensate for

[72] *See* 35 U.S.C. § 154 (c)(2),(3) (1994).
[73] 80 F.3d 1543 (Fed. Cir. 1996).
[74] *Id.* at 1548.
[75] 60 Fed. Reg. 30,069-71 (1995).
[76] 80 F.3d 1543, 1548 (Fed. Cir. 1996).
[77] *Id.*
[78] *Id.* at 1550.

time lost during regulatory review. Thus, the "original expiration date" was simply the date the patent would expire absent an extension under § 156.[79] While patentees were limited to one § 156 extension, the "original expiration date" language did not prevent patentees from enjoying an extension under the URAA as well as a § 156 extension. The combined extension was, however, limited by the fourteen-year post-approval term cap in § 156(c)(3); thus, some pre-June 8, 1995 extensions might require recalculation.[80]

Next, the court addressed the problem of the different remedies available to patentees during successive extension periods under § 156 and the URAA. The court was not overly troubled by the possibility that a patentee might be entitled to full remedies for the first seventeen years after filing, then only equitable remuneration with regard to certain activities during the delta period, and finally full remedies again, but only with respect to the approved product, during the § 156 extension period.[81] Drug patent infringers whose activities were protected by the URAA were few in number and were likely to be generic drug manufacturers with additional limits on their infringing behavior. A generic manufacturer could not seek market approval for its drug during the delta period without exposing itself to suit for infringement.[82] If the patentee sued, FDA would stay approval of the generic drug until the patent expired, the suit was resolved, or thirty months, a period almost certainly longer than the delta period, passed.[83] Thus, the court decided that the minimal possibility of problems in a few special cases should not prevent the majority of patentees from enjoying an extension under § 156 as well as a twenty-year term under the URAA.[84]

Finally, the court turned to the patents in suit that were in force on June 8, 1995 only because they had been extended under § 156. The court agreed with the PTO that these patents were not entitled to the twenty-year term under the

[79] *Id.* at 1550-51.
[80] *Id.* at 1551.
[81] *Id.*
[82] *See DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995).
[83] *See* 21 U.S.C. § 355 (j)(5)(B)(iii) (1994).
[84] 80 F.3d 1543, 1552 (Fed. Cir. 1996).

URAA.[85] The court reasoned that allowing combined § 156 and URAA extensions for these patents would violate the limits contained 35 U.S.C. § 156(a)(2) and (g)(6), which require that the patent term be extended only once under § 156 and that the total extension not exceed two years.[86] The court also noted that the inconsistent remedy problem would be serious for these patents. Their enforcement had been restricted to one approved product before the URAA was enacted; "[t]o follow this period of limited enforcement with enforcement for all products covered by the patent (or delta enforcement in some cases) and then return to one product enforcement again can only be characterized as bizarre."[87] Thus, the court concluded that patents in force on June 8, 1995 only as a result of an extension under § 156 were not entitled to a twenty-year term under the URAA; however, all other patents in force on June 8, 1995 were eligible for a twenty-year URAA term as well as a § 156 extension.

III.

Litigation of Infringement and the Safe Harbor under 35 U.S.C. § 271(e)

A.

Scope of the § 271(e)(1) Safe Harbor

1.

Products

§ 271(e)(1) provides 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* (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and

[85] *Id.*
[86] *Id.*
[87] *Id.* at 1553.

submission of information under a *Federal law which regulates the manufacture, use, or sale of drugs* or veterinary biological products.[88]

"

Patented invention" is defined in § 100(a) to include any "invention or discovery," and is not limited to drug-related inventions.[89] Thus, Medtronic sought to defend an infringement suit brought against it by Eli Lilly in 1983 by arguing that all of the activity involving its implantable cardiac defibrillator, a medical device used in the treatment of heart patients, fell within the safe harbor of § 271(e)(1).[90] Eli Lilly argued that "a Federal law which regulates the manufacture, use, or sale of drugs,"[91] referred only to provisions within the Federal Food Drug and Cosmetic Act (FFDCA)[92] relating to regulatory approval of drugs, and not the entire FFDCA, which also governs the regulatory approval of medical devices.[93] The Supreme Court rejected this view, instead accepting Medtronic's reading, which applied § 271(e)(1) to activities seeking FDA approval for any product governed by the FFDCA. Justice Scalia, writing for the majority, reasoned that the most common understanding of taking an action "under a federal law" involves acting within a comprehensive regulatory scheme.[94] He also found it persuasive that the immediately proceeding provision in the Hatch-Waxman Act used the narrower term "provision of law" rather than the more ambiguous "law"; if Congress had meant to restrict the safe harbor to drug, as opposed to device, inventions, it would have done so using such clear, simple language.[95]

Scalia went on to discuss the role of the Hatch-Waxman Act as a compromise between the interests of generic and pioneer pharmaceutical manufacturers. The Act was designed to eliminate distortions present at both ends of the patent term due to FDA review: pioneer manufacturers could receive patent extensions to compensate for the regulatory review period, during which they were unable to

[88] 35 U.S.C. § 271(e)(1) (1994) (emphasis added).
[89] 35 U.S.C. § 100(a) (1994).
[90] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 664 (1990).
[91] 35 U.S.C. § 271(e)(1) (1994).
[92] 21 U.S.C. §§ 301- 395 (1994).
[93] 496 U.S. 661, 664 (1990).
[94] *Id.* at 667.
[95] *Id.*

capitalize on their patents, and generic manufacturers were permitted to make, use, and sell patented technology before the patent's expiration date, as long as their activities were related to seeking FDA approval.[96] Because patents on medical devices are eligible for patent term extension, Scalia reasoned that the balance sought by the Act required that they also be subject to the § 271(e)(1) safe harbor. Scalia noted that his interpretation of the statute would lead to a near-perfect correspondence between the products eligible for patent term extension and those qualifying for the § 271(e)(1) safe harbor, since the products eligible for patent term extension are generally also subject to pre-market approval under the FFDCA.[97]

The FFDCA divides medical devices into Classes I, II, and III, which cover increasingly risky products subject to increasingly stringent regulatory approval requirements. While Class III medical devices, such as Medtronic's implantable cardiac defibrillator, are subject to an exacting pre-market approval process, the regulatory requirements for Class I and II devices are much less demanding.[98] In an unpublished opinion in *Chartex International, PLC v. M.D. Personal Products Corp.*, the Federal Circuit first addressed, and rejected in a footnote, the possibility that the § 271(e)(1) safe harbor might only apply to Class III medical devices, because only they are subject pre-market approval requirements as stringent as those for drugs.[99]

In *Abtox, Inc. v. Exitron Corp.*,[100] a suit involving a plasma sterilizer, a Class II medical device, the court analyzed the issue fully, applying the Supreme Court's *Eli Lilly* decision. Judge Rader, writing for the court, recognized a tension between the Supreme Court's specific reasoning and its somewhat broader holding.[101] Justice Scalia's rationale, which hinged on the balance between patent term extensions for time lost during a demanding regulatory review process and a safe harbor for activities seeking approval of a generic product, suggests that

[96] *Id.* at 669-70.
[97] *Id.* at 672-74.
[98] *See Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).
[99] 5 F.3d 1505 (table, text in Westlaw), 1993 WL 306169, at *4 (Fed. Cir. 1993).
[100] 122 F.3d 1019 (Fed. Cir. 1997).
[101] *Id.* at 1029.

§ 271(e)(1) should apply to only those products whose patents are eligible for patent term extensions; since patents on Class II medical devices cannot be extended, Class II devices should not be covered by the safe harbor. However, Class II medical devices should be covered by § 271(e)(1) under the Supreme Court's broad holding that the language "a federal law which regulates the manufacture, use, or sale of drugs" extends the § 271(e)(1) safe harbor to any product regulated by the FFDCA. Judge Rader felt bound by the Supreme Court's broader holding and noted that the Supreme Court explicitly adopted an interpretation creating some situations where patent term extension and safe harbor coverage would not correspond; thus, he held that Class II medical devices are covered by the § 271(e)(1) safe harbor.[102]

2.

Activities

Courts have also struggled with the language "solely for uses reasonably related to the development and submission of information"[103] for FDA approval in defining the scope of the § 271(e)(1) safe harbor. Initially, district courts were divided, some applying a stringent analysis focusing on the word "solely," and others applying a more lenient analysis based on the words "reasonably related to." For example, in *Scripps Clinic and Research Foundation v. Genentech, Inc.*,[104] the U.S. District Court for the Northern District of California found that Genentech's activities involving Factor VIII:C, a protein involved with human blood clotting, were not covered by the safe harbor because Genentech had not made and used Factor VIII:C "solely" for generation of information required for FDA approval.[105] The court explained that, "[e]ven if the uses to which Genentech... put the Factor VIII:C were reasonably related to meeting FDA requirements, they certainly were not solely related to that purpose";

[102] *Id.*
[103] 35 U.S.C. § 271(e)(1) (1994).
[104] 666 F. Supp. 1379 (N.D. Cal. 1987).
[105] *Id.* at 1396.

the uses also involved preparation of foreign patent applications, development of commercial manufacturing processes, receipt of funds for supplying product, and contemplation of foreign marketing before Scripps' patent expired.[106] The court concluded that , "[t]hese sales and uses of Factor VIII:C, serving multiple purposes unrelated to meeting FDA requirements, clearly lie beyond the protection of § 271(e)(1)."[107]

However, in *Scripps Clinic and Research Foundation v. Baxter Travenol*,[108] another Factor VII:C case involving similar facts, the District Court for the District of Delaware was less sympathetic to Scripps' arguments. The court denied a motion to strike Baxter's § 271(e)(1) defense, maintaining that it is "still unclear... what is meant by the phrase 'solely for uses reasonably related to' gathering and submitting information and whether Section 271(e)(1) should apply even if the data are also given to foreign regulatory agencies."[109] The court found merit in Baxter's argument that its activities, which involved submitting data for foreign patents and regulatory approval and thus could result in marketing before Scripps' patent expired, might still qualify for the § 271(e)(1) safe harbor because all of the experiments generated information required for FDA approval, and all of the foreign regulatory data were also submitted to FDA to aid in U.S. approval.[110] The court noted that the Northern California District Court described above had "interpreted the statute to only cover activities that were 'solely related' to FDA approval and did not consider what acts are 'reasonably related' to it." The court then reserved for trial "[t]he question of law... whether any foreign activities can be 'reasonably related' to FDA drug approval."[111]

In *Elan Transdermal Ltd. v. Cygnus Therapeutic Systems*,[112] the Northern District of California reconsidered its position. Relying heavily on *Intermedics Inc.*

[106] *Id.*
[107] *Id.*
[108] 1988 WL 22602 (D. Del. 1988).
[109] *Id.* at *4.
[110] *Id.* at *5.
[111] *Id.*
[112] 24 U.S.P.Q.2d 1926 (N.D. Cal. 1992).

v. Ventritex Co.,[113] a case it had decided since *Scripps Clinic* that focused on the phrase "reasonably related to" rather than word "solely" and thus engaged in a much more permissive analysis under § 271(e)(1), the court recognized that "'solely' in Section 271(e)(1) is correctly read as modifying 'uses,' not 'reasonably related.'"'[114] Thus, the court rejected its narrower *Scripps Clinic* analysis and held that "[i]f the otherwise infringing uses were reasonably related to gathering information for submission to the FDA, then Cygnus is protected by the statutory exemption in Section 271(e)(1).... That other purposes may also be served is irrelevant, because Congress chose the term 'uses' not 'purposes.'"'[115] The court also noted that provision of data about the accused device to foreign agencies and potential investors is not infringing activity under 35 U.S.C. § 271(a), which prohibits only making, using, selling, offering for sale, or importing the accused device; thus, the application of the safe harbor in § 271(e)(1) to data dissemination is irrelevant.[116]

In *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*,[117] the Federal Circuit resolved the issue in favor of a broad interpretation similar to the *Elan* court's. The Federal Circuit affirmed a grant of summary judgment for defendant Ventritex, finding that all of its activities, including clinical trials, sales of the device for implantation during clinical trials, display of the device at medical conferences to physicians and non-physicians, and description of clinical trial progress to physicians, investors, analysts, and journalists for fund-raising purposes, were either non-infringing data dissemination or "solely for uses reasonably related" to obtaining FDA approval.[118] Demonstration to non-physicians did not fall outside the § 271(e)(1) safe harbor because the demonstrations were designed to attract clinical investigators for FDA-mandated clinical trials; the fact that a few non-physicians, who couldn't implant the device anyway, witnessed the

[113] 775 F. Supp. 1269 (N.D. Cal. 1991).
[114] 24 U.S.P.Q.2d 1926, 1932 (N.D. Cal. 1992).
[115] *Id.*
[116] *Id.*
[117] 982 F.2d 1520 (Fed. Cir. 1992).
[118] *Id.* at 1523-25.

demonstration, did not preclude safe harbor protection.[119] The court recognized that data dissemination is not an infringing activity under § 271(a) and thus requires no safe harbor under § 271(e)(1); it also rejected Telectronics' argument that using data for purposes unrelated to FDA reporting should revoke the safe harbor for the activities that generated the data.[120] The statutory language was clear and created no such limitation. Moreover, the legislative history of the Hatch-Waxman Act showed Congress' awareness of the need for pre-patent expiration fund-raising and marketing preparation activities by generic manufacturers: "By permitting the testing and regulatory approval process to begin well before a controlling patent had run its course, Congress must have intended to allow competitors to be in a position to market their products as soon as it was legally permissible."[121]

The Federal Circuit again affirmed summary judgment for the defendant in *Intermedics, Inc. v. Ventritex Co.*,[122] finding that all of Ventritex's otherwise infringing activity fell within the § 271(e)(1) exemption. The court rejected Intermedics' assertion that Ventritex's use and sale of its implantable cardiac defibrillator in Germany might not be exempt, finding that each device sold and used in Germany was implanted by a clinical investigator and used to generate data only submitted for FDA approval.[123] The court then cited *Telectronics* in finding Ventritex's trade show displays exempt, reasoning that Ventritex could continue to recruit potential investigators throughout the FDA approval process because it had no way to know how much clinical data FDA would require.[124] Finally, the Federal Circuit rejected Intermedics' contention that § 271(e)(1) protection should be barred if the defendant seeks to commercialize the accused device before the allegedly infringed patent expires. As in *Telectronics*, the court relied on the plain language of the statute and the legislative history suggesting a Congressional desire for generic commercialization immediately upon patent

[119] *Id.* at 1523.
[120] *Id.* at 1524.
[121] *Id.* at 1525.
[122] 991 F.2d 808 (table, text in Westlaw), 1993 WL 87405 (Fed. Cir. 1993).
[123] *Id.* at *3.
[124] *Id.* at *4.

expiration to rule out such a limitation. The court concluded that "[r]eliance on section 271(e)(1) is not precluded by manifestation of an intent to commercialize upon FDA approval."[125]

The Federal Circuit's current analytical stance is summarized well in its opinion in *Abtox, Inc. v. Exitron Corp.*:

> Section 271(e)(1) requires only that the otherwise infringing act be performed "solely for uses reasonably related to" FDA approval. The statute, therefore, does not look to the underlying purposes or attendant consequences of the activity... as long as the use is reasonably related to FDA approval. In other words, the statutory language allows [generic manufacturers] to use... data... for more than FDA approval. As long as the activity is reasonably related to obtaining FDA approval,... intent or alternative uses are irrelevant to [invocation of] the section 271(e)(1) shield.[126]

Amgen, Inc. v. Hoechst Marion Roussel, Inc.[127] exemplifies the current permissive § 271(e)(1) analysis employed by district courts. Amgen sued Hoechst Marion Roussel for activities allegedly infringing its patents on recombinant erythropoietin, a hormone involved in red blood cell production. The U.S. District Court for the District of Massachusetts formulated its inquiry as follows: to fall within the § 271(e)(1) safe harbor, the defendants "must make, use, or sell the patented invention in ways that objectively bear reasonable prospects of yielding information that might be relevant in the FDA approval process."[128] The court went on to explain that, "[i]f the Defendants have confined themselves to such uses, then their subsequent use of the information gathered, their ulterior motives for engaging in the research, and the existence of other more promising or less extensive uses that also might have lead to FDA acceptance are all statutorily irrelevant factors."[129] Under this broad test, the court found that all of the following activities fell within the § 271(e) safe harbor: export to Japan for use in developing an alternative manufacturing procedure; tests not submitted to FDA, but used to confirm data that were submitted; production of consistency batches required for FDA approval but abandoned due to dis-

[125] *Id.* at *5.
[126] 122 F.3d 1019, 1030 (Fed. Cir. 1997) (citation omitted).
[127] 3 F. Supp. 2d 104 (D. Mass. 1998).
[128] *Id.* at 108.
[129] *Id.*

satisfaction with product quality; use of protein characterization data required for FDA approval to assess infringement under plaintiff's patent; and designing clinical trials, the results of which were submitted to FDA, to meet more stringent foreign regulatory approval requirements.[130]

While the trend has clearly been toward an expansive interpretation of the § 271(e)(1), district courts have not been blindly permissive in applying the exemption. In *NeoRx Corp. v. Immunomedics, Inc.*,[131] the U.S. District Court for the District of New Jersey refused to find all of defendant Immunomedics' activities exempt on a motion for summary judgment. While the court found that some of Immunomedics' activities clearly fell within the safe harbor, it denied summary judgment regarding shipment of samples to foreign regulatory agencies and work by one foreign investigator.[132] The court held that manufacture within the U.S. for shipment to foreign regulatory agencies or foreign investigators whose tests are not suitable for or intended for submission to FDA is a non-exempt, infringing activity.[133]

In *Amgen, Inc. v. Elanex Pharmaceuticals, Inc.*,[134] the U.S. District Court for the Western District of Washington similarly refused summary judgments for the defendants. The court explained that, although Elanex asserted an intention to seek FDA approval, it had not actually sought FDA approval of any of its studies or submitted any information to FDA, and it had admitted that much of its U.S. activity was conducted to support its European marketing effort. Thus, an issue of fact clearly remained as to whether Elanex's infringing activities were exempt under § 271(e)(1).[135]

Finally, in *Biogen, Inc. v. Schering AG*,[136] the U.S. District Court for the District of Massachusetts held that Biogen's activities in connection with its multiple sclerosis drug Avonex were not exempt because "Biogen had done far

[130] *Id.* at 109-11.
[131] 877 F. Supp. 202 (D.N.J. 1994).
[132] *Id.* at 214.
[133] *Id.* at 209-11.
[134] 1996 WL 84590 (W.D. Wash. 1996).
[135] *Id.* at *4.
[136] 954 F. Supp. 391 (D. Mass. 1996).

more than merely do clinical trials for submission to the FDA[. I]t had spent $24 million to stockpile and prepare to market Avonex immediately upon the anticipated, imminent FDA approval in order to access promptly the lucrative market for beta interferon drugs to combat multiple sclerosis."[137] The court also cited *NeoRx*[138] in holding that Biogen's production of Avonex in the U.S. for shipment to foreign regulatory authorities was not covered by the § 271(e)(1) safe harbor.[139] Thus, while the § 271(e)(1) safe harbor has been interpreted as a broad license for generic drug manufacturers to engage in otherwise infringing activity, courts will put bounds on the allowable breadth of such activity in extreme cases.

B.

Scope of the § 271(e)(2) Infringement Analysis

§ 271(e)(2) allows adjudication of patent disputes involving generic drugs during the FDA regulatory approval process, despite the § 271(e)(1) safe harbor, by making into an act of infringement the submission of an ANDA seeking FDA approval for commercial manufacture, use, or sale of a generic product before the pioneer patent has expired.[140] In *Glaxo, Inc. v. Novopharm, Ltd.*,[141] the Federal Circuit outlined the scope of the infringement analysis under § 271(e)(2), which poses difficulties because it involves a product that is still undergoing

[137] *Id.* at 396-97.
[138] 877 F. Supp. 202 (D.N.J. 1994).
[139] 954 F. Supp. 391, 397 (D. Mass. 1996).
[140] 35 U.S.C. § 271(e)(2) (1994) provides that:
It shall be an act of infringement to submit -
(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 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.
[141] 110 F.3d 1562 (Fed. Cir. 1997).

development. In affirming the dismissal of Glaxo's infringement claims, the court rejected Glaxo's argument that the infringement analysis should focus on whether the scope of ANDA approval sought would allow Novopharm to commercialize an infringing product. Instead, the court agreed with Novopharm that the inquiry properly focused on what Novopharm would actually sell under the ANDA, if and when it obtained approval. Additionally, the burden remained on patentee Glaxo to prove infringement by a preponderance of the evidence; the broad ANDA scope did not shift the burden to defendant Novopharm to prove that the drug it would market would not infringe.[142]

The court explained that the statute creates an act of infringement only when the ANDA seeks pre-expiration approval for commercial manufacture, use, or sale of the patented drug. Thus, the statute mandates an infringement analysis based on the product that will likely be sold upon FDA approval; the analysis should consider all relevant evidence, including the ANDA itself and materials submitted to FDA.[143] The court noted that in *Eli Lilly v. Medtronic*,[144] Justice Scalia described infringement under § 271(e)(2) as "artificial," because no infringing device that had actually been made, sold, or used, was available for the court to compare to the patent claims. [145] The court concluded that, because of this artificiality:

> [t]he patentee's burden of proving ultimate infringement is not met by the filing of the ANDA. The relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product. What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists.[146]

C.

Interaction with the URAA

As described above, the Uruguay Round Agreements Act (URAA),[147] signed into law December 8, 1994, amended the U.S. Patent Code to change the term

[142] *Id.* at 1567.
[143] *Id.* at 1568.
[144] 496 U.S. 675, 677 (1990).
[145] 110 F.3d 1562, 1568 (Fed. Cir. 1997).
[146] *Id.* at 1570.
[147] Pub. L. No. 103-465, 108 Stat. 4983 (1994).

of a U.S. patent from seventeen years from the issue date to twenty years from the filing date.[148] For patents already in force on June 8, 1995, the URAA's effective date, the term would be the greater of twenty years from filing or seventeen years from issuance.[149] The URAA created a limited safe harbor for parties who, before June 8, 1995, had begun or made a substantial investment in activities that became infringing only as a result of a term extension under the URAA.[150] This safe harbor prevents patentees from asserting traditional patent remedies under 35 U.S.C. §§ 283-85 against such activities during the period of URAA extension (the "delta period"); the patentee is entitled only to equitable remuneration.[151]

The Federal Circuit examined the interplay between the Hatch-Waxman Act and the URAA in two 1995 cases. First, in *DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*,[152] several generic manufacturers asserted the right to manufacture and sell generic captopril, a heart drug, during the delta period of Bristol-Myers Squibb's captopril patent. The generic companies claimed that such marketing would be covered by the URAA's safe harbor. The court explained that FDA required generic manufacturers wishing to market their drugs during the delta period of a pioneer patent to amend their ANDAs to include a paragraph IV certification; however, filing a paragraph IV certification constitutes infringement under § 271(e)(2) and requires FDA to suspend approval of the ANDA until the patentee has had an opportunity to bring an infringement suit.[153] The court then held that the URAA adjusts the remedies for certain infringing acts during the delta period but does not affect the definition of infringement under § 271(e)(2) or the FDA regulatory approval procedures for ANDAs.[154] Thus, the generic manufacturers were not entitled to any relief; they were required to comply with the usual ANDA paragraph IV certification

[148] *See* 35 U.S.C. § 154(a)(2) (1994).
[149] *See* 35 U.S.C. § 154(c)(2) (1994).
[150] *Id.*
[151] *See* 35 U.S.C. § 154 (c)(2),(3) (1994).
[152] 62 F.3d 1397 (Fed. Cir. 1995).
[153] *Id.* at 1400.
[154] *Id.* at 1402.

procedures allowing the pioneer drug patentee to litigate an infringement suit to the full extent permitted by law.[155]

Royce Laboratories amended its captopril ANDA to include a paragraph IV certification. However, the certification did not assert invalidity or non-infringement of the captopril patent; instead, it alleged that marketing generic captopril during the delta period was allowable under the URAA safe harbor. Bristol-Myers Squibb then sued Royce Laboratories under § 271(e)(2).[156] The Federal Circuit agreed with Bristol-Myers Squibb that the URAA safe harbor did not permit marketing of generic drugs during the delta period of a pioneer drug patent. As in *DuPont Merck*,[157] the court explained that the URAA does not make infringing conduct non-infringing during the delta period; instead, it merely limits the remedies patentees may assert against certain infringing conduct during that time.[158] Thus, the URAA did not change the fact that Royce had committed an act of infringement under § 271(e)(2) by submitting an ANDA with a paragraph IV certification. Because Royce had asserted neither invalidity nor non-infringement of the captopril patent, the paragraph IV certification was incorrect, and Bristol-Myers Squibb was entitled to the usual remedy for such incorrect certification: Royce could not obtain FDA approval of its ANDA until the captopril patent expired.[159]

D.

Declaratory Judgment

One of the first courts to address the issue of a declaratory judgment in relation to § 271(e) was the U.S. District Court for the District of New Jersey in *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*[160] Zenith sued under the Declaratory Judgments Act, 28 U.S.C. § 2201, seeking a declaration that its activities in relation to its generic antibiotic cefadroxil DC did not infringe

[155] *Id.*
[156] *Bristol-Myers Squibb Co. v. Royce Laboratories, Inc.*, 69 F.3d 1130 (Fed. Cir. 1995).
[157] 62 F.3d 1397 (Fed. Cir. 1995).
[158] 69 F.3d 1130, 1136 (Fed. Cir. 1995).
[159] *Id.* at 1137-38.
[160] 1991 WL 267892 (D.N.J. 1991).

Bristol-Myers Squibbs' (Bristol's) patent. The court began by explaining that actions for declaratory judgment can be heard only if an "actual case or controversy" exists; the existence of such case or controversy is determined from the totality of the circumstances. The court then laid out the Federal Circuit's test for the existence of an actual case or controversy: first, the plaintiff must have a "reasonable apprehension," based on the defendant's conduct, that the defendant will sue him for infringement if he continues his allegedly infringing activity and, second, the plaintiff must have actually produced or prepared to produce the allegedly infringing device.[161]

The court found that Zenith had an objectively reasonable apprehension of suit based on Bristol's conduct: Bristol had already sued Zenith's intended supplier under the patent at issue and had sued Zenith under a different patent.[162] The court then went on to consider whether Zenith had made the "meaningful preparation" to infringe that is necessary to satisfy the second prong of the Federal Circuit's declaratory judgment test. To meet the "meaningful preparation" standard, Zenith would have to have the "immediate intention and ability to infringe."[163] The court held that Zenith could not satisfy this standard with respect to the future marketing of cefadroxil DC because too many contingent factors were involved. Zenith had not yet received FDA approval or secured a supplier with FDA approval, and its only potential supplier had rested its decision to supply on several contingent conditions. Thus, the court found that the required case or controversy was lacking for a declaration that future marketing of cefadroxil DC by Zenith would not infringe Bristol's patent.[164]
However, the court found that there was sufficient case or controversy for it to hear a declaratory judgment suit regarding Zenith's activities before FDA in seeking approval for cefadroxil DC. Zenith clearly had present ability and intention to infringe under § 271(e)(2): for several years it had actively sought FDA

[161] *Id.* at *4.
[162] *Id.* at *5.
[163] *Id.* at *5-6.
[164] *Id.* at *6.

approval to market cefadroxil DC before Bristol's patent expired.[165] The court then explained that its jurisdiction under the Declaratory Judgments Act was discretionary; however, in this case it would exercise its discretion to hear the case. The court noted Zenith's interest in determining whether it was worthwhile to continue prosecuting its application for FDA approval, which required knowing whether it could obtain such approval before Bristol's patent expired. The court also emphasized the public interest in obtaining early access to Zenith's generic product, especially since Bristol had a monopoly on cefadroxil drugs. Thus, because a declaratory judgment would serve these two "useful purposes," the court decided it would hear the suit.[166]

Another early declaratory judgment case regarding infringement under § 271(e) was *Farmaceutisk Laboratorium Ferring A/S v. Solvay Pharmaceuticals Inc.*[167] Initially, Farmaceutisk sued Solvay for patent infringement and Solvay counterclaimed, seeking a declaration of invalidity and non-infringement. After discovery, Farmaceutisk realized all of Solvay's activities fell within the § 271(e)(1) safe harbor and dismissed its infringement claims; however, Solvay sought to maintain its declaratory judgment claims.[168] The U.S. District Court for the Northern District of Georgia began by setting out the declaratory judgment doctrine described in *Zenith*.[169] The court then explained that under the first prong of the Federal Circuit test, which requires reasonable apprehension of suit by the patentee, an express charge of infringement is not required. If there is no express infringement charge, the court must examine the totality of the circumstances to determine whether the plaintiff has a reasonable apprehension of suit. In this case, because Farmaceutisk's infringement claims were dismissed without prejudice and were dropped solely based on the § 271(e)(1) safe harbor, Solvay had a reasonable apprehension of suit once its drug was approved and the safe harbor no longer applied.[170]

[165] *Id.* at *7.
[166] *Id.* at *8.
[167] 25 U.S.P.Q.2d 1344 (N.D. Ga. 1992).
[168] *Id.* at 1346-47.
[169] 1991 WL 267892 (D.N.J. 1991).
[170] 25 U.S.P.Q.2d 1344, 1349 (N.D. Ga. 1992).

The court then explained that the second or "immediacy" prong of the Federal Circuit test, which requires immediate intent and ability to infringe, was an issue of degree to be decided on a case-by-case basis. In this case, Solvay met the "meaningful preparation" standard required for immediacy. Solvay had committed substantial resources to developing its drug, and it intended to diligently prosecute an application for FDA approval until such approval was granted and it could market its drug. The fact that Solvay had not yet actually filed an application for FDA approval was not determinative.[171]

The court then decided to exercise its discretion to hear the invalidity claim but not the non-infringement claim. The patent itself was a "fixed target," and a ruling on its validity would clarify the positions of both Solvay and Farmaceutisk in any future infringement dispute. However, Solvay's drug product had yet to obtain FDA approval and could be changed or even set aside during the approval process; thus the infringement issue was not ripe for determination. Solvay's stipulation that it would not change its product between the time of suit and the time of commercial marketing did not sway the court. Thus, the court declined to hear the infringement issue but decided to hear the invalidity claim to clarify Farmaceutisk's patent rights, allow Solvay to better assess its infringement risks, and thus serve the Hatch-Waxman Act's purpose of encouraging investment in the development and marketing of generic drugs.[172]

The Federal Circuit addressed declaratory judgment in the § 271(e) context in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*[173] Telectronics sued for a declaratory judgment that, upon FDA approval, Ventritex's sales of its implantable defibrillator would infringe Telectronics' patent. The district court dismissed the suit and Telectronics appealed.[174] The Federal Circuit began by explaining that a patentee may seek a declaration that another party's future conduct will infringe its patent. However, the plaintiff must present "sufficient

[171] *Id.* at 1350.
[172] *Id.* at 1351-52.
[173] 982 F.2d 1520 (Fed. Cir. 1992).
[174] *Id.* at 1521.

allegation of immediacy and reality" to prove that an actual case or controversy exists and the court's jurisdiction is discretionary.[175] The court held that the evidence supported a decision that the immediacy prong of the actual case or controversy test was not satisfied: Ventritex had just recently started clinical trials, had already changed its product during testing, and was years away from obtaining FDA approval. Thus, it was uncertain whether the device Ventritex was currently testing would be the same one that received FDA approval and was eventually marketed.[176] Even if an actual case or controversy existed, the district court did not clearly err in exercising its discretion to refuse to hear the suit at such a preliminary stage. Thus, the court affirmed the district court's summary judgment for defendant Ventritex.[177]

In *Intermedics, Inc. v. Ventritex, Inc.*,[178] the Federal Circuit again affirmed a district court's dismissal of a declaratory judgment suit related to § 271(e). Intermedics sought a declaratory judgment that Ventritex would infringe its patent when it obtained FDA approval and began marketing its implantable defibrillator. The district court dismissed the claims because all of Ventritex's activities were covered by the § 271(e)(1) safe harbor.[179] The court framed the actual case or controversy test as follows:

> [T]he patentee... must show that the defendant [is] engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. s 271(a) (1982), or be making meaningful preparation for such activity; and [the] acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming.[180]

The court held that the district court did not abuse its discretion in dismissing the claims because no actual controversy existed: Ventritex had not yet obtained FDA approval and might be required to change its device during the approval process.[181] Finally, the court reasoned that hearing Intermedics'

[175] *Id.* at 1526.
[176] *Id.* at 1527.
[177] *Id.*
[178] 991 F.2d 808 (table, text in Westlaw), 1993 WL 87405 (Fed. Cir. 1993).
[179] 1993 WL 87405 at *1 (Fed. Cir. 1993).
[180] *Id.* at *4 (citation omitted).
[181] *Id.*

declaratory judgment claim would undermine the § 271(e)(1) safe harbor: "[t]o permit Ventritex to be protected from direct suit for infringement and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical."[182]

Since *Intermedics*,[183] many courts have been reluctant to let declaratory judgment suits go forward in the § 271(e) context. For example, in *NeoRx Corp. v. Immunomedics, Inc.*[184] the U.S. District Court for the District of New Jersey denied NeoRx's request for declaratory judgment that Immunomedics' infringed NeoRx's patent by developing its technology for using antibodies to deliver radioactive labels to infection and tumor sites. The court held that NeoRx had not made "sufficient allegation of immediacy and reality" to satisfy the test for an actual case or controversy, since it was unclear whether Immunomedics' technology would receive FDA approval and whether it would have to be altered to obtain approval.[185]

In *Abbott Laboratories v. Zenith Laboratories, Inc.*,[186] the U.S. District Court for the Northern District of Illinois similarly dismissed Abbott's suit for declaratory judgment of infringement of its terazosin hydrochloride patent for lack of justiciable controversy. Zenith's pursuit of FDA approval effective prior to the patent's expiration date and its refusal to deny an intent to enter the market before the patent expired were insufficient evidence of the required immediate ability and intent to infringe. Zenith's terazosin hydrochloride product had not yet received FDA approval and it was possible that Zenith would change its marketing plans. In addition, Zenith's continued defense of Abbott's lawsuits was not sufficient evidence of a definite intent to market a generic terazosin hydrochloride product to satisfy the actual controversy test.[187] Finally, the court explained that, even if there were a justiciable controversy, it would exercise

[182] *Id.*
[183] 1993 WL 87405 (Fed. Cir. 1993).
[184] 877 F. Supp. 202 (D.N.J. 1994).
[185] *Id.* at 214.
[186] 934 F. Supp. 925 (N.D. Ill. 1995).
[187] *Id.* at 938.

its discretion not to hear the case. The court cited *Intermedics*[188] in reasoning that allowing patentees to pursue this type of declaratory judgment suit against a generic manufacturer before that manufacturer has obtained FDA approval would undermine the safe harbor in § 271(e)(1).[189]

The U.S. District Court for the District of Massachusetts also dismissed a declaratory judgment request in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*[190] Amgen sought a declaration that Hoechst would infringe its recombinant erythropoietin patent through the marketing of its own erythropoietin product, which was still under development. The court found that there was sufficient case or controversy under the Federal Circuit's declaratory judgment test: Hoechst clearly intended to market its erythropoietin product as soon as possible, regardless of Amgen's patent claims, and Hoechst had the capacity to bring its product to market immediately upon FDA approval.[191] However, the court chose to exercise its discretion not to hear the case. The court reasoned that FDA approval was still uncertain and Hoechst's product might be altered during the approval process.[192] The court also reiterated the concerns of the *Abbott* and *Intermedics* courts that issuing a declaratory judgment in favor of the patentee before the generic manufacturer received FDA approval might derogate the congressional policy behind the § 271(e)(1) safe harbor, which was intended to foster expeditious marketing of generic drugs: "the declaratory action could easily become a tool of harassment and intimidation for use in discouraging early efforts at competition."[193] Thus, the court dismissed Amgen's declaratory judgment claims. However, the court held that it would reopen the claims for "good cause," including the issuance of an FDA product license for Hoechst's erythropoietin product.[194]

[188] 1993 WL 87405 (Fed. Cir. 1993).
[189] 934 F. Supp. 925, 938-39 (N.D. Ill. 1995).
[190] 3 F. Supp. 2d 104 (D. Mass. 1998).
[191] *Id.* at 112.
[192] *Id.*
[193] *Id.*
[194] *Id.* at 113.

Some courts have been more sympathetic to declaratory judgment suits in the § 271(e) context, especially when the judgment is sought by the generic manufacturer, the potential infringer, rather than the patentee. In these cases, like the earlier *Farmaceutisk*[195] case in which the Northern District of Georgia allowed the invalidity declaratory judgment claims to go forward, the target of the declaratory judgment is often a static patent, rather than a dynamic technology under development. Additionally, a declaratory judgment in these situations helps the generic manufacturer to assess the potential gains and risks of its investment, but does not allow the patentee to assert its rights during the developmental stage, which would seem to contradict the policy behind the § 271(e)(1) safe harbor.

In *Infinitech, Inc. v. Vitrophage, Inc.*,[196] the U.S. District Court for the Northern District of Illinois decided that it would hear Infinitech's claims for a declaratory judgment that it had intervening rights under Vitrophage's liquid perfluorocarbon patent and that the patent was unenforceable. The court applied the two-prong Federal Circuit test for sufficient case or controversy in a declaratory judgment suit, finding that Infinitech had reasonable apprehension of suit and had undertaken meaningful preparations to produce an infringing product.[197] Even though Infinitech had a good argument that all of its activities fell within the § 271(e)(1) safe harbor, accusations of infringement in letters from Vitrophage's counsel supported a reasonable apprehension of suit. Infinitech's huge investment in developing, testing, and seeking regulatory approval for its liquid perfluorocarbon product constituted meaningful preparation to produce an infringing product under a totality of the circumstances analysis.[198]

The fact that Infinitech's current activities were covered by the § 271(e)(1) safe harbor and that it had yet to obtain FDA approval did not preclude the existence of an actual case or controversy. The court refused to endorse a rule that "no actual controversy can exist if the declaratory plaintiff does not have the

[195] 25 U.S.P.Q.2d 1344 (N.D. Ga. 1992).
[196] 842 F. Supp. 332 (N.D. Ill. 1994).
[197] *Id.* at 336.
[198] *Id* at 336.

present ability to market a potentially infringing product.[199] The court distinguished *Intermedics*[200] and *Telectronics*,[201] cases in which the Federal Circuit dismissed declaratory judgment suits because the generic manufacturer's conduct was exempt under § 271(e)(1), because those suits were brought by patentees seeking declarations of infringement. In such cases, the goals of the Hatch-Waxman and Declaratory Judgment Acts are not harmed by forcing a patentee to wait to assert its rights until an infringer's activities actually fall outside the § 271(e)(1) safe harbor; the patentees interests cannot be harmed at least until the generic product receives FDA approval.[202] However, a generic manufacturer has an important interest in determining as early as possible whether a patent that could be asserted against it is valid and enforceable. Thus,

> [t]he court decline[d] to construe the Declaratory Judgment Act as placing all of the burden and risk on those who would seek to develop new medical and surgical products that require extensive development, investment, and clinical testing on the road to the government approval necessary for actual marketing and sale. Whether the declaratory plaintiff has 'a true interest to be protected'... should not depend on final government approval in these circumstances.[203]

Even if the product Infinitech eventually brought to market differed from the version it was currently testing, the unenforceability and intervening rights issues would remain the same. Thus, the court decided to hear Infinitech's declaratory judgment claims.[204]

In *Biogen, Inc. v. Schering AG*,[205] Biogen sought a declaration that its beta interferon multiple sclerosis drug did not infringe Schering's patent, and that the patent was invalid. The U.S. District Court for the District of Massachusetts found that a sufficient case or controversy existed to give it jurisdiction over the declaratory judgment suit. Schering's conduct, through its subsidiary Berlex Laboratories, was sufficient to invoke a reasonable apprehension of suit in Biogen under a totality of the circumstances analysis. Berlex had asserted the

[199] *Id.* at 337.
[200] 991 F.2d 808 (Fed. Cir. 1993).
[201] 982 F.2d 1520 (Fed.Cir.1992).
[202] 842 F. Supp. 332, 337 (N.D. Ill. 1994).
[203] *Id.* (citation omitted).
[204] *Id.* at 338.
[205] 954 F. Supp. 391 (D. Mass. 1996).

ability to use its patent to block Biogen's marketing of its beta interferon drug, had sought but failed to negotiate a license with Biogen, and had even filed suit to thwart FDA approval of Biogen's drug.[206] Biogen's submission of product for foreign regulatory approval as well as its stock-piling of product in anticipation of FDA approval took it outside the § 271(e)(1) safe harbor; thus, the court dismissed the defendant's argument that Biogen could not have a reasonable apprehension of suit because its activities before FDA were covered by the safe harbor.[207] Biogen's huge monetary investment in research and development of its drug, stock-piling of product for marketing immediately upon FDA approval, and other concrete and expensive steps in preparation for prompt marketing satisfied the "meaningful preparation" prong of the case or controversy test. The court cited *Infinitech*[208] in explaining that lack of final FDA approval does not preclude a finding that a sufficient case or controversy exists to allow a declaratory judgment suit to go forward.[209] Thus, because Biogen had a reasonable apprehension of suit and had made meaningful preparations toward producing an infringing product, the court declined to dismiss Biogen's declaratory judgment suit.[210]

In *Glaxo, Inc. v. Novopharm, Ltd.*[211] the Federal Circuit showed a willingness to hear a declaratory judgment suit by a patentee, even though it was based partly on a generic manufacturer's actions that were still covered by the § 271(e)(1) safe harbor. Glaxo sought a declaratory judgment that Novopharm would infringe its ranitidine hydrochloride patent if and when Novopharm received FDA approval for its generic ulcer treatment and began to import and market the drug.[212] The court found that a sufficient case or controversy existed to allow the district court to hear Glaxo's declaratory judgment claims. Although the § 271(e)(1) safe harbor currently protected some of Novopharm's

[206] *Id.* at 396.
[207] *Id.*
[208] 842 F. Supp. 332 (N.D. Ill. 1994).
[209] *Id.*
[210] *Id.* at 398.
[211] 110 F.3d 1562 (Fed. Cir. 1997).
[212] *Id.* at 1564.

activities, this "protected status... d[id] not by itself prevent the district court from considering Glaxo's request for declaratory relief because such relief is directed to the time after the ANDA is approved, when s 271(e)(1) no longer provides a shelter against infringement liability."[213]

Here, Glaxo's allegations that FDA approval of Novopharm's product was imminent and that Novopharm expressly intended to market its product before Glaxo's patent expired were sufficient to support a finding of an actual case or controversy.[214] The court distinguished *Telectronics*,[215] where it had dismissed a similar declaratory judgment suit by the patentee: in that case FDA approval was unlikely to occur for years and there was some doubt surrounding the generic manufacturer's intent to market its product before the patent expired.[216] However, the court found no clear error in the district court's conclusion that Glaxo had not proven that Novopharm's drug would contain the form of ranitidine hydrochloride covered by Glaxo's patent. Thus, the Federal Circuit upheld the district court's dismissal of Glaxo's declaratory judgment on the merits even though an actual case or controversy existed.[217]

Glaxo, along with the district court cases allowing declaratory judgment suits by generic manufacturers to proceed, suggests that the declaratory judgment suit will become an important tool for patentees and generic manufacturers to determine their respective rights during the regulatory approval process. Glaxo in particular suggests that the actual case or controversy hurdle may not provide a sufficient screen against suits inconsistent with the policy behind the § 271(e)(1) safe harbor. Thus, generic manufacturers will have to rely on the courts' discretion to allow early and meaningful determinations of generic and pioneer manufacturers' rights where possible, while preventing the declaratory suit from becoming "a tool of harassment and intimidation for use in discouraging early efforts at competition."[218]

[213] *Id.* at 1571.
[214] *Id.*
[215] 982 F.2d. 1520 (Fed. Cir. 1992).
[216] 110 F.3d 1562, 1571 (Fed. Cir. 1997).
[217] *Id.*
[218] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d. 104, 112 (D. Mass. 1998).

E.

Orange Book Listing and Certification Procedures

21 U.S.C. § 355(b)(1)(F) requires anyone submitting an NDA to include information about any patents that cover the new drug.[219] FDA publishes this patent information in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book." § 355(b)(2) and § 355(j)(2)(A)(vii) require anyone submitting an NDA that relies on data in another NDA or an ANDA, which necessarily relies on data from the pioneer NDA, to submit a "certification" with respect to each patent listed in the Orange Book for the original NDA. The certification must specify (I) that no patent information has been listed for the drug, (II) that the patent has expired, (III) the patent's expiration date, or (IV) that the patent is invalid or will not be infringed by the commercial manufacture and marketing of the ANDA applicant's drug.[220]

§ 355(j)(2)(B) requires any ANDA applicant who submits a certification of

[219] 21 U.S.C. § 355 (b)(1)(F) (1994) provides that an NDA applicant:

shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the receding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.

[220] 21 U.S.C. § 355(j)(2)(A) (1994) requires that every ANDA applicant submit the following:

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section -

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted....

21 U.S.C. § 355(b)(2) (1994) requires the same certification of an NDA applicant for any "drug for which the investigations... relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted...."

type IV, a "paragraph IV certification" to notify the patentee of the certified patent and the marketing entity for the corresponding pioneer drug that an ANDA has been submitted seeking approval for a generic drug before expiration of the pioneer patent and to specify why the ANDA applicant believes the certified patent is invalid or not infringed.[221] 35 U.S.C. § 271(e)(2) makes filing an NDA or ANDA seeking marketing approval before patent expiration into an act of patent infringement.[222] 21 U.S.C. § 355(j)(5)(B) completes the statutory framework by allowing FDA to make approval of an ANDA containing a paragraph IV effective immediately unless the patentee sues for infringement within forty-five days of receiving notice of the ANDA and its paragraph IV certification. If the patentee does sue, approval will be stayed for thirty months, or until a court declares the patent invalid or not infringed.[223]

[221]35 U.S.C. § 355(j)(2)(B) (1994) mandates that:

(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to -

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

[222]35 U.S.C. § 271(e)(2) (1994) provides that:

It shall be an act of infringement to submit... 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... 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... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

[223]21 U.S.C. § (j)(5)(B) (1994) provides that:

(iii) 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. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that -

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been

In *Marion Merrell Dow, Inc. v. Hoechst-Roussel Pharmaceuticals, Inc.*,[224] Marion Merrell Dow (MMD) accused Hoechst-Roussel (H-R) of infringing its patents by submitting an NDA for a sustained release form of diltiazem, a heart drug. H-R originally submitted a paragraph IV certification with respect to MMD's patents; however, it later amended its NDA application to remove the paragraph IV certification. H-R argued that the certification was not required because H-R's NDA relied on only one study submitted in a prior NDA; that study, involving "diltiazem itself," was included in the NDA for immediate release diltiazem, the patent on which had expired. Thus, H-R urged the court to dismiss MMD's complaint for lack of justiciable controversy.[225]

The court found that, under § 355(b)(2)[226] and § 271(e)(2)[227] H-R had laid itself open to an infringement suit by relying upon the study submitted for immediate release diltiazem.[228] H-R's removal of the paragraph IV certifications for MMD's patents from its NDA was not determinative.[229] In setting out an infringement cause of action, § 271(e)(2) does not require certification, it just requires that the pioneer patent claim the drug, or its use, described in the subsequent NDA or ANDA. Additionally, the pioneer patentee's rights under § 271(e)(2) would be meaningless if the patentee had to rely on subsequent NDA and ANDA applicants' candor in certification in order to assert them. Thus, the court concluded that the proper inquiry to determine whether the § 271(e)(2) suit could go forward was whether the patents should have been certified.[230]

In deciding whether H-R should have certified MMD's patent, the court noted

infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action....

[224] 1994 WL 424207 (D.N.J. 1994).

[225] *Id.* at *1.

[226] *See supra* note 220.

[227] *See supra* note 222.

[228] 1994 WL 424207 at *2 (D.N.J. 1994).

[229] *Id.*

[230] *Id.*

that § 355(b)(2)(A) requires certification for "each patent which claims the drug for which such investigations [those relied upon by the subsequent applicant] were conducted." In H-R's own words, it had relied on a study of "diltiazem itself"; thus, the "drug for which [the] investigations were conducted" was diltiazem, not just immediate release diltiazem. The plain meaning of the statute required H-R to certify any patent covering diltiazem, including MMD's patents on the sustained release form.[231] Thus, because H-R should have certified MMD's patents, the court refused to dismiss MMD's claims.[232]

In *Abbott Laboratories v. Zenith Laboratories, Inc.*,[233] Zenith argued that the court should dismiss Abbott's suit for infringement under § 271(e)(2) because Abbott had not listed its terazosin hydrochloride patent in the NDA for its drug Hytrin as required under § 355(b)(1). Thus, Zenith maintained that its ANDA for a generic version of Hytrin was not required to certify Abbott's patent and that Abbott should not be allowed to assert its patent against Zenith under § 271(e)(2).[234] The U.S. District Court for the Northern District of Illinois agreed with Zenith, rejecting Abbott's argument that the plain language of § 271(e)(2),[235] which does not expressly refer to patent listing or certification, allows an infringement suit against an ANDA applicant who had no notice of the patent that covers its drug because the pioneer NDA applicant failed to properly list the patent with FDA.[236] The court held that § 271(e)(2) expressly refers to applications under §§ 355(b) and (j), and thus must be read in conjunction with those provisions as a whole to require that a patent be listed for an NDA before the pioneer patentee may assert it against a subsequent applicant for FDA approval. The court also reasoned that requiring ANDA applicants to address patents not listed by the pioneer drug manufacturer would undermine the Hatch-Waxman Act's purpose of promoting expeditious marketing of

[231] *Id.* at *3.
[232] *Id.* at *4.
[233] 1995 WL 117984 (N.D. Ill. 1995).
[234] *Id.* at *6.
[235] *See supra* note 222.
[236] 1995 WL 117984 at *9-10 (N.D. Ill. 1995).

generic drugs. Thus, the court dismissed Abbott's claims.[237]

Abbott later amended its NDA application to list its patent and the patent was published in the Orange Book. However, in a subsequent opinion,[238] the court held that Abbott still could not assert its patent against Zenith's ANDA because Abbott's amendment was not timely and Zenith's ANDA was filed before the amendment was made. 21 U.S.C. § 355(c)(2) requires that an NDA holder who, like Abbott, did not list a patent in its NDA because the patent had not yet issued, must file the patent information with FDA within thirty days after the patent issues. Abbott did not report its patent to FDA within the required thirty-day period.[239]

The statute provides no explicit guidance about what is required of ANDA applicants when the NDA holder is delinquent in listing its newly-issued patent. However, FDA's regulation at 21 C.F.R. § 314.94(a)(12)(vi) (1995) specifies that if a newly-issued patent is not listed within the required thirty-day period, ANDA applicants need not amend previously-submitted ANDA applications to certify the patent; only applicants submitting future ANDAs for the drug must certify the untimely-listed patent.[240] This regulation prevents the disruption of the ANDA process that would occur if ANDA applicants were required to amend pending applications to address untimely-filed patents. Thus, the court felt that the regulation furthered the statutory concerns, first, that the Orange Book give notice to ANDA applicants of any patents covering their generic drugs and, second, that generic drugs quickly be made widely available at low prices.[241] Since Zenith's ANDA was filed before Abbott's untimely patent listing, the regulation did not require Zenith to amend its ANDA application to certify Abbott's patent. As in its earlier opinion, the court reasoned that § 271(e)(2) only allows infringement suits against patents that are properly listed and therefore must be certified under § 355 (b) or (j). Zenith was not required to certify Abbott's

[237] *Id.* at *10-11.
[238] *Abbott Laboratories v. Zenith Laboratories, Inc.*, 934 F. Supp. 925 (N.D. Ill. 1995).
[239] *Id.* at 932.
[240] *Id.* at 935.
[241] *Id.*

patent, so Abbott could not maintain its infringement suit under § 271(e)(2).[242] Thus, Abbott could not assert its patent rights until Zenith began commercially marketing its drugs and lost the benefit of the safe harbor under § 271(e)(1).[243] In *Pfizer, Inc. v. FDA*,[244] the U.S. District Court for the District of Maryland addressed the provisions in 21 U.S.C. §§ 355(b)(1)(F) and (c)(2) requiring NDA applicants to file patent information for any patent that "claims the drug for which the applicant submitted the application." Each of these patents "claims the listed drug" in the NDA and must therefore be certified by ANDA applicants under 21 U.S.C. § 355(j)(2)(A)(vii). Pfizer sought an order compelling FDA to list patents on an unapproved tablet form of its approved drug nifedipine, such that ANDA applicants would be required to certify the patents, allowing Pfizer to sue them under 35 U.S.C. § 271(e)(2).[245] In support of its position, Pfizer argued that "drug" in §§ 355(b)(1)(F) and (c)(2) is broad enough to cover the drug substance or active ingredient, and not just the drug product approved under the NDA. FDA refused to publish Pfizer's patent, arguing that "drug" in these provisions is limited to the "drug product" for which the NDA was filed.[246] Because Pfizer had never filed or received approval for an NDA for the tablet form of nifedipine, FDA could not list patents covering this form of the drug. Even if FDA did publish the patents on the tablet form of nifedipine, ANDA applicants would not be required to certify those patents because they do not pertain to the "listed" drug, which was the approved capsule form of nifedipine.[247]

The court found FDA's interpretation reasonable and consistent with the statutory language, congressional intent, previous court opinions addressing § 355, and FDA's own regulations.[248] The court explained that the definition of "drug" in 21 U.S.C. § 321(g)(1) is broad enough to cover a final drug product as well

[242] *Id.* at 936.
[243] *Id.* at 939.
[244] 753 F. Supp. 171 (D. Md. 1990).
[245] *Id.*
[246] *Id.*
[247] *Id.* at 174-75.
[248] *Id.* at 175.

as its active ingredients. However, "drug" in §§ 355(b)(1) and (c)(2) is modified by the phrase "for which the applicant submitted the application." FDA's interpretation comports with this qualifying phrase: Pfizer had submitted an NDA for nifedipine capsules, not nifedipine in general or the tablet formulation covered by the patents at issue.[249]

The court also noted that FDA's interpretation of "drug" fostered internal consistency within the Hatch-Waxman Act. Other provisions in § 355(b) using the word "drug" made sense if "drug" meant "drug product," but not if it meant "active ingredient." Further, FDA was correct that ANDA applicants need only certify patents for "listed drugs," drugs on FDA's list of approved products; while nifedipine capsules were a "listed drug," nifedipine tablets were not.[250] FDA's interpretation of "drug" was also consistent with the dual congressional intent of expediting the generic drug approval process, yet still providing sufficient incentives for investment in pioneer drugs. Since Pfizer had not benefited ANDA applicants or consumers by obtaining approval for nifedipine tablets, the patents covering these tablets deserved no special protection.[251] The court also noted that Congress enacted the Hatch-Waxman provisions with full knowledge of FDA's interpretation of "drug" under § 355 as the product for which approval is sought; this suggested Congress' acquiescence in the interpretation. Thus, the court granted summary judgment in favor of FDA.[252]

In *Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp.*,[253] the U.S. District Court for the District of New Jersey denied Ben Venue's request for a preliminary injunction compelling Novartis to remove a patent from FDA's Orange Book. Novartis' approved bone loss drug Aredia contained the active ingredient pamidronate disodium, while the patent covered only the pentahydrate form of pamidronate. Thus, Ben Venue argued that the patent did not "claim" Aredia and was improperly listed under § 355(b); further, the incor-

[249] *Id.* at 176.
[250] *Id.* at 176-77.
[251] *Id.* at 177.
[252] *Id.* at 178.
[253] 10 F. Supp. 2d 446 (D.N.J. 1998).

rect listing had wrongly forced Ben Venue to certify the patent and suffer the resulting thirty-month stay of ANDA approval when Novartis sued for infringement.[254] The court began by holding that Ben Venue's suit was not barred by the provision in 35 U.S.C. § 355 (j)(5)(B)(iii) prohibiting suits under the Declaratory Judgment Act "with respect to the patent" in the first forty-five days after the patentee receives notice of a paragraph IV certification. Reading the statute in light of its statutory context and legislative purpose, the court decided that suits "with respect to the patent" under § 355(j)(5)(B)(iii) referred only to suits regarding patent validity and infringement. Thus, although Ben Venue's suit was filed less than forty-five days after it gave Novartis notice of its paragraph IV certification, the suit was not barred because it raised only the issue of proper Orange Book listing.[255]

The court then turned to the factors that must weigh in favor of relief for a court to grant a declaratory judgment, beginning with likelihood of success on the merits. Ben Venue's success on the merits depended on the interpretation of the provision in 21 U.S.C. § 355(b)(1) requiring NDA applicants to file patent information for "any patent which claims the drug for which the applicant submitted the application."[256] Ben Venue relied on *Pfizer*[257] for the proposition that "drug" in § 355(b)(1) means only "approved drug product," and thus Novartis' patent on a related active ingredient that was absent from the final drug product was improperly listed.[258] The court rejected BenVenue's argument. *Pfizer* was distinguished, first, as involving an attempt to list a patent for a new, unapproved product merely because it contained the same active ingredient as an approved product and, second, as occurring before FDA promulgated its full formal regulations on patent listing under § 355(b)(1).[259]

FDA's 1994 regulations at 21 C.F.R. § 314.53(b) address the types of patents that should be listed under § 355(b)(1):

[254] *Id.* at 450.
[255] *Id.* at 451.
[256] *Id.* at 453-54.
[257] 753 F. Supp. 171 (D. Md. 1990).
[258] 10 F. Supp. 2d 446, 454-55 (D.N.J. 1998).
[259] *Id.* at 455.

> For purposes of this part, such patents consist of drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents.... For patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product.

The regulations make clear that certain drug substance (active ingredient) patents may be listed. The court upheld FDA's regulation as a permissible interpretation of the statute, thus ruling against Ben Venue's argument that only patents on the specific approved drug product can be listed.[260] The court then undertook to determine whether Novartis' patent was properly listed because the patented drug substance was a "component" of Aredia even though it was not present in the final approved drug product.[261]

The court held that FDA's interpretation of "component" and common understandings of the term do not require that a "component" be present unaltered in the final product.[262] FDA's good manufacturing regulations at 21 C.F.R. § 210.3(b) specifically define "component" to include any manufacturing ingredient, even if it is not present in the final product. That section further defines "active ingredient" to include components present only in modified form in the final drug product. At 21 C.F.R. § 60.3(b)(2), FDA defines "active ingredient" identically for the patent restoration provisions of the Hatch-Waxman Act. FDA's NDA regulations at 21 C.F.R. § 314.50(d)(1)(ii) also refer to "components used in the manufacture of the drug product (regardless of whether they appear in the drug product)." Clearly, the need for a consistent regulatory scheme supported FDA's interpretation of "drug" in the § 355(b)(1) context.[263] Thus, the court held that under 21 C.F.R. § 314.53(b), a "drug substance" or "active ingredient" can be a "component" of a drug product even if it does not appear unaltered in the final product. In this case, the pentahydrate form of pamidronate was an ingredient in the manufacture of the approved drug Aredia.

[260] *Id.*
[261] *Id.*
[262] *Id.* at 456.
[263] *Id.* at 457.

Thus, the patented drug substance was a "component" of the approved drug product and Novartis had properly listed the patent. Ben Venue's motion for a preliminary injunction would be denied because it had little likelihood of success on the merits.[264]

Despite a finding of little likelihood of success on the merits, the court went on to address the other relevant factors for preliminary injunctive relief. The economic harm from the thirty-month stay in FDA approval asserted by Ben Venue was insufficient to warrant injunctive relief.[265] However, Novartis' ability to assert its patent rights would be harmed and the statutory protection for pioneer drug patentees would be undermined if the court ruled in favor of Ben Venue; thus the balance of hardships weighed against a preliminary injunction. In addition, the public interest in enforcing the statutory and regulatory scheme of the Hatch-Waxman weighed against relief. Thus, the court denied Ben Venue's motion for a preliminary injunction.[266]

IV. Litigation of the Generic Exclusivity Period in 21 U.S.C. § 355

A.

The Successful Defense Requirement

21 U.S.C. § 355(j)(5)(B)(iv) creates a 180-day market exclusivity period for the first generic manufacturer to file a paragraph IV certification for a given drug.[267] Under this provision, subsequent ANDAs containing paragraph IV certifications cannot be approved until 180 days after either the first commercial marketing of the drug (the "commercial marketing trigger"), or a court decision

[264] *Id.* at 458.
[265] *Id.*
[266] *Id.* at 459.
[267] 21 U.S.C. § 355(j)(5)(B) (1994) provides that:
(iv) 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 -
(I) 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 (II) 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.

holding the patent invalid or not infringed (the "court decision trigger"). The FDA regulations under this provision also required that the first applicant successfully defend a patent infringement suit before the market exclusivity period can begin (the "successful defense" requirement).[268]

In *Mova Pharmaceutical Corp. v. Shalala*,[269] Mova challenged the validity of the successful defense requirement. Mova filed the first ANDA with a paragraph IV certification for generic micronized glyburide and was sued by Upjohn, the pioneer patentee. While this litigation was pending, Mylan submitted an ANDA for micronized glyburide and amended it to include a paragraph IV certification. However, Upjohn did not sue Mylan within forty-five days of receiving notice of the paragraph IV certification as required under 21 U.S.C. § 355(j)(5)(B)(iii) in order to stay approval for thirty months, so FDA approved Mylan's application.[270] Mova successfully sought a preliminary injunction ordering FDA to render approval of Mylan's ANDA effective no earlier than 180 days after Mova began commercial marketing of its micronized glyburide or won the infringement suit brought against it by Upjohn.[271]

The U.S. Court of Appeals for the District of Columbia Circuit began by explaining FDA's rationale for the successful defense requirement: a literal interpretation of the § 355(j)(5)(B)(iv) produces unreasonable results contrary to congressional intent if the first applicant either is never sued or loses its suit. If the first applicant is not sued, the court decision trigger cannot be satisfied

[268] 21 C.F.R. § 314.107(c)(1) (1997) stated:

If an abbreviated new drug application contains a certification that a relevant patent is invalid, unenforceable, or will not be infringed and the application is for a generic copy of the same listed drug for which one or more substantially complete abbreviated new drug applications were previously submitted containing a certification that the same patent was invalid, unenforceable, or would not be infringed and *the applicant submitting the first application has successfully defended against a suit for patent infringement* brought within 45 days of the patent owner's receipt of notice submitted under s 314.95, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:

(i) The date the applicant submitting the first application first commences commercial marketing of its drug product; or

(ii) The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.

(emphasis added).

[269] 140 F.3d 1060 (D.C. Cir. 1998).

[270] *Id.* at 1065.

[271] *Id.* at 1065-66.

and later ANDA applicants will be forced to wait for the first applicant to begin marketing its product to trigger the exclusivity period.[272] However, failure to obtain FDA approval of production facilities or a collusive agreement with the pioneer manufacturer might cause the first applicant to wait indefinitely to market its product. If the first applicant loses its suit, it obviously cannot satisfy the court decision trigger; in addition, it will never satisfy the commercial marketing trigger because a court has held that such marketing would constitute patent infringement. Thus, the successful defense requirement was designed to prevent these scenarios, which would preclude marketing of any generic product until after the pioneer patent expired. Because a first applicant who is not sued or loses its suit has not "successfully defended against a suit for patent infringement,"[273] it would not be eligible for the 180-day exclusivity period; thus, other generic manufacturers would be free to seek FDA approval and enter the market as early as possible, just as Congress intended.[274]

The D.C. Circuit cited *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*[275] for the proposition that an agency attempting to interpret a statute to avoid absurd results produced by a literal reading may deviate only as far from the statutory language as is required to honor congressional intent.[276] In this situation, the court believed that the successful defense requirement deviated further than necessary from the statute: "FDA has embarked upon an adventurous transplant operation in response to blemishes in the statute that could have been alleviated with more modest corrective surgery."[277] The court noted that one less-restrictive option would be to require subsequent applicants to "wait and see" whether the first applicant was sued and won its suit. Another possibility would be to allow any court decision holding the pioneer patent invalid or not infringed, not just a court decision in the suit against the first

[272] *Id.* at 1067.
[273] 21 C.F.R. § 314.107(c)(1) (1997).
[274] 140 F.3d 1060, 1067 (D.C. Cir. 1998).
[275] 467 U.S. 837 (1984).
[276] 140 F.3d 1060, 1068 (D.C. Cir. 1998).
[277] *Id.* at 1069.

ANDA applicant, to satisfy the court decision trigger.[278] A third alternative would be to require a first applicant who is not sued to begin commercial marketing within a set period of time in order to obtain the market exclusivity period.[279] To solve the problem of first applicants who lose their suits, FDA could require such applicants to amend their ANDAs to replace the paragraph IV certification with a paragraph III certification, which does not seek approval until after the pioneer patent expires. Since only applicants whose ANDAs contain paragraph IV certifications are entitled to an exclusivity period, the first applicant would no longer pose a barrier to FDA approval of other ANDAs containing paragraph IV certifications.[280]

The court went on to explain that the successful defense requirement did more that just contradict the plain meaning of the statute by creating an additional obstacle to obtaining market exclusivity beyond those explicitly required; the successful defense requirement also essentially eviscerated the commercial marketing trigger to the detriment of the first ANDA applicant. Until a first applicant won its infringement suit, commencement of commercial marketing would not allow its exclusivity period to begin and other generic manufacturers could seek FDA approval and enter the market. However, once the first applicant won its suit, its 180 days of exclusivity would be counted from the date it began commercial marketing, if that occurred before the suit was concluded. The court found this one-sided reading of the commercial marketing trigger against the first ANDA applicant contrary to congressional intent.[281] Because the successful defense requirement contradicted the plain statutory language, created problems in the functioning of the statutory scheme, and went further than necessary to implement congressional intent, the D.C. Circuit affirmed the district court's invalidation of the requirement.[282]

In compliance with the district court injunction in *Mova*,[283] FDA awarded

[278] *Id* at 1072-73.
[279] *Id.* at 1071.
[280] *Id.*
[281] *Id.* at 1070.
[282] *Id.* at 1076.
[283] 955 F. Supp. 128 (D.D.C.1997).

market exclusivity to Genpharm, the first applicant whose ANDA contained a paragraph IV certification seeking to market a generic ulcer drug. Granutec, Genpharm's competitor who had filed a subsequent ANDA for the same drug, brought suit seeking an injunction compelling FDA to follow the successful defense requirement and deny Genpharm the exclusivity period. Although the district court ruled in Granutec's favor, the U.S. Court of Appeals for the Fourth Circuit reversed the district court's injunction against FDA and invalidated the successful defense requirement in an unpublished opinion in *Granutec, Inc. v. Shalala*.[284] The court's reasoning was similar to that of the D.C. Circuit in *Mova*[285]: the successful defense requirement undesirably rendered the commercial marketing trigger superfluous and constituted an impermissible extra requirement for exclusivity beyond those explicitly provided for by Congress.[286] In response to *Mova*[287] and *Granutec*[288] FDA revised its position, informing the industry that, at least until the completion of new rulemaking proceedings on the subject, it would award a 180-day market exclusivity period to the first applicant to submit a substantially complete ANDA containing a paragraph IV certification, regardless of whether that applicant had been sued for patent infringement. However, FDA urged that first applicants market their products promptly once approved.[289] In November, 1998, FDA issued an interim rule amending its regulations to remove the successful defense requirement.[290] In *Purepac Pharmaceutical Co. v. Friedman*,[291] Purepac argued that FDA's amendments were impermissibly broad: although FDA was required to remove the successful defense requirement, it should have retained a requirement that a first applicant be sued in order to obtain a market exclusivity period. Thus, Purepac alleged that its competitor Torpharm, who had not been sued, should

[284] 139 F.3d 889 (table, text in Westlaw), 1998 WL 153410 (4th Cir. 1998).
[285] 140 F.3d 1060 (D.C. Cir. 1998).
[286] 1998 WL 153410 at *6-7 (4th Cir. 1998).
[287] 140 F.3d 1060 (D.C. Cir. 1998).
[288] 139 F.3d 889 (table, text in Westlaw), 1998 WL 153410 (4th Cir. 1998).
[289] *See* Purepac Pharmaceutical Co. v. Friedman, 162 F.3d 1201, 1203 (D.C. Cir. 1998).
[290] 63 Fed. Reg. 59,710 (1998).
[291] 162 F.3d 1201, 1204 (D.C. Cir. 1998).

not be entitled to market exclusivity.[292] The D.C. Circuit rejected Purepac's arguments, holding that FDA's current position was a rational response to the *Mova* decision and was completely consistent with the statutory provisions of the Hatch-Waxman Act, which makes no reference to the type of "lawsuit requirement" favored by Purepac.[293]

B.

The Court Decision Trigger

After invalidating the successful defense requirement, the Fourth Circuit in *Granutec*[294] was required to determine the starting date for Genpharm's 180 days of market exclusivity. Because Genpharm had not commenced commercial marketing, the exclusivity period began on the date that the court decision trigger was satisfied, "the date of a decision of a court... holding the patent... invalid or not infringed."[295] FDA's regulations defined "a decision of a court" as a "final judgment from which no appeal can be or has been taken"; the "date" of such final decision was "the date of the first decision or order by a higher court" affirming a district court holding of invalidity or non-infringement or, if no appeal was taken, "the date on which the right to appeal lapse[d]."[296] Further, FDA interpreted "a decision of a court" to mean a ruling by any court on the disputed patent, not just a decision by the court in the infringement suit against the ANDA applicant whose exclusivity period would be triggered.[297] The Fourth Circuit held that FDA's interpretations of the court decision trigger were permissible readings of an ambiguous statutory provision.[298]

The court explained that "a decision" could mean either a district court judgment or an appellate ruling, and "a court" could mean "the court" or "any

[292] *Id.*
[293] *Id.* at 1204-1205.
[294] 139 F.3d 889 (table, text in Westlaw), 1998 WL 153410 (4th Cir. 1998).
[295] 21 U.S.C. § 355(j)(5)(B)(iv)(II) (1994).
[296] 21 C.F.R. § 314.107(e) (1997).
[297] 1998 WL 153410 at *8 (4th Cir. 1998).
[298] *Id.* at *8-9.

court"; each interpretation would create problems in applying the statutory scheme.[299] FDA's interpretation would seemingly deny a first applicant the benefit of part of its exclusivity period by allowing the period to begin while the applicant was still waiting for the infringement suit against it to be resolved; however, the first applicant could still profit by waiving its exclusivity in favor of another generic manufacturer in exchange for payment by that manufacturer. The interpretation urged by Genpharm, that "a court" means "the court" involved in the infringement suit against the generic manufacturer entitled to exclusivity assures that manufacturer the full benefit of its exclusivity period. Unfortunately, this interpretation would allow pioneer drug manufacturers to capture the generic market: for example, the pioneer manufacturer could settle its case with the first ANDA applicant, such that the court decision trigger could never be satisfied, and then pay that applicant to refrain from marketing its generic product, such that the commercial marketing trigger could also never be met.[300] The court found this possibility "antithetical to the very purpose of the exclusivity incentive and the entire ANDA regime," which was designed to make low cost generic drugs more widely available.[301] "A situation where no generic can come to market because the pioneer has imposed a stranglehold by gaining entitlement to an exclusive marketing period for its captured generic, yet never exercises that right, could not have been contemplated by Congress."[302] Recognizing the careful balance and intricate framework involved in the statutory drug approval scheme, the court decided to defer to FDA's reasonable interpretation of the ambiguous statutory provision setting out the court decision trigger.[303]

Teva Pharmaceuticals, wishing to market its generic version of a treatment for stroke victims, decided to test FDA's interpretation of the court decision trigger.[304] One of Teva's competitors was entitled to 180 days of market exclusivity;

[299] *Id.*
[300] *Id.* at *9.
[301] *Id.*
[302] *Id.*
[303] *Id.*
[304] *See Teva Pharmaceuticals, USA, Inc. v. FDA*, 182 F.3d 1003, 1004 (D.C. Cir. 1999).

Teva hoped to trigger the start of the exclusivity period so that it would pass and the market would be open for other generic products as soon as possible. Rather than wait for a suit between the patentee and the generic manufacturer entitled to exclusivity, Teva decided to bring its own declaratory judgment suit for non-infringement against the patentee. This suit was dismissed for lack of subject matter jurisdiction after the patentee admitted non-infringement; however, FDA refused to recognize the dismissal as a court decision sufficient to trigger the market exclusivity period for the stroke drug.[305] In *Teva Pharmaceuticals, USA, Inc. v. FDA*,[306] the D.C. Circuit found FDA's refusal arbitrary and capricious, since FDA had taken an inconsistent position in a previous case and had failed to explain the inconsistency; thus, the court remanded for a determination of whether injunctive relief was appropriate.

Teva argued that the dismissal of the declaratory judgment suit was equivalent to a final court decision of noninfringement: the suit was dismissed because the court found that Teva had no reasonable apprehension of being sued for patent infringement, and thus there was no justiciable case or controversy, in light of an express written promise by the patentee that it would not sue.[307] FDA conceded that the statute, which requires a "decision of a court holding the patent... invalid or not infringed,"[308] did not mandate its position. A "decision" can include a dismissal for lack of subject matter jurisdiction and "holding" is an ambiguous term. The court reasoned that, often, the key to a "decision" or "holding" is its preclusive effect. While most dismissals for lack of subject matter jurisdiction have no preclusive effect, the dismissal here rested "exclusively and necessarily" on the patentee's express admission of non-infringement and promise not to sue."[309] Thus, from the dismissing court's point of view, no declaratory judgment was required, because the patentee was estopped from asserting that Teva's marketing of its generic product constituted patent in-

[305] *Id.*
[306] 182 F.3d 1003 (D.C. Cir. 1999).
[307] *Id.* at 1006.
[308] 21 U.S.C. § 355(j)(5)(B)(iv)(II) (1994).
[309] 182 F.3d 1003, 1008 (D.C. Cir. 1999).

fringement.[310] The court concluded that:

> Although the dismissal was not a judgment on the merits after consideration of evidence presented by the parties, there was no need for such a procedure here because the dismissal sufficed to estop [the patentee] from suing Teva for patent infringement.... This is the result that appears to be the purpose of the triggering "court decision" provision.[311]

The court analyzed FDA's position in light of its June, 1998 *Guidance for Industry*,[312] which announced that the agency would "regulate directly from the statute" on a "case-by-case basis" until it could comprehensively address the triggering of the generic market exclusivity period in a new rulemaking. Based on this guidance pronouncement, the court found FDA's position regarding Teva arbitrary and capricious.[313] Since the dismissal could qualify as a triggering "court decision" under the statutory language and FDA had announced its intent to regulate on a "case-by-case basis," the court found FDA's refusal to even consider Teva's position unjustifiable. The court specifically criticized FDA's unexplained refusal of Teva's position as inconsistent with its recognition of a partial grant of summary judgment based on the patentee's admission of non-infringement as a "court decision" in *Granutec*.[314] The court was also unable to reconcile FDA's position regarding Teva with its promise to "regulate directly from the statute": Teva's position was consistent with the statute's language as well as its goal of making generic drugs widely available as early as possible, yet FDA had provided no rationale for its rejection of Teva's arguments. Thus, the court remanded for a determination of whether injunctive relief against FDA was in order.[315]

On remand, the D.C. District Court reviewed the entire record, including the appellate court's decision, and decided that FDA's refusal of Teva's position was arbitrary and capricious.[316] FDA argued that it refused to recognize the

[310] *Id.*
[311] *Id.* at 1009 (citation omitted).
[312] U.S. Food and Drug Administration, Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act 4 (1998).
[313] 182 F.3d 1003, 1007 (D.C. Cir. 1999).
[314] 1998 WL 153410, at *5 (4th Cir. 1998).
[315] 182 F.3d 1003, 1011 (D.C. Cir. 1999).
[316] *Teva Pharmaceuticals, USA, Inc. v. FDA*, 1999 Westlaw 1042743 (D.D.C. 1999).

dismissal of Teva's declaratory judgment suit as satisfying the court decision trigger because it was not obvious from the face of the court order that the patent had been held invalid or not infringed. It would be too burdensome to require FDA personnel to make a thorough substantive review of every court order submitted to the agency in order to determine whether the order satisfied the court decision trigger.[317] The court rejected this argument, finding that the administrative burden required to determine the estoppel effect of the order in Teva's case would be minimal.[318] The court also noted that FDA had failed to adequately explain the discrepancy between its treatment of Teva and its treatment of the partial dismissal of summary judgment at issue in *Granutec*; since both court orders estopped the patentee from suing for infringement, they should be treated equally for purposes of the court decision trigger provision.[319] Thus, the court held that Teva's drug was entitled to "immediate final effective approval" by FDA.[320]

In *Mylan Pharmaceuticals, Inc. v. Shalala*,[321] the D.C. District Court again addressed FDA's interpretation of the date of the court decision trigger as the date of an appellate court decision affirming a district court holding of invalidity or non-infringement or, if no appeal is taken, the date that the right to appeal lapses.[322] Mylan could not market its generic hypertension and prostate drug until its competitor Geneva had enjoyed 180 days of market exclusivity; thus, Mylan supported the earliest possible start date for Geneva's market exclusivity period. Mylan argued that the statute mandated that the exclusivity period begin on the date of the first district court decision holding the patent invalid or not infringed.[323] The court agreed with Mylan: the plain, unambiguous meaning of the phrase "decision of a court" in § 355(j)(B)(iv)(II) included a decision by a district court, whether appealed or not.[324] The court specifically rejected

[317] *Id.* at *5.
[318] *Id.*
[319] *Id.* at *6.
[320] *Id.* at *7.
[321] 2000 WL 19250 (D.D.C. 2000).
[322] *See* 21 C.F.R. § 314.107(e) (1999).
[323] 2000 WL 19250 at *5 (D.D.C. 2000).
[324] *Id.* at *6-7.

the Fourth Circuit's conclusion in *Granutec*[325] that the statutory language was ambiguous and thus the court should defer to the agency's reasonable interpretation of the law.[326]

The court explained that FDA's interpretation was grounded in its belief that prudent generic manufacturers would be unwilling to market their products until the patent infringement issue was fully resolved on appeal. These manufacturers would be denied the full benefit of their exclusivity period if it began on the date of the district court decision.[327] The court was not convinced that allowing a district court decision to act as the court decision trigger would diminish the exclusivity period incentive enough to harm the Hatch-Waxman Act's goal of making generic drugs available quickly and at reasonable prices. The court also noted that, while the exclusivity period provided an incentive for the first generic manufacturer, delaying the period's onset prevented other generic products from entering the market as early as possible. Thus, because a literal interpretation of the statute would not clearly conflict with Congressional intent or create an unworkable regulatory framework, the court issued a declaratory judgment rejecting FDA's interpretation in favor of the reading supported by Mylan.[328]

In *TorPharm, Inc. v. Shalala*,[329] the D.C. District Court had made a similar finding regarding the type of court decision that can terminate the thirty-month stay of FDA approval for an ANDA applicant who is sued by the pioneer manufacturer. TorPharm filed a paragraph IV certification for Glaxo's patent in its ANDA for ranitidine hydrochloride. Torpharm notified Glaxo as required and Glaxo sued TorPharm for infringement within forty-five days. Thus, 21 U.S.C. § 355(4)(B)(iii) required that the ANDA's "approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice [of the paragraph IV certification]... except that... if before the

[325] 139 F.3d 889 (table, text in Westlaw), 1998 WL 153410 at *8-9 (4th Cir. 1998).
[326] 2000 WL 19250 at *7 (D.D.C. 2000).
[327] *Id.* at *9.
[328] *Id.* at *11.
[329] 1997 U.S. Dist. LEXIS 21983 (D.D.C. 1997), appeal withdrawn and remanded, 1998 U.S. App. LEXIS 4681 (D.C. Cir. 1998), vacated No. 97-1925 (D.D.C. 1998).

expiration of such period the court decides that such patent is invalid or not infringed, the approval may be effective on the date of the court decision."

The Illinois district court granted summary judgment for TorPharm in Glaxo's infringement suit. TorPharm then sued for a preliminary injunction compelling FDA to make approval of its ANDA effective on the date of the district court's decision.[330] FDA would have delayed approval under its regulations at 21 C.F.R. § 314.107(e), which defined "the court decision" under § 344(4)(B)(iii) as "a final judgment from which no appeal can be or has been taken." As in *Mylan*, FDA justified its regulations as protecting the prudent ANDA applicant who would wait for an appellate court decision to begin marketing its generic product.[331] However, the court rejected FDA's interpretation and held that a district court decision qualified as a court decision that could end the thirty-month stay of approval under § 355(4)(B)(iii): "[t]he natural meaning of the statute's reference to 'the court' is 'the court that decides that the patent is invalid or not infringed.' That court in this case was the [district court]. The district court's decision has a binding effect on the parties unless stayed or overturned on appeal."[332] The court also noted that its interpretation was consistent with the legislative policy of getting generic drugs to market quickly.[333] Although this case was later vacated on other grounds, it gives added force to the court's holding in Mylan.[334]

C.

Dosage Level

The issue of whether multiple market exclusivity periods could be granted for different dosage levels of the same drug arose in *Apotex, Inc. v. Shalala*.[335] Apotex sued to enjoin FDA from granting an exclusivity period to its competitor Novopharm for generic over-the-counter (OTC) strength ranitidine

[330] 1997 U.S. Dist. LEXIS 21983 at *4 (D.D.C. 1997).
[331] *Id.* at *11.
[332] *Id.* at *8.
[333] *Id.* at *12.
[334] 2000 WL 19250 (D.D.C. 2000).
[335] 53 F. Supp. 2d 454 (D.D.C. 1999).

hydrochloride, because an exclusivity period had already been awarded for the prescription strength of the drug.[336] 21 U.S.C. § 355(j)(2) requires an ANDA applicant to reference the approved pioneer drug product or "listed drug" that it will duplicate and submit data demonstrating that the "route of administration, the dosage form, and *the strength* of the new drug are the same as those of the listed drug" (emphasis added). Thus, FDA asserts that different strengths of the same drug product constitute different listed drugs which are in turn eligible for separate generic market exclusivity periods.[337]

Apotex argued that only one exclusivity period should be granted for each patent challenged. Novopharm took on no additional risk by filing its ANDA for OTC ranitidine hydrochloride since it had already litigated the relevant patent in connection with its prescription strength ANDA; thus, Novopharm deserved no additional reward for filing the OTC ANDA.[338] In response, FDA reasoned that different strengths of the same drug could represent different formulations, and thus present different issues in a patent infringement analysis. The court agreed with FDA, noting also that the statute clearly does not mandate that only one exclusivity period be granted per challenged patent.[339] Even if the statute were ambiguous, the court found that FDA's interpretation was reasonable and therefore required deference by the court. FDA's interpretation furthered the statutory goal by creating incentives for market entry by a large variety of generic drug products; in contrast, Apotex's interpretation would impose an unduly strict limit of one exclusivity period per patent, regardless of how different various drug products covered by the same patent were in strength, dosage, formulation, or indication. Thus, the court denied Apotex's requested relief and upheld FDA's position.[340]

D.

[336] *Id.* at 459.
[337] *Id.* at 456.
[338] *Id.* at 461.
[339] *Id.*
[340] *Id.* at 462-63.

Recent FDA Interpretations

In response to the onslaught of recent court decisions, in August, 1999 FDA issued a proposed rule redefining the eligibility requirements for the 180-day generic market exclusivity period under the Hatch-Waxman Act.[341] FDA accepted comments on the proposed rule but has yet to issue a final regulation. FDA asserted that, "[c]onsistent with the legislative purpose of section 505(j)(5)(B)(iv) of the act, the proposed regulations continue to provide an incentive for challenging a listed patent, while at the same time preventing prolonged or indefinite delays in the availability of generic drug products."[342] FDA noted that one important purpose of its proposed regulations was to prevent first ANDA applicants from placing a stranglehold on generic drug markets through strategic behavior, including collusive agreements with pioneer manufacturers.[343]

First, FDA decided to maintain its current position that only the first applicant to submit a "substantially complete" ANDA containing a paragraph IV certification for a listed patent is eligible for the market exclusivity period. If the first applicant withdraws its ANDA or amends it to delete the paragraph IV certification, no applicant is entitled to exclusivity.[344] Second, FDA would amend its current regulations to provide that the first applicant is eligible for exclusivity even if it is not sued for patent infringement. If the applicant is sued and loses, it must withdraw its paragraph IV certification, such that no applicant is eligible for exclusivity. [345] Next, FDA addressed the situation where multiple ANDA applications are filed on the same day when no ANDA application for that drug has been previously filed: in this case, each ANDA applicant who filed an application that day qualifies as a "first" applicant and is eligible for an exclusivity period that is shared with all other applicants who filed that

[341] 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873 (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999).
[342] *Id.* at 42,874.
[343] *Id.*
[344] *Id.* at 42,875.
[345] *Id.* at 42,876.

day.[346] FDA then confirmed its current position that no generic exclusivity period may extend beyond the expiration date of the pioneer patent.[347]

FDA went on to address the troublesome provisions regarding the triggering of the market exclusivity period.[348] FDA proposed the adoption of a time limit for triggering the exclusivity period, noting that this approach was suggested by the *Mova* and *Purepac* courts as a way to prevent strategic behavior by first ANDA applicants from closing off generic markets. Within a 180-day "triggering period," either commencement of commercial marketing or a court decision holding the pioneer patent invalid or non-infringed must occur; otherwise, the first ANDA applicant loses its eligibility for market exclusivity and other generic drugs may be approved and enter the market. In general, the triggering period would begin on the date that a subsequent ANDA applicant received approval that would be effective but for the first applicant's entitlement to exclusivity.[349] FDA also explained that it was considering a shortened sixty-day triggering period in cases where the first applicant has received final FDA approval but has not been sued, or has been sued but the suit was settled or dismissed without decision on the merits, by the time a subsequent ANDA applicant obtains tentative approval. This shortened provision would provide an additional disincentive for first applicants to strategically foreclose generic drug markets.[350]

Next, FDA addressed the court decision trigger. FDA proposed to maintain its position that a only a "final judgment from which no appeal can be or has been taken" satisfies the court decision trigger.[351] However, it seemed unlikely that FDA would adopt this interpretation in its final rule in light of the D.C. District

[346] *Id.*

[347] *Id.* at 42,877.

[348] *Id.*

[349] *Id.* FDA also provided for three special situations:

First, if the first applicant was sued for patent infringement as a result of its paragraph IV certification and the litigation is ongoing, the triggering period would not begin until expiration of the 30-month stay of ANDA approval (see section II.B.3 of this document). Similarly, if a court issued a preliminary injunction prohibiting the first applicant from commercially marketing its drug product, the triggering period would not begin until the injunction expired. Finally, the triggering period would not begin until expiration of the statutorily described time period corresponding with any existing exclusivity periods for the listed drug (see sections 505(j)(5)(D)(ii) and 505A(a) of the act).

[350] *Id.* at 42,878.

[351] *Id.* at 42,879.

Court's decision in *Mylan*. In fact, in March, 2000 FDA issued a *Guidance for Industry*[352] indicating that it would revise its final regulation to comply with the decisions in *Mylan* and *TorPharm*. The *Guidance* sets out FDA's new interpretation of "court" in §§ 505(j)(5)(B)(iii)(I) and 505(j)(5)(B)(iv) as "the first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed," including a district court. Thus, FDA can approve an ANDA and the 180-day exclusivity period will begin to run on the date of the district court decision.[353] Stay or reversal of the district court decision will not affect the running of the exclusivity period, nor will it affect the ANDA's approval unless the pioneer drug patentee obtains a court injunction barring marketing of the approved drug under the ANDA. The new definition of "court" will apply prospectively only to protect parties who reasonably relied on the old definition in making their business decisions.[354]

FDA's proposed rule went on to suggest modifying its regulations to provide that any court decision against the patentee in an infringement or declaratory judgment suit involving the patent at issue will satisfy the court decision trigger. The suit need not involve the first ANDA applicant.[355] However, FDA maintained that the suit must be a judgment on the merits holding the patent invalid, not infringed, or unenforceable; specifically, dismissal of a declaratory judgment suit for lack of justiciable case or controversy would not qualify.[356] It seems likely that FDA will abandon this position in view of the *Teva* decision. FDA went on to expressly permit any first applicant to waive its exclusivity period in favor of another applicant once the period has begun. Before the period has begun, an applicant may surrender its right to exclusivity completely but may not waive it in favor of another specific applicant.[357] Next, FDA noted

[352] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (Mar., 2000).

[353] *Id.* at 8.

[354] *Id.* at 9.

[355] 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873 at 42,879-80 (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999).

[356] *Id.* at 42,881.

[357] *Id.*

that the first applicant for each strength of a drug is entitled to a separate exclusivity period; this interpretation is designed to promote a generic market with as many drug strengths as possible available as early as possible.[358]

V.
Conclusion

The litigation under the Hatch-Waxman Act in the almost sixteen years since its enactment demonstrates the Act's complexity and the difficulty involved in crafting its provisions into a coherent regulatory framework. Many commentators have expressed frustration with the Act based on the difficulties surrounding its implementation.[359] Some have even argued that the statute over-regulates and has failed to achieve its goals.[360] FDA's most recent proposed rule represents yet another attempt to implement the difficult language of the Hatch-Waxman Act in compliance with the Act's consumer-friendly goals. However, recent cases demonstrate that at least some of FDA's well-intentioned proposals cannot be reconciled with courts' interpretation of the statutory language. FDA's consistent efforts to mold the Act's tortuous language into a cohesive regulatory scheme consistent with legislative intent are commendable. However, it appears that, after over fifteen years of trying, the agency is still unable to fashion the awkward statute into a meaningful regulatory system that cannot be manipulated to the advantage of industry players and the detriment of consumers. Rather than continue to sit back and watch FDA's continued attempts to tame the beast that it created, Congress should take the initiative and revisit the Hatch-Waxman Act to clarify the ambiguities and correct the unintended consequences that have become apparent through over fifteen years of litigation under the statute.

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[358] *Id.* at 42,882.

[359] *See, e.g.*, David J. Bloch, *If It's Regulated Like a Duck... Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act*, Food Drug L.J. 111 (1999).

[360] *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, IDEA 389 (1999); David Harnden, *Can Generics Survive Under Hatch-Waxman?*, Scrip Mag., Dec. 1998, at 32.