

A SAFE HARBOR FOR DRUGS MADE OFFSHORE: THE
FEDERAL CIRCUIT RENDERS THE BOLAR AMENDMENT
AVAILABLE IN § 337 ACTIONS IN *AMGEN V. U.S.*
INTERNATIONAL TRADE COMMISSION

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I. INTRODUCTION

In April 2009 the U.S. Court of Appeals for the Federal Circuit rendered an important decision regarding U.S. patent holders' ability to block the importation of pharmaceuticals made overseas.¹ The case addressed a complex interaction of laws pertaining to the infringement of pharmaceutical-related patents and international trade regulation, and held that the International Trade Commission ("ITC" or "Commission") must determine whether the importation it is investigating, at the behest of a patent holder, is being done in pursuit of Food and Drug Administration ("FDA") approval of a pharmaceutical, before taking remedial action.²

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¹ *Amgen, Inc. v. U.S. Int'l Trade Comm'n (Amgen III)*, 565 F.3d 846 (Fed. Cir. 2009). The Federal Circuit first issued a panel decision on this case in March 2008. *Amgen, Inc. v. U.S. Int'l Trade Comm'n (Amgen D)*, 519 F.3d 1343 (Fed. Cir. 2008), *vacated en banc*, 564 F.3d 1358 (Fed. Cir. 2009), *modified*, 565 F.3d 846 (Fed. Cir. 2009). The en banc court vacated *Amgen I* and remanded the case to the panel for revision. *Amgen, Inc. v. U.S. Int'l Trade Comm'n (Amgen II)*, 564 F.3d 1358, 1359 (Fed. Cir. 2009). Specifically, the panel was authorized to revise part II of the *Amgen I* decision, which pertained to a jurisdictional challenge. *Amgen III*, 565 F.3d at 848 n.1; *see infra* note 225 and accompanying text. The holding of part II of *Amgen I* (that the ITC had jurisdiction to hear Amgen's complaint) was not changed by *Amgen III*, though the rationale for the holding was modified, and *Amgen I* and *III* did not differ from each other in any other respect. *See infra* note 225 and accompanying text; Tony Dutra, *Revised Amgen Opinion Eliminates Prior Ruling on Blocking Imminent Importations*, [2009] 78 Pat. Trademark & Copyright J. (BNA) No. 1916, at 43-44 (May 8, 2009); Patently-O, <http://www.patentlyo.com/patent/2009/04/federal-circuit-revises-amgen-v-itc.html> (Apr. 30, 2009, 13:57 EST); Posting of Andrew Williams to Patent Docs, <http://www.patentdocs.org/2009/05/amgen-inc-v-international-trade-commission-fed-cir-2009.html> (May 4, 2009, 22:10 EST).

² *See* Patently-O, <http://www.patentlyo.com/patent/2008/03/in-defiance-of.html> (Mar. 19,

This paper discusses the decision in light of the legislation, legislative history, administrative action, and case law that shaped it. Part II discusses the Bolar Amendment of the Hatch-Waxman Act, a provision of patent law that exempts from patent infringement liability conduct done in pursuit of FDA approval of a pharmaceutical. In Part III, the role of the ITC in enforcing patent protection, as an alternative or adjunct to litigation in federal courts, is presented. Part IV discusses the Process Patent Amendments Act of 1988, which established patent infringement liability for the importation of the products of U.S. patents, subject to several safe-harbor provisions. In Part V, Federal Circuit precedent pertaining to the applicability of the safe harbor provisions of the Process Patent Amendments Act of 1988 to ITC actions, which set the stage for the controversy in *Amgen III*, is presented. Finally, in Part VI, *Amgen III*, as well as additional pending federal litigation, is discussed. In conclusion, Part VII articulates the current state of patent law as it pertains to importation and the pharmaceutical industry, in light of *Amgen III*. A suggestion is made that the decision in *Amgen III* is in keeping with recent Supreme Court precedent that the extraterritorial reach of U.S. patent law is limited absent express congressional intent.

II. THE BOLAR AMENDMENT OF THE HATCH-WAXMAN ACT

The Drug Price Competition and Patent Term Restoration Act of 1984,³ also known as the Hatch-Waxman Act, was enacted to serve dual purposes in fostering patent protection for pharmaceuticals.⁴ One purpose it served was to extend the term of patent protection afforded by the Patent Act for developers of new drugs.⁵ Generally, the term of a patent's protection terminates twenty years from the date on which the application for it was filed.⁶ Because a patent might not issue until several years after the application for it was filed, due to the time it takes the U.S. Patent and Trademark Office ("PTO") to examine a patent application, there is typically a period of market exclusivity from the time a patent issues to the time its

2008, 15:14 EST).

³ Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-c, 70b (1994); 21 U.S.C. §§ 301, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

⁴ Hasneen Karbalai, *The Hatch-Waxman (Im)Balancing Act 4-5* (2003) (unpublished third year paper, Harvard Law School), available at <http://leda.law.harvard.edu/leda/data/551/Paper1.html>.

⁵ 35 U.S.C. § 156 (2006).

⁶ § 154(a)(2).

term expires of between seventeen and twenty years.⁷

Prior to the Hatch-Waxman Act, however, the actual period of market exclusivity for pharmaceuticals corresponded to a period of less than seventeen years.⁸ Before entering the market, pharmaceuticals must undergo regulatory review for efficacy and safety by the Food and Drug Administration, which typically is not completed by the time a patent on the drug issues.⁹ As a result, newly-patented pharmaceuticals generally do not enter the market until substantially more than three years after the filing of a patent application, meaning they are afforded less than the approximately seventeen-year term enjoyed by other patentees.¹⁰ The Hatch-Waxman Act was intended to remedy this disparity by extending the term of pharmaceutical patent protection in accordance with the delay in market entry attributable to FDA review.¹¹

A second function of the Hatch-Waxman Act was to expedite the development and entry into the marketplace of generic pharmaceuticals.¹² As with original pharmaceuticals, the period of regulatory approval of generic drugs by the FDA delayed their entry into the market, typically until several years after the expiration of the terms of the original pharmaceuticals upon which they were based.¹³ The reason for this delay was that manufacture and testing of a generic—required for FDA review—constituted infringement if performed before the expiration of the original's patent.¹⁴ Thus, there was an artifactual extension of the period of market exclusivity for original drugs after the expiration of their patents while FDA approval of generics was pending.¹⁵ Although, to some degree, this artifactual period compensated patentees of original drugs for their delay in market exclusivity attributable their initial FDA approval period, the net result was a delay in the availability of more affordable generics to consumers.¹⁶

⁷ § 154(b)(1)(B); Katherine A. Helm, Note, *Outsourcing the Fire of Genius: The Effects of Patent Infringement Jurisprudence on Pharmaceutical Drug Development*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 153, 172 n.73 (2006).

⁸ See H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

⁹ Karbalai, *supra* note 4, at 4.

¹⁰ See H.R. REP. NO. 98-857, pt. 1, at 17.

¹¹ 35 U.S.C. § 156(a)(4)(A); Helm, *supra* note 7, at 174 n.84.

¹² Karbalai, *supra* note 4, at 1–2.

¹³ *Id.* at 4–5.

¹⁴ Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861 (Fed. Cir. 1984), *superseded by statute*, 35 U.S.C. 271(e)(1) (1984), *as recognized in* Eli Lilly & Co. v. Medtronic, Inc., 486 U.S. 661 (1990).

¹⁵ Karbalai, *supra* note 4, at 4–5.

¹⁶ *Id.* Other major accomplishments of the Hatch-Waxman Act, not addressed in this article, were the establishment of a procedure for seeking expedited FDA review of generic

Thus, through a provision commonly known as the Bolar Amendment,¹⁷ the Hatch-Waxman Act also exempted from infringement otherwise infringing activities of the makers of generic drugs undertaken with the intention of seeking FDA approval.¹⁸ In its current form, 35 U.S.C. § 271(e)(1) states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (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 submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.¹⁹

pharmaceuticals, and seeking approval for *marketing* generic pharmaceuticals *before* the expiration of patents protecting original pharmaceuticals upon which they were based (such as by asserting that such patents are invalid, or would not be infringed by the generics). *Id.* at 6–8.

¹⁷ 35 U.S.C. § 271(e)(1).

¹⁸ Section 202 of the Hatch-Waxman Act added subsection (e), with numerous subparagraphs, to 35 U.S.C. § 271. *See* Pub. L. No. 98-417, 98 Stat. 1585, 1603 (1984). 35 U.S.C. § 271(e)(1) is referred to as the Bolar Amendment because it effectively overruled the decision in *Bolar*. *See* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 n.3 (1990); H.R. REP. NO. 98-857, pt. 2, at 27 n.18 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711 (“The purpose of the provision is to overturn the ruling in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*” (citation omitted)); Karbalai, *supra* note 4, at 3 n.4.

¹⁹ The provision currently contains some difficult language that excludes biotechnological animal drugs from its safe harbor. *See* § 271(e)(1). This exclusion has a somewhat tortuous history. The Hatch-Waxman Act, including the Bolar Amendment, was reported by the House Judiciary Committee as H.R. 3605, 98th Congress (2d Sess. 1984). *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 100-417, 98 Stat. 1585, 1605 note (1984). In the initial committee report on the bill, no animal drugs were excluded from the safe harbor. H.R. REP. NO. 98-857, pt. 1, at 13–14. The bill was amended, however, to exclude all veterinary pharmaceuticals, without distinction between traditional chemical drugs and biotechnological drugs, because the committee was simultaneously considering a separate bill, H.R. 6034, 98th Congress (2d Sess. 1984), that dealt with analogous issues for patents on such products. *See* H.R. REP. NO. 98-857, pt. 2, at 2 (excluding “new animal drug[s] or veterinary biological product[s]” from the Bolar Amendment); *id.* at 7 (explaining that H.R. 3605 was amended to exclude “animal drugs, because these substances were dealt with in another bill before the Committee, H.R. 6034”); H.R. REP. NO. 98-1122, at 7 (1984) (accompanying H.R. 6034 and explaining that the committee had also adopted an amendment to H.R. 3605 excluding animal drugs from that bill, in anticipation of considering H.R. 6034 which “grants patent extensions to certain animal drugs . . . which must undergo regulatory review prior to commercial marketing”). H.R. 6034 was not ultimately enacted by the 98th Congress, however. Four years later, similar legislation was enacted by the 100th Congress in the Generic Animal Drug and Patent Term Restoration Act. Pub. L. No. 100-670, 102 Stat.

This exemption allowed manufacturers of generic drugs to begin seeking FDA approval of their products during the term of the original drug's patents, such that they could enter the market sooner.²⁰

The Supreme Court mandated an expansive construction of the "reasonably related to the development and submission" language of this statute in *Merck KGaA v. Integra Lifesciences I, Ltd.*²¹ In that case, the holder of several patents pertaining to a particular amino acid sequence sued a competitor for infringement.²² The alleged infringer had provided materials covered by those patents to a collaborating researcher, who had identified a possible therapeutic

3971 (1988). The initial committee report accompanying introduction of this bill included an expansion of the safe harbor of § 271(e)(1), eliminating the language that excluded "animal drug[s] or veterinary biological product[s]." H.R. REP. NO. 100-972, pt. 1, at 32 (1988). In the final version of that bill as reported from committee, however, language excluding the subset of veterinary pharmaceuticals that were "primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques" was added. H.R. REP. NO. 100-972, pt. 2, at 13. The report explained the rationale for excluding "biotechnology-generated animal drugs" from the safe harbor of § 271(e)(1): "This amendment [offered by Rep. Moorhead] was agreed to in order to further the likelihood of this bill becoming law this Congress. . . . [U]nder this amendment, there will be no generic animal drug approvals for products made primarily through the use of biotechnology" *Id.* at 17. One representative stated, during the floor debate on the bill:

As this bill was introduced, I believe it was especially unfair to those in the biotechnology industry who are developing new animal drugs. If we want the biotech industry to develop new products to prevent, treat, and diagnose animal diseases we cannot remove the incentive for innovators to work on these projects. For this reason the Judiciary Committee decided to exempt the biotech industry from the application of this bill. . . . I believe now we have a bill that has a fairer balance between promoting generic competition on the one hand and ensuring that research drug firms continue to have the necessary incentives to develop new drugs.

134 CONG. REC. 29,030, 29,037–38 (1988) (statement of Rep. Moorhead).

The committee report also added, however, that "[b]ecause there are an insignificant number of such [biotechnological veterinary] drugs on the market today the short term effect of [Rep. Moorhead's] amendment will be minor. In the longer term, however, this set of issues will need to be revisited." H.R. REP. NO. 100-972, pt. 2, at 17. As of this writing, however, some twenty-odd years after enactment of the Generic Animal Drug and Patent Term Restoration Act, biotechnological animal drugs remain excluded from the safe harbor of the Bolar Amendment. 35 U.S.C. § 271(e)(1) (2006).

²⁰ The Committee report states that:

[E]xperimental use of a drug product prior to the expiration date of a patent claiming that drug product . . . [when] the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires . . . does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.

H.R. REP. NO. 98-857, pt. 1, at 45–46; Karbalai, *supra* note 4, at 6.

²¹ 545 U.S. 193, 202 (2005) ("Though the contours of [§ 271(e)(1)] are not exact in every respect, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.")

²² *Id.* at 200.

use for the materials in the treatment of angiogenesis, and performed tests of its “efficacy, specificity, and toxicity . . . as [an] angiogenesis inhibitor[], and evaluated [its] mechanism of action and pharmacokinetics in animals.”²³

The alleged infringer argued that these acts were exempted from infringement by the Bolar Amendment because they were performed with the intention of confirming the compound’s usefulness as a therapeutic treatment and ultimately for submission to the FDA for approval.²⁴ The patentee disagreed, arguing that preclinical data pertinent for FDA review of drugs need only concern the safety of the drug in humans, and that “preclinical studies related to a drug’s efficacy, mechanism of action, pharmacokinetics, and pharmacology are not reasonably included in [a drug application with the FDA], and are therefore outside the scope of the exemption.”²⁵ The Supreme Court disagreed with the patentee, holding that when a drug manufacturer believes a compound to have pharmaceutical utility “and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is ‘reasonably related’ to the ‘development and submission of information’” to the FDA.²⁶

In *Eli Lilly & Co. v. Medtronic, Inc.*, the Supreme Court held that § 271(e)(1) applied not only to pharmaceuticals but to medical devices as well.²⁷ In that case, the holder of patents on ventricular defibrillators sued a competitor who was marketing and testing an allegedly infringing implantable cardiac defibrillator.²⁸ The alleged infringer, in defense, argued that its actions were exempt from infringement under § 271(e)(1).²⁹ The patent holder disagreed, arguing that, because § 271(e)(1) refers to activities undertaken in seeking federal approval for “drugs,” not devices, the alleged infringer’s uses of the defibrillators did not qualify for the exemption.³⁰ The Court ruled for the alleged infringer, concluding that because the FDA operates, in the words of the statute, under “a Federal law which *regulates* the manufacture, use, or sale of drugs,” and FDA approval is required for marketing medical devices such as the alleged infringer’s defibrillator, the § 271(e)(1) exemption is

²³ *Id.* at 198–99.

²⁴ *Id.* at 200.

²⁵ *Id.* at 203.

²⁶ *Id.* at 207.

²⁷ 496 U.S. 661, 667 (1990).

²⁸ *Id.* at 664.

²⁹ *Id.*

³⁰ *Id.* at 665–66.

not limited to uses of pharmaceuticals but includes uses of medical devices as well.³¹

The Court of Appeals for the Federal Circuit has also held that § 271(e)(1) exempts activity from infringement even if it not undertaken with the subjective purpose of submitting information to the FDA, provided that, objectively, the activity is “reasonably related to obtaining FDA approval.”³² In *AbTox, Inc. v. Exitron Corp.*, the holder of a patent for sterilizing medical instruments sued a competitor for infringement.³³ The competitor had performed tests on its own, allegedly infringing the patent on the sterilizer, and although the data produced by the tests were such as would be required in seeking FDA approval for the medical device, the competitor had not yet sought FDA approval.³⁴ Rather, the patentee argued that the actual purpose of the tests was to create a market for the technology by demonstrating its effectiveness to potential purchasers, thereby taking the tests out of the § 271(e)(1) exemption.³⁵ The court held for the competitor, concluding that “[a]s long as . . . activity is reasonably related to obtaining FDA approval . . . intent or alternative uses are irrelevant to . . . qualification to invoke the section 271(e)(1) shield.”³⁶

Thus, the federal courts have construed the language of the Bolar Amendment to give fairly wide latitude to the types of activities that can qualify for exemption from infringement, as well as the types of products to which such activities relate. Testing need not provide the type of data which itself would be submitted to the FDA, no application need in fact be submitted to the FDA, tests on pharmaceuticals and medical devices alike can qualify for the exemption, and objective evaluation of the fruits of testing determine whether the exemption applies, not the subjective intent of the experimenter. As developed below, the Federal Circuit perpetuated this relatively broad construction of the Bolar Amendment in *Amgen III* by expanding its reach beyond infringement litigation in federal court, into administrative actions before the ITC.³⁷

³¹ *Id.* at 666–67 (alteration in original).

³² *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997).

³³ *Id.* at 1020.

³⁴ *Id.* at 1027.

³⁵ *Id.* at 1027–28.

³⁶ *Id.* at 1030; *see also* *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1275 (N.D. Cal. 1991) (“[T]he availability of the [§ 271(e)(1)] exemption turns on actual uses, not on the ‘purposes’ of the party doing the using.”).

³⁷ *See infra* Part VI.

III. THE TARIFF ACT AND § 337 ACTIONS

The Patent Act enumerates conduct that amounts to infringement³⁸ and establishes remedies in the federal courts.³⁹ Under 35 U.S.C. § 271(a), “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”⁴⁰ And under § 281, “[a] patentee shall have remedy by civil action for infringement of his patent.”⁴¹ Additional means of protecting patent rights are also available under federal law. For example, the Tariff Act of 1930,⁴² as amended, establishes a procedure for patentees to prevent the importation and/or distribution of infringing items.⁴³ The Tariff Act provides that:

[T]he following are unlawful, and when found by the [ITC] to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

.....

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—(i) infringe a valid and enforceable United States patent [or copyright]; or (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.⁴⁴

³⁸ See 35 U.S.C. § 271 (2006).

³⁹ § 281.

⁴⁰ § 271(a).

⁴¹ § 281.

⁴² See 19 U.S.C. § 1337 (2006).

⁴³ § 1337(b)–(f).

⁴⁴ § 1337(a)(1)(B). The current language of § 1337(a)(1)(B) differs from the original language of the Tariff Act of 1930 as enacted, which somewhat nonspecifically declared unlawful “[u]nfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale.” Tariff Act of 1930, ch. 497, sec. 337(a), 46 Stat. 703 (current version at 19 U.S.C. § 1337 (2006)). The original language of the Tariff Act of 1930 was taken from the Tariff Act of 1922, which the 1930 act replaced. Ch. 356, sec. 316, 42 Stat. 943 (1922); Alfred G. Musrey, *Tariff Act’s Section 337: Vehicle for the Protection and Extension of Monopolies*, 5 LAW & POLY INT’L BUS. 56, 56–57 (1973). As to the construction of this language, the federal judiciary had held that “[w]hat constitutes unfair methods of competition or unfair acts is ultimately a question of law for the court,” and that importing and selling products covered by a U.S. patent constituted unfair methods of competition. *Frischer & Co. v. Bakelite Corp.*, 39 F.2d 247, 259, 260 (C.C.P.A. 1930); see Musrey, *supra*, at 66–67. Subsequently, the court held that, in contrast to the importation of a product that itself infringed a U.S. patent, the importation of a product made overseas by a process covered by a U.S. patent did not constitute an unfair method of competition or unfair act. *In*

Under 19 U.S.C. § 1337, known generally as § 337,⁴⁵ patentees can file complaints with the ITC alleging that such violations of the Tariff Act have occurred, whereupon the ITC “shall investigate.”⁴⁶ Upon initiating an investigation, the Commission assigns the case to an administrative law judge (“ALJ”),⁴⁷ who conducts a hearing, then files an initial determination with the Commission as to whether § 337 has been violated.⁴⁸

Subsequently, the Commission makes its final determination.⁴⁹ If it determines that a violation of § 337 has occurred, its determination is published in the Federal Register and transmitted to the President for approval or disapproval.⁵⁰ Consequences for a determination that a violation has occurred include excluding the entry of the violative item(s) into the country⁵¹ and/or issuance of orders mandating that the importation and or sale of the violative item(s) cease.⁵² Appeal of ITC determinations can be made to the Court of Appeals of the Federal Circuit.⁵³

Section 337 actions present an important, useful means for companies to protect their intellectual property rights,⁵⁴ presenting

re Amtorg Trading Corp., 75 F.2d 826, 832–34 (C.C.P.A. 1935). Congress overruled this holding in 1940, declaring the importation “of a product made, produced, processed, or mined under or by means of a process covered by the claims of” a U.S. patent equivalent to the importation of an infringing product “for the purposes of section 337 of the Tariff Act of 1930.” Act of July 2, 1940, ch. 515, 54 Stat. 724, *repealed by* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1215; *see* Musrey, *supra*, at 69–70. The current language of 19 U.S.C. § 1337(a)(1)(B), explicitly declaring it a violation to import patented products or products produced by patented processes, was adopted in the Omnibus Trade and Competitiveness Act of 1988, replacing the language from the Tariff Act of 1930 as originally enacted. The Omnibus Trade and Competitiveness Act of 1988 also repealed 19 U.S.C. § 1337a, rendered unnecessary by the addition of § 1337(a)(1)(B)(ii). *See* Amgen, Inc. v. U.S. Int’l Trade Comm’n, 902 F.2d 1532, 1534 n.2, 1538–39 (Fed. Cir. 1990) (discussing the relevant legislative history).

⁴⁵ William P. Atkins, *Appreciating 337 Actions at the ITC: A Primer on Intellectual Property Issues and Procedures at the U.S. International Trade Commission*, 5 U. BALT. INTELL. PROP. L.J. 103, 104 (1997). 19 U.S.C. § 1337 derives historically from § 337 of the Tariff Act of 1930. 19 U.S.C. § 1337 (2006) (note on “Prior Provisions” following text of statute); *see supra* note 44.

⁴⁶ 19 U.S.C. § 1337(b)(1).

⁴⁷ 19 C.F.R. § 210.30(b)(2) (2009).

⁴⁸ § 210.42(f).

⁴⁹ 19 U.S.C. § 1337(c).

⁵⁰ § 1337(j)(1).

⁵¹ § 1337(d).

⁵² § 1337(f).

⁵³ § 1337(c); Robert A. Caplen, *Recent Trends Underscoring International Trade Commission Review of Initial Determinations and Federal Circuit Appeals from Final Commission Determinations Under Section 337 of the Tariff Act of 1930*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 337, 360 (2007).

⁵⁴ Caplen, *supra* note 53, at 351.

some attractive alternatives to litigation in federal court.⁵⁵ In recent years, they have become an increasingly popular pathway for patentees: a 2008 study reported that the number of 337 actions per year tripled in the preceding decade.⁵⁶ Such expanded use, however, has raised concerns about substantive differences in the application of patent law by the ITC and the federal judiciary.⁵⁷

For example, in investigating disputes, the ITC is authorized to make determinations on patent issues, such as whether, as alleged by a complainant, an imported item does in fact infringe a U.S. patent.⁵⁸ Such determinations, however, are not binding on collateral actions taken in federal courts,⁵⁹ where patentees can pursue civil actions to prevent the importation of infringing items concomitantly with initiating 337 actions.⁶⁰ Indeed, as developed in the sections that follow, in recent years the Federal Circuit has had occasion to determine whether and how certain nuances of the Patent Act impact 337 actions at the ITC.⁶¹

IV. THE PROCESS PATENT AMENDMENTS ACT OF 1988 AND THE ITC

As noted above, § 271(a) of the Patent Act renders importation of items covered by a U.S. patent an act of infringement.⁶² When an imported item is the subject of a patent on a “machine, manufacture, or composition of matter,”⁶³ determining infringement entails comparing the imported matter to the claims of an allegedly

⁵⁵ Atkins, *supra* note 45, at 130; Neil F. DuChes, Note, *Synopsis of the Extraterritorial Protection Afforded by Section 337 as Compared to the Patent Act*, 14 MICH. TELECOMM. & TECH. L. REV. 447, 447–48 (2008).

⁵⁶ Colleen V. Chien, *Patently Protectionist? An Empirical Analysis of Patent Cases at the International Trade Commission*, 50 WM. & MARY L. REV. 63, 68 (2008). *But see* Posting of Dennis Crouch to Patently-O, <http://www.patentlyo.com/patent/2007/12/appeals-from-th.html> (Dec. 17, 2007, 14:12 EST) (stating that, despite some attractive characteristics, § 337 actions, are still fairly rare relative to the number of civil cases brought in federal court).

⁵⁷ Chien, *supra* note 56, at 68.

⁵⁸ 19 U.S.C. § 1337(a)(1)(B).

⁵⁹ *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1568–69 (Fed. Cir. 1996) (citing legislative history and federal court precedent in explaining that ITC determinations have no claim-preclusive effect in the federal courts); *see also Tandon Corp. v. Int'l Trade Comm'n*, 831 F.2d 1017, 1019 (Fed. Cir. 1987) (“[A]ppellate treatment of decisions of the [International Trade] Commission [by the Federal Circuit] does not estop fresh consideration by other tribunals.”).

⁶⁰ *Tex. Instruments Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1330 (Fed. Cir. 2000) (“[A] patentee can bring suit both in a district court and in the ITC against an alleged infringer who is importing an allegedly infringing product.”).

⁶¹ *See infra* Parts IV–V.

⁶² 35 U.S.C. § 271(a) (2006).

⁶³ § 101 (establishing subject matter upon which patents may be obtained).

infringed patent.⁶⁴ Patents can also be obtained on processes, however.⁶⁵ Although as a practical matter, a process cannot be imported per se, a process subject to a U.S. patent can be performed overseas and the product of that process can then be imported.⁶⁶ According to the language of § 271(a), such activity does not constitute infringement, because it does not entail the “import[ation] into the United States [of] any patented invention.”⁶⁷

Consequently, the value of U.S. process patents was somewhat diluted.⁶⁸ Competitors needed only to practice a patented process offshore and import the products made by that patented process, to avoid incurring liability for infringement.⁶⁹ To address this problem, the Process Patent Amendments Act was enacted as part of the Omnibus Trade and Competitive Act of 1988.⁷⁰ Under this Act, § 271 was amended to add subsection (g), which states:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.⁷¹

⁶⁴ See, e.g., *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998).

⁶⁵ 35 U.S.C. § 101; see also § 100(b) (“[For the purposes of title 35], [t]he term ‘process’ means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”).

⁶⁶ S. REP. NO. 100-83, at 30 (1987).

⁶⁷ 35 U.S.C. § 271(a).

⁶⁸ *Process Patent Legislation: Hearing Before the Subcomm. on Patents, Copyrights and Trademarks of the S. Comm. on the Judiciary on S. 568, S. 573, and S. 635*, 100th Cong. 4 (1987) [hereinafter *1987 Hearing*] (opening statement of Sen. Charles E. Grassley, Subcomm. Member on Patents, Copyrights and Trademarks).

⁶⁹ Senator Grassley’s statements accentuate the concern that many had with respect to this loophole:

[I]t is a very serious problem . . . and I am glad that there is a growing consensus that legislation needs to be enacted in the necessary area of process patent protection, particularly abroad. There, of course, is something very inherently unfair about U.S. research-based industries pouring resources into a product or a process patent and then having that product or process pirated abroad and shipped back into this country for sale. The inventor, of course, is required to disclose his or her process patent, and it is available in the Patent Office just like some recipe in a cookbook for all to see.

Id.

⁷⁰ Pub. L. No. 100-418, §§ 9001–07, 102 Stat. 1107, 1563 (1988) (codified as amended at 35 U.S.C. §§ 154, 271, 287, 295 (2006)); see *1987 Hearing*, *supra* note 68, at 4 (opening statement of Sen. Charles E. Grassley, Subcomm. Member on Patents, Copyrights and Trademarks); S. REP. NO. 100-83, at 29 (discussing the legislative history of the Process Patent Amendments Act of 1988). Recall that this Act also amended 19 U.S.C. § 1337. See *supra* note 44.

⁷¹ 35 U.S.C. § 271(g). The provision continues:

In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there

Thus, under § 271(g), parties that attempt to avoid infringement by practicing patented processes offshore no longer evade civil liability if the products made using the patented process are then imported to the United States.⁷²

This subsection concludes, however, with two safe harbors: “A product which is made by a patented process will, for purposes of this title, not be considered to be so made after (1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.”⁷³ Thus, whereas 271(g) generally renders the importation of a material made overseas by a patented process an act of infringement, under certain conditions such importation is not infringement.⁷⁴

Anticipating the possible difficulties that patentees, manufacturers, and the courts may have in construing the phrase “materially changed,” the Senate Judiciary Committee articulated a “two-phased test”:

1. A product will be considered made by the patented process regardless of any subsequent changes if it would not be possible or commercially viable to make that product but for the use of the patented process. In judging commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.

2. A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of the product in a manner which changes the basic utility of the product by the patented process. However, a change in the physical or chemical properties of a product, even though minor, may be “material” if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually a change in the

is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product.

Id.

⁷² *Id.*; see also *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1377–78 (Fed. Cir. 2003) (“[For conduct to be infringing under § 271(g),] the process must be used directly in the manufacture of the product A drug product, the characteristics of which were [merely] studied using the claimed research processes, therefore, is not a product ‘made by’ those claimed processes.”).

⁷³ § 271(g)(1)–(2).

⁷⁴ *Id.* Note that the federal courts have also extended the safe harbor of the Bolar Amendment to protect the importation of the product of a patented process when reasonably related to seeking FDA approval. See *infra* note 180 and accompanying text.

physical form of a product (e.g., the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a “material” change.⁷⁵

Thus, the Senate Committee asserted that if a patented process is essential for the production (or commercially viable production) of an imported product, a product of that process cannot be deemed “materially changed” for the purposes of § 271(g), irrespective of whether or in what way it is further altered subsequent to practicing the patented process.⁷⁶ Furthermore, if a product is produced overseas with a patented process, even if its chemical or physical properties are altered prior to importation, if neither its “basic utility” nor any “important feature” is also altered, it is not “materially changed.”⁷⁷ In such cases, “minor” changes notwithstanding, its importation is infringement.⁷⁸ Despite this guidance, the committee recognized that “courts may frequently find themselves in a quandary on [the phrase] materially changed.”⁷⁹ Indeed, the Process Patents Amendments Act of 1988 has been the subject of substantial litigation; the federal courts have attempted to develop guidelines for its application, in some cases finding that an alleged infringer had “materially changed” a product of a patented process before importation, thereby exempting the importation from infringement under § 271(g)(1), while in other cases finding that it had not.⁸⁰

For example, in *Genentech, Inc. v. Boehringer Mannheim GmbH*, the defendant in a patent infringement suit moved for summary judgment on the grounds that its actions fell within § 271(g)(1).⁸¹ The parties were competitors in the market for thrombolytics, drugs that dissolve blood clots.⁸² The plaintiff held a patent on a process for combining synthetic DNA sequences with segments of cloned genes so as to create plasmids that better enabled microbial production of desired proteins, an important step in the production

⁷⁵ S. REP. NO. 100-83, at 50 (1987).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ See Elizabeth D. Lauzon, Annotation, *When Has Imported Product Made by Patented Process Been “Materially Changed” by Subsequent Process in Order to Avoid Infringement of Patented Process*, 184 A.L.R. FED. 369, 377–83 (2003) (describing some federal cases in which the “materially changed” language of § 271(g)(1) has been interpreted); see also *infra* note 234 and accompanying text.

⁸¹ 47 F. Supp. 2d 91, 93 (D. Mass. 1999).

⁸² *Id.* at 93, 98.

of the thrombolytics it sold in the United States.⁸³

The defendant was practicing this method overseas, as part of its own production of a thrombolytic for sale within the U.S.⁸⁴ It argued, however, that its subsequent processing steps, in which the DNA sequence of its plasmids were further altered, led to material changes in the product of the patented process.⁸⁵ After concluding that the product of the patented process was indeed changed prior to importation,⁸⁶ the court considered “the substantiality of the change between the product of the patented process and the product that [was] being imported,”⁸⁷ and applied the “two-phased test” suggested by Congress in assessing whether this change was material.⁸⁸ Citing several changes made to the product of the patented process (e.g., removal of entire portions of the gene sequence, subsequent absence of glycosylation of the gene product, and pharmacokinetic properties of the defendant’s thrombolytic that differed in clinically notable ways from those of the thrombolytic yielded by the patented process), the court concluded that “there has been a significant change in both . . . structure and properties.”⁸⁹

Additionally, the court noted that the defendant and plaintiff both held product patents on their thrombolytics, and that the plaintiff’s had been cited to the PTO during prosecution of the defendant’s.⁹⁰ Thus, the court suggested that when a patent applicant claims the derivative of a previously-patented compound, and a patent issues thereon though the senior patent was considered by the PTO during examination, such prosecution history supports the inference that conversion between the compounds amounts to a material change for the purpose of a § 271(g)(1) analysis.⁹¹

⁸³ *Id.* at 97.

⁸⁴ *Id.* at 106–07.

⁸⁵ *Id.* at 110–11.

⁸⁶ *Id.* at 111.

⁸⁷ *Id.* at 107.

⁸⁸ *Id.* at 109.

⁸⁹ *Id.* at 110–12.

⁹⁰ *Id.* at 110.

⁹¹ *Id.* *But see infra* note 234 (describing a recent Federal Circuit holding that does not comport with this suggestion). *Cf.* *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp, Inc.*, 249 F.3d 1341, 1352 (Fed. Cir. 2001). In *BioCorp.*, the district court held that the defendant had infringed the plaintiff’s process patent under § 271(g). On appeal, the Federal Circuit affirmed, holding that the product was not materially changed after employing the patented process even though it passively underwent transient modifications during importation that temporarily took it out of the literal claims of the product patent, because the specification of the product patent alluded to the product’s tendency to undergo this modification.

As to the “commercial viability phase of the congressional test,” the court noted that the plaintiff had not raised evidence on this point.⁹² Because the court found that the plaintiff bore the burden of proof in rebutting a material change defense,⁹³ it held that the plaintiff had “waived” this prong, and the defendant’s motion for summary judgment was granted.⁹⁴

In *Eli Lilly & Co. v. American Cyanamid Co. (Eli Lilly II)*, the defendant was practicing overseas the plaintiff’s process for manufacturing an antibiotic, but moved for summary judgment against a claim of infringement, citing § 271(g)(1).⁹⁵ The patent at issue claimed a process for making a compound whose predominant utility was as a precursor to the broad-spectrum antibiotic cefaclor, which itself had been claimed by the plaintiff in an expired product patent.⁹⁶ The product of the patented process, referred to as “compound 6” in the court’s opinion, underwent several chemical modifications by the defendant to produce the imported cefaclor, leading the court to analyze whether the modifications amounted to a material change.⁹⁷ On several grounds, the court concluded that there was a material change, thus shielding the defendant’s conduct under § 271(g)(1), and granted the defendants’ summary judgment motion.⁹⁸

The court noted four distinct covalent modifications that were made to compound 6 in producing cefaclor that, when taken together, amounted to more than a minor change.⁹⁹ Such changes satisfied the materiality criterion, despite the court’s acknowledgement that compound 6 itself, like cefaclor, was capable of functioning as an antibiotic; the plaintiff had raised this issue in an attempt to minimize the materiality of the changes the defendant made to compound 6 in producing cefaclor.¹⁰⁰ Also dismissed was the plaintiff’s argument that because compound 6 had no commercial utility other than as a precursor to cefaclor, the two compounds did not materially differ for the purposes of a §

⁹² *Genentech*, 47 F. Supp. 2d at 112.

⁹³ *Id.* at 108.

⁹⁴ *Id.* at 112.

⁹⁵ 66 F. Supp. 2d 924, 927 (S.D. Ind. 1999).

⁹⁶ *Id.* at 926.

⁹⁷ *Id.*

⁹⁸ *Id.* at 937.

⁹⁹ *Id.* at 929 (citing *Eli Lilly & Co. v. Am. Cyanamid Co. (Eli Lilly I)*, 82 F.3d 1568, 1573 (Fed. Cir. 1996) (affirming the district court’s denial of the plaintiff’s prior motion for a preliminary injunction)).

¹⁰⁰ *Id.* at 931–32.

271(g)(1) analysis; thus, changes to a compound can be considered “material” even if such changes were necessary to realize the compound’s commercial utility.¹⁰¹ Finally, cefaclor can be taken orally, whereas compound 6 cannot—another indication of a material change.¹⁰²

The plaintiff further argued, however, that even if compound 6 and cefaclor differed substantially, cefaclor was not materially changed from compound 6 because the defendant had no commercially viable alternative to practicing the patented process in manufacturing cefaclor.¹⁰³ Although the patented process was not the only known method for producing compound 6, the only other known process was also claimed by a patent held by the plaintiff, and therefore was “not a commercially viable alternative,” according to the plaintiff.¹⁰⁴ The court dismissed this argument as well, holding that the “commercially viable” test articulated by Congress was not “strong” enough to outweigh the undisputed existence of another means of producing compound 6.¹⁰⁵

The court concluded that practicing another’s patented process is not the only commercially viable alternative if other methods are known, even if they too are patented.¹⁰⁶ This analysis raises the interesting question of whether a party could qualify for the safe harbor of § 271(g)(1) even if it owned its own patent on a method that was an alternative to a competitor’s, such as if using its own patented process was a less commercially advantageous option than using the competitor’s.

In the foregoing cases, the federal courts exempted importation from infringement under § 271(g)(1). In other cases, however, the court has found infringement where an alleged infringer’s conduct did not result in a material change to the product of a patented process. For example, in *Pfizer Inc. v. F & S Minerals Corp.*, the court held that the flavor modifiers maltol and ethyl maltol were not changed materially from the precursor pyromeconic acid, which

¹⁰¹ *Id.* at 930 (citing *Eli Lilly I*, 82 F.3d at 1577 (holding that other antibiotics could also be derived from compound 6)).

¹⁰² *Id.* at 931–32.

¹⁰³ *Id.* at 932–33.

¹⁰⁴ *Id.* at 933.

¹⁰⁵ *Id.* at 934.

¹⁰⁶ *See id.* (“Further, we must state the obvious, that [Congress] explanatory language nowhere mentions the fact that an alternative method is subject to a patent as a barrier to commercial viability, nor even provides meaningful guidance as to what is meant by ‘commercially viable.’”).

it concluded had been produced overseas via a patented process.¹⁰⁷ In this case, however, the court's analysis was rather brief, going no further than recognizing that transforming pyromeconic acid into maltol and ethyl maltol required only alkylation, "a common reaction well known to organic chemists" without changing "the basic . . . structure of [the] compound."¹⁰⁸ This analysis would appear to fall somewhat short of Congress's "two-phased test."¹⁰⁹

The court's analysis in *Pfizer* is comparable to that in *Marion Merrell Dow, Inc. v. American Cyanamid Co.*¹¹⁰ In *Marion Merrell Dow*, the court not only articulated that the changes an alleged infringer made to the product of a plaintiff's patented process to produce a pharmaceutical compound were "minor chemical conversions," but also held that they did not impart any changes of medicinal significance.¹¹¹ Rather, because the court found that these changes merely produced "simple derivatives of the product of a patented process," the defendant's "additional steps [did] not escape the reach of 35 U.S.C. § 271(g)."¹¹²

In summary, where courts have held that the § 271(g)(1) exemption from infringement applies (e.g., *Genentech* and *Eli Lilly II*), the final imported product has differed from the product of the patented process not only in its chemical structure, but also in its physical or medicinal properties. Courts have yet to address situations where there are alternatives, but no commercially viable alternatives, to practicing a patented process. When a modification results merely in the formation of a functionally equivalent derivative, such as in *Marion Merrell Dow*, courts have not exempted importation from infringement. In *Pfizer*, the court held that limited covalent chemical modifications were not enough to

¹⁰⁷ 856 F. Supp. 808, 816 (S.D.N.Y. 1994).

¹⁰⁸ *Id.* at 816 (quoting the defendant's expert witness).

¹⁰⁹ See *supra* note 75 and accompanying text. The Senate Judiciary Committee Report notes that a change in the physical or chemical properties of a compound, "even though minor," may nonetheless be material if the change "relates to a physical or chemical property which is an *important feature* of the product produced by the patented process." S. REP. NO. 100-83, at 50 (1987) (emphasis added).

¹¹⁰ 36 U.S.P.Q.2d (BNA) 1036 (D.N.J. 1994).

¹¹¹ *Id.* at 1041.

¹¹² *Id.* In turn, the defendant's motion for summary judgment was denied. *Id.*; see also *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1560 (Fed. Cir. 1996) (holding that the § 271(g)(1) exemption did not insulate an alleged infringer from a patentee's motion for preliminary injunction when it did not merely fail to go so far as to *materially* change the product it produced with the plaintiff's patented process, but its imported product itself could be *directly* made by the use of the patented process; thus, the product of a patented process is not materially changed if the composition resulting from a purported change could itself have been directly produced by the patented process).

satisfy § 271(g)(1), though a more thorough analysis of the functional consequences of the modifications in that case was lacking.

Recall, however, that the Patent Act does not provide the only federal remedy for patentees seeking redress for infringement. If a patentee's process patent is being practiced overseas and the product of that patent is being imported and/or sold in the United States,¹¹³ the patentee can file a complaint with the ITC, potentially blocking importation and/or ceasing further distribution of the goods.¹¹⁴ Importantly, however, unlike § 271 of the Patent Act, § 1337 of the Tariff Act does not provide a safe harbor exemption from infringement for the importation of items that are materially changed from the products of patented processes.¹¹⁵ This difference between the Tariff and Patent Acts became a central issue in *Kinik Co. v. International Trade Commission*,¹¹⁶ discussed below.

V. THE SAFE HARBORS OF § 271(G) DO NOT APPLY TO § 337 ACTIONS AT THE ITC

In March 2002, the ITC issued a final determination that a company had violated § 337 by practicing a complainant's process patents overseas, and importing the goods made by the process.¹¹⁷ On appeal to the Federal Circuit, the alleged importer contested the determination that the process patents were being practiced overseas and that the safe harbor provisions of § 271(g)(1) and (2) did not apply to § 337 actions.¹¹⁸ The importer argued that, even if its process did rely on the complainant's patent, it "materially changed" the product of this process before importation.¹¹⁹ Because such an argument was available as a defense to infringement under the Patent Act,¹²⁰ the importer urged that it should also be allowed to raise this defense under the Tariff Act.¹²¹

The importer referred to § 1337(c) of the Tariff Act, which states that "[a]ll legal and equitable defenses may be presented in all" §

¹¹³ See *supra* note 44 and accompanying text.

¹¹⁴ See *supra* Part III.

¹¹⁵ See 19 U.S.C. § 1337 (2006).

¹¹⁶ 362 F.3d 1359 (Fed. Cir. 2004).

¹¹⁷ Notice of Commission Decision Not to Review a Final Initial Determination Finding a Violation of Section 337, 67 Fed. Reg. 16,116 (Apr. 4, 2002).

¹¹⁸ *Kinik*, 362 F.3d at 1361.

¹¹⁹ *Id.*

¹²⁰ 35 U.S.C. § 271(g)(1) (2006).

¹²¹ *Kinik*, 362 F.3d at 1363.

337 actions before the ITC.¹²² In turn, because materially changing the product of a patented process before importation had been rendered a defense to infringement under the Patent Act when the Process Patent Amendments Act of 1988 was enacted,¹²³ the importer argued that § 1337(c) of the Tariff Act made this defense available in § 337 actions.¹²⁴ It also raised the policy argument “that it is anomalous to create a legislative distinction in the defenses available in different tribunals.”¹²⁵

The court found these arguments unavailing, and affirmed the ITC’s determination that the safe harbor provisions under § 271 of the Patent Act do not pertain to 337 actions.¹²⁶ Central to the court’s analysis was the legislative history of 35 U.S.C. § 271 and 19 U.S.C. § 1337(a)(1)(B)(ii).¹²⁷ Recall that both of these provisions were enacted as part of the Omnibus Trade and Competitive Act of 1988.¹²⁸ Although prior to this Act there had been no redress available under the Patent Act for the unauthorized importation of the product of a patented process,¹²⁹ such conduct had been cause for a § 337 action under the Tariff Act since 1940.¹³⁰ Thus, despite the importer’s admonition against making different legal defenses available in proceedings before different federal bodies, the court noted that the “contemporaneous record” in the legislative history of the provisions at issue “shows that such conflict was recognized,” concluding that Congress had intended the safe harbor provisions enacted under § 271 to “deprive the patent owner of a remedy [already] available under the Tariff Act.”¹³¹

In fact, the court held that the legislative history and the language of the Process Patent Amendments Act of 1988 itself contravened the importer’s arguments:

There is no intention to impose [the limitations of § 271(g)(1) or (2)] on owners . . . of process patents in suits they are able to bring under existing law. Neither is there any intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International

¹²² 19 U.S.C. § 1337(c) (2006).

¹²³ 35 U.S.C. § 271(g)(1); *see supra* notes 70–74 and accompanying text.

¹²⁴ *Kinik*, 362 F.3d at 1362.

¹²⁵ *Id.* at 1363.

¹²⁶ *Id.*

¹²⁷ *Id.* at 1362–63.

¹²⁸ *See supra* notes 44, 71 and accompanying text.

¹²⁹ *Kinik*, 362 F.3d at 1362.

¹³⁰ *See supra* note 44.

¹³¹ *Kinik*, 362 F.3d at 1362.

Trade Commission.¹³²

Thus, Congress had explicitly rejected the position relied upon by the importer that the defense to infringement created upon enacting § 271(g) should scale back protection afforded by the Tariff Act.¹³³ Furthermore, such congressional intent was made explicit in the language of the Process Patent Amendments Act.¹³⁴ For example, as noted by the court, the Act “states, in adding § 271(g) to Title 35, that “[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available . . . under section 337 of the Tariff Act of 1930, or any other provision of law”¹³⁵ Furthermore, § 271(g) explicitly states that its safe harbor provisions are intended “for [the] purposes of this title,” that is, the Patent Act.¹³⁶

Thus, the safe harbor provisions of § 271(g) may shield an importer from infringement under the Patent Act, but they afford no protection in § 337 actions before the ITC.¹³⁷ Interestingly, although the court affirmed the ITC’s determination that the safe harbor provisions of § 271(g) were inapplicable to § 337 actions, this affirmation ultimately amounted to dictum and was not dispositive because the court reversed the ITC’s determination that the importer had practiced the complainant’s process overseas.¹³⁸

Although the court’s construction of the Process Patent Amendments Act of 1988 appears consistent with the Act’s plain language (which explicitly limits the applicability of the safe harbor provisions to the Patent Act) and legislative history (manifesting Congress’s intention that the safe harbor provisions not apply to § 337 actions),¹³⁹ the holding has not been universally embraced,¹⁴⁰ and the 110th Congress contemplated whether *Kinik* should be overruled by statute.¹⁴¹ Although applauded on the policy grounds

¹³² *Id.* at 1362–63 (quoting S. REP. NO. 100-83, at 60–61 (1987)).

¹³³ *Id.* at 1362.

¹³⁴ *Id.* at 1362–63.

¹³⁵ *Id.* at 1362 (quoting Pub. L. No. 100-418, § 9006(c), 102 Stat. 1107 (1988) (alterations in original)).

¹³⁶ 35 U.S.C. § 271(g) (2006).

¹³⁷ *Kinik*, 362 F.3d at 1363.

¹³⁸ *Id.*; Anandashankar Mazumdar, *Witnesses Disagree on Whether Patent Exceptions Should Apply to ITC Actions*, [2007] 74 Pat. Trademark & Copyright J. (BNA) No. 1817, at 15 (May 4, 2007).

¹³⁹ *But see* John M. Eden, Note, *Unnecessary Indeterminacy: Process Patent Protection After Kinik v. ITC*, 2006 DUKE L. & TECH. REV. 9, 10–17 (2006) (articulating five arguments against the *Kinik* court’s interpretation of the legislative history).

¹⁴⁰ Mazumdar, *supra* note 138, at 15.

¹⁴¹ At a hearing on process patents in 2007, Senator Leahy said that:

The ITC has held that our 271(g) defenses are not available in ITC exclusion proceedings because the plain language of the statute, confirmed by its history, applies them only to

that it protects U.S. patentees, businesses, and jobs,¹⁴² others have cautioned that *Kinik* may defy treaty obligations of the U.S., and undercut U.S. arguments advocating for better international enforcement of American intellectual property rights.¹⁴³ Furthermore, notwithstanding Congress's intent in passing the Process Patent Amendments Act of 1988, there has been debate as to whether the federal courts and the ITC should differ from each other in their treatments of the offshore practice of process patents.¹⁴⁴ Ultimately, however, the Senate Committee on the Judiciary of the 110th Congress did not recommend any legislation that would have overruled *Kinik*,¹⁴⁵ perhaps not surprisingly in light of the Committee Chairman's stated hesitancy to facilitate the importation of products made overseas by patented processes.¹⁴⁶

Another notable aspect of the court's decision in *Kinik*, in addition to its adherence to statutory language, was its proclaimed deference to the ITC's determination.¹⁴⁷ "To the extent that there is any uncertainty or ambiguity in the interpretation of . . . § 1337(a)(1)(B)(ii), deference must be given to the view of the agency that is charged with its administration," the court wrote.¹⁴⁸ The

patent infringement claims being considered in Federal court pursuant to the 1988 amendment. So we will decide whether this distinction should remain.

Process Patents: Hearing Before the S. Comm. on the Judiciary, 110th Cong. 1–2 (2007) [hereinafter *2007 Hearing*] (opening statement of Sen. Patrick J. Leahy, Chairman, S. Comm. on the Judiciary); Posting of Dennis Crouch to Patently-O, http://www.patentlyo.com/patent/2005/10/amendment_to_27.html (Oct. 14, 2005, 18:38 EST).

¹⁴² *2007 Hearing*, *supra* note 141, at 73 (statement of Michael K. Kirk, Exec. Director, American Intellectual Property Law Association).

¹⁴³ *Id.* at 87 (prepared statement of John R. Thomas, Professor of Law, Georgetown University Law Center); Eden, *supra* note 139, at 22–30; Anne Elise Herold Li, Comment, *Is the Federal Circuit Affecting U.S. Treaties? The ITC, §271(g), GATT/TRIPS & the Kinik Decision*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 601, 636 (2006); *see also* John A. Kelly, Comment, *Amgen, Inc. v. ITC: Defying Kinik While Complying With TRIPS*, 19 Fed. Cir. B.J. 81, 82 (2009) (published during prepublication editing of this article).

¹⁴⁴ Mazumdar, *supra* note 138, at 15–16; *compare 2007 Hearing*, *supra* note 141, at 5 (statement of John R. Thomas, Professor of Law, Georgetown University Law Center) ("[L]ike cases should be decided alike, regardless of the forum in which the case is heard."), *with 2007 Hearing*, *supra* note 141, at 7 (statement of Michael K. Kirk, Exec. Director, American Intellectual Property Law Association) ("[T]here are significant differences between a Section 337 proceeding in the ITC and an action for patent infringement in a Federal court that make Section 271(g) exceptions inappropriate for Section 337.").

¹⁴⁵ *See generally* S. REP. NO. 110-259, at 38–41 (2008).

¹⁴⁶ *2007 Hearing*, *supra* note 141, at 2 (opening statement of Sen. Patrick J. Leahy, Chairman, S. Comm. on the Judiciary) ("[I]f we permit products to enter the United States that were made abroad by a process patented here—where the creation of the product would itself be an act of infringement if it occurred here—well, then, we are doing nothing less than offshoring infringement and outsourcing jobs.")

¹⁴⁷ *Kinik v. U.S. Int'l Trade Comm'n*, 362 F.3d 1359, 1363 (Fed. Cir. 2004).

¹⁴⁸ *Id.* (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984)).

court's deference to the ITC's interpretation in this case has also been questioned on the grounds that the ITC was interpreting 35 U.S.C § 271(g)(1), a provision of the Patent Act, which the ITC is not charged with administering.¹⁴⁹

Recall that the Hatch-Waxman Act also introduced a safe harbor, the Bolar Amendment, into the Patent Act.¹⁵⁰ As discussed below, the ITC had occasion to determine whether this safe harbor was inapplicable to § 337 actions, a determination which the Federal Circuit would have occasion to review as well.¹⁵¹

VI. THE SAFE HARBOR OF § 271(E)(1) DOES APPLY TO § 337 ACTIONS

Kinik rendered the “materially changed” safe harbor of § 271(g)(1) unavailable to respondents in § 337 actions before the ITC,¹⁵² but it did not address the availability vel non of the Bolar Amendment.¹⁵³ Prior to the Federal Circuit's decision in *Kinik*, however, the ITC had addressed whether the exemption from patent infringement set out in § 271(e)(1) also shielded parties from § 337 violations, though it had not definitively resolved the question.

For example, in ITC Investigation No. 337-TA-267, the complainant moved to terminate the investigation with respect to a respondent because, according to the complainant, all of the respondents' activities at issue were “for noninfringing experimental purposes covered by . . . 35 U.S.C. § 271(e)(1).”¹⁵⁴ Pursuant to ITC rules, whereby parties may move to terminate investigations, the ALJ granted the motion to terminate;¹⁵⁵ the ITC determined not to review the initial determination, rendering the termination final.¹⁵⁶ In that investigation, the ITC did not directly rule on the relevance of § 271(e)(1) to § 337 actions, because its action was limited to responding to a complainant's motion to terminate.¹⁵⁷

¹⁴⁹ Eden, *supra* note 139, at 19–21.

¹⁵⁰ 35 U.S.C. § 271(e)(1) (2006); *see also supra* Part II.

¹⁵¹ *See infra* Part VI.

¹⁵² *See supra* Part V.

¹⁵³ *See supra* Part II.

¹⁵⁴ In the Matter of Certain Minoxidil Powder, Salts and Compositions for Use in Hair Treatment, Investigation No. 337-TA-267, Initial Determination, (Order No. 36) (Dec. 12, 1987) [hereinafter Minoxidil Initial Determination], 1987 ITC LEXIS 19, *1.

¹⁵⁵ *Id.*

¹⁵⁶ In the Matter of Certain Minoxidil Powder, Salts and Compositions for Use in Hair Treatment, 53 Fed. Reg. 292, 292 (Int'l Trade Comm'n Jan. 6, 1988) (decision not to review initial determination).

¹⁵⁷ Minoxidil Initial Determination, *supra* note 154, at *1.

Similarly, in ITC Investigation No. 337-TA-358, the ITC addressed but did not directly determine the question.¹⁵⁸ In that investigation, the conduct complained of was the importation of the product of a patented process.¹⁵⁹ The respondent, in its defense, argued that such importation was permissible because it was done only for the purposes of conducting clinical trials domestically, permissible under the Bolar Amendment.¹⁶⁰ The ALJ determined that “nothing in section 337 or section 271(e)(1), nor in their legislative histories . . . suggests that Congress did not intend for section 271(e)(1) to apply in section 337 investigations.”¹⁶¹ The ITC did not rule on this portion of the initial determination, however, terminating the investigation on other grounds and explicitly withholding an opinion on the applicability of the § 271(e)(1) safe harbor to § 337 actions.¹⁶²

The conduct that was the subject matter of ITC Investigation No. 337-TA-358 was also litigated in a patent infringement suit.¹⁶³ There, the court indicated that the § 271(e)(1) exemption did apply in patent infringement suits brought under § 271(g),¹⁶⁴ much as the ALJ had determined it did in § 337 actions.¹⁶⁵ The defendant had been importing the product of a patented process since the mid-1980s, but the patent holder did not file a complaint of infringement until 1995.¹⁶⁶ On account of the lapse between when the

¹⁵⁸ In the Matter of Certain Recombinantly Produced Human Growth Hormones, 60 Fed. Reg. 4923, 4923 (Int'l Trade Comm'n Jan. 25 1995) [hereinafter Growth Hormones Final Determination] (notice of final determination), *vacated on other grounds*, Genentech, Inc. v. U.S. Int'l Trade Comm'n, 122 F.3d 1409 (Fed. Cir. 1997).

¹⁵⁹ In the Matter of Certain Recombinantly Produced Human Growth Hormones, Investigation, No. 337-TA-358, Initial Determination (Nov. 29, 1994) [hereinafter Growth Hormones Initial Determination], 1994 ITC LEXIS 640, at *4 (part 1 of 10).

¹⁶⁰ *Id.* at *8.

¹⁶¹ *Id.* at *43 n.72 (part 3 of 10). Note that the ALJ's determination of this question was based in part on the fact that several previous ITC exclusion orders were supposedly fashioned so as to take account of the safe harbor of § 271(e)(1). *Id.*; see also Amgen, Inc. v. U.S. Int'l Trade Comm'n (*Amgen III*), 565 F.3d 846, 855 (Fed. Cir. 2009) (Linn, J., concurring in part and dissenting in part) (“Section 1337(a)(1)(B)(i) declares unlawful the importation of articles that ‘infringe a valid and enforceable United States patent.’ Thus, there is no dispute that the safe harbor of § 271(e) applies to *product* claims before the Commission.” (quoting 19 U.S.C. § 1337(a)(1)(B)(i) (2006) (emphasis added))).

¹⁶² Growth Hormones Final Determination, *supra* note 158, at 4923.

¹⁶³ *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1563 (Fed. Cir. 1996); see *supra* note 112 and accompanying text (discussing *Bio-Tech Gen. Corp.* in the context of construing the Process Patent Amendments Act of 1988).

¹⁶⁴ *Bio-Tech. Gen. Corp.*, 80 F.3d at 1564–65.

¹⁶⁵ Growth Hormones Initial Determination, *supra* note 159, at *43 n.72 (part 3 of 10).

¹⁶⁶ *Bio-Tech. Gen. Corp.*, 80 F.3d at 1557. Note that the plain language of 19 U.S.C. § 1337(a)(1)(B)(i) applies the protections of the Bolar Amendment to importation of *products* seeking FDA approval, for the purposes of § 337 actions. Section 1337(a)(1)(B)(i) makes it a

complainant allegedly became aware of the importation and the filing of the complaint of infringement the respondent raised a defense of laches,¹⁶⁷ a defense which the federal circuit rejected.¹⁶⁸

First, the court held that because the conduct in question—importation of the product of a patented process—did not constitute a cause of action in federal court until passage of the Process Patent Amendments Act of 1988, “it cannot be said that [the plaintiff] unreasonably delayed” bringing suit prior to such time.¹⁶⁹ Furthermore, even after passage of the Act, the defendant had been importing the product of the patented process “only . . . for use in clinical trials in support of its application for FDA approval . . . [which is] non-infringing activity [under] § 271(e)(1).”¹⁷⁰ Because the plaintiff was not aware of any importation for uses other than seeking FDA approval until 1993, the court held the actual delay between when the plaintiff knew of its claim (in 1993) and filed suit (in 1995) was not unreasonably long.¹⁷¹ In so holding, the court implicitly indicated that the safe harbor of § 271(e)(1) exempted from infringement importation that would otherwise be infringing under § 271(g), in the context of infringement litigation in federal courts.¹⁷²

The Federal Circuit also ruled on availability of a § 271(e)(1) defense in infringement suits brought under § 271(g) in *Glaxo, Inc. v. Novopharm, Ltd.*¹⁷³ While seeking FDA approval, the defendant in *Glaxo* was alleged to have been practicing the plaintiff’s patented process overseas, then importing the product made by the covered process.¹⁷⁴ The plaintiff sought declaratory relief that any

violation to import articles that “infringe a valid and enforceable United States patent.” See *supra* note 44 and accompanying text (emphasis added). Conduct done in pursuit of FDA approval, however, is explicitly exempted from patent infringement by 35 U.S.C. § 271(e)(1). See *supra* notes 18–20 and accompanying text. By contrast, the language of 19 U.S.C. § 1337(a)(1)(B)(ii) does not require that the imported articles infringe a patent, only that they were made by “a process covered by the claims of a valid and enforceable United States patent.” See *supra* note 44 and accompanying text.

¹⁶⁷ *Bio-Tech. Gen. Corp.*, 80 F.3d at 1564. The equitable defense of laches requires the defendant to prove two factors: “(1) the plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant, and (2) the delay operated to the prejudice or injury of the defendant.” *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1032 (Fed. Cir. 1992).

¹⁶⁸ *Bio-Tech. Gen. Corp.*, 80 F.3d at 1564–65.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 1564–65.

¹⁷² *Id.* at 1566.

¹⁷³ 110 F.3d 1562, 1571 (Fed. Cir. 1997).

¹⁷⁴ *Id.* at 1570.

importation that continued after FDA approval was obtained would amount to infringement under § 271(g).¹⁷⁵ In analyzing the court's jurisdiction in such circumstances, the court held that the threat of importation following FDA approval created the requisite case or controversy to support declaratory judgment jurisdiction, but that § 271(e)(1) shielded the defendant from liability under § 271(g) for conduct occurring before such regulatory approval.¹⁷⁶

Thus, before *Kinik* established that materially changing the product of a patented process before importation did not shield respondents from liability in § 337 actions,¹⁷⁷ the ITC had suggested that § 337 was not violated if the product in question was imported solely for the purposes of pursuing FDA approval,¹⁷⁸ and the Federal Circuit had indicated that such importation was exempted from liability in infringement suits if done pursuant to seeking FDA approval.¹⁷⁹ Neither tribunal, however, had definitively held that the safe harbor of § 271(e)(1) did in fact apply to § 337 actions, particularly in regard to importing the products of patented processes, and the *Kinik* holding introduced the possibility that the federal courts might exclude such an exemption from § 337 actions, as it had with the safe harbor of § 271(g)(1).¹⁸⁰

It was in this context that the Federal Circuit decided *Amgen, Inc. v. U.S. International Trade Commission*,¹⁸¹ anticipated to have been among the most notable patent cases of 2008.¹⁸² Amgen, Inc. ("Amgen") filed a complaint with the ITC on April 11, 2006, requesting permanent exclusion and permanent cease and desist orders against its competitors, Roche Holding Ltd., F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively, "Roche").¹⁸³ Amgen held several patents pertaining to recombinant erythropoietin and various derivatives (collectively

¹⁷⁵ *Id.*

¹⁷⁶ *Id.* at 1571. Nonetheless, the court affirmed dismissal of the declaratory judgment claim on the grounds that the plaintiff had failed to prove that the defendant was infringing the process patent. *Id.*

¹⁷⁷ *See supra* Part V.

¹⁷⁸ *See supra* notes 155–62 and accompanying text.

¹⁷⁹ *See supra* notes 163–76 and accompanying text.

¹⁸⁰ *See supra* Part V.

¹⁸¹ *Amgen, Inc. v. U.S. Int'l Trade Comm'n (Amgen I)*, 519 F.3d 1343 (Fed. Cir. 2008), *vacated en banc*, 564 F.3d 1358 (Fed. Cir. 2009), *modified*, 565 F.3d 846 (Fed. Cir. 2009). For a brief procedural history of the case, see *supra* note 1.

¹⁸² Harold C. Wegner, *Wegner's Top Ten Patent Cases*, July 16, 2007, <http://www.patentlyo.com/patent/TopTenJuly16.pdf>.

¹⁸³ In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, 71 Fed. Reg. 27,742, 27,742–43 (Int'l Trade Comm'n May 12, 2006) [hereinafter EPO Notice of Investigation] (notice of investigation).

“EPO”¹⁸⁴ and their production.¹⁸⁵ It claimed that Roche had been practicing Amgen’s patented processes overseas in the production of EPO and importing materials made by the protected process, conduct which it alleged constituted a violation of § 337.¹⁸⁶

Roche moved for a summary determination that it had not violated § 337.¹⁸⁷ It held a patent on the form of EPO it was importing for EPO conjugated to polyethylene glycol (“PEG-EPO”).¹⁸⁸ Roche asserted that it was importing PEG-EPO in pursuit of FDA approval, thus importation was shielded by § 271(e)(1) and did not constitute a violation of § 337.¹⁸⁹ Amgen disagreed.¹⁹⁰ Amgen argued that unlike § 271(g), which renders the importation of a “product which is made by a process patented in the United States” an act of infringement, § 271(e)(1) exempts only the importation of a “patented invention,” and not of the product of a patented process.¹⁹¹ Amgen argued further that the Tariff Act itself did not exempt from violation action taken in pursuit of FDA approval, irrespective of § 271(e)(1) of the Patent Act.¹⁹² Thus, whereas the court in *Kinik* held that the safe harbor provisions of § 271(g) do not apply to § 337 actions,¹⁹³ Amgen argued that neither should the safe harbor provision of § 271(e)(1).¹⁹⁴

The ALJ disagreed with Amgen’s analysis.¹⁹⁵ Citing ITC, Federal Circuit, and Supreme Court precedent,¹⁹⁶ as well as the legislative

¹⁸⁴ EPO is used to treat anemia. See *Amgen Claims Victory in Federal Circuit, Vows to Continue Trial Court EPO Fight*, [2008] 75 Pat. Trademark & Copyright J. (BNA) No. 1861, at 555 (Mar. 28, 2008) [hereinafter *Amgen Claims Victory*].

¹⁸⁵ EPO Notice of Investigation, *supra* note 183, at 27,742–43.

¹⁸⁶ *Amgen, Inc. v. U.S. Int’l Trade Comm’n (Amgen III)*, 565 F.3d 846, 848 (Fed. Cir. 2009).

¹⁸⁷ In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, Investigation No. 337-TA-568, Initial Determination (July 7, 2006) [hereinafter *EPO Initial Determination*], 2006 ITC LEXIS 443, at *1.

¹⁸⁸ *Id.* at *2–3; see U.S. Patent No. 6,583,272 (filed June 27, 2000), available at <http://patft.uspto.gov> (follow “Patent Number Search” hyperlink; then search “6,583,272”) [hereinafter *Roche’s patent*]; *Amgen Claims Victory*, *supra* note 184, at 555.

¹⁸⁹ *EPO Initial Determination*, *supra* note 187, at *3.

¹⁹⁰ *Id.* at *4–5.

¹⁹¹ *Id.* at *27.

¹⁹² *Id.* at *28–29.

¹⁹³ See *supra* Part V.

¹⁹⁴ *EPO Initial Determination*, *supra* note 187, at *28–29.

¹⁹⁵ *Id.* at *28.

¹⁹⁶ *Id.* at *26–27; see also *id.* at *1 n.2 (“In instituting this investigation, the Commission is mindful of the provision of 35 U.S.C. § 271(e), which states that ‘[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs’ Accordingly, the Commission directs the presiding administrative law judge to consider at an early date any motions for summary determination based upon 35 U.S.C. § 271(e).” (alterations in original)).

history of the Process Patent Amendments Act of 1988,¹⁹⁷ the ALJ held that the enactment of § 271(g) did not render conduct that was protected by § 271(e)(1) infringing.¹⁹⁸ The ALJ's citation to the Senate Report accompanying the Process Patent Amendments Act of 1988 was particularly apt:

[T]he Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of a drug." Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.¹⁹⁹

Furthermore, the judge held that "*Kinik* provides no support for the contention that Section 271(e)[(1)] should not apply to allegations under Section 337(a)(1)(B)(ii)."²⁰⁰ Whereas the Process Patent Amendments Act of 1988, consistent with its legislative history, specified that § 271(g) did not affect remedies available under § 337,²⁰¹ no analogous legislation had been enacted excluding the safe harbor of § 271(e)(1) from ITC investigations.²⁰² Consequently, the ALJ issued an initial determination granting Roche's motion for summary determination,²⁰³ subsequently rendered final by the ITC, terminating the investigation.²⁰⁴

On appeal, the Federal Circuit affirmed the ITC's ruling that conduct that was exempted from infringement under the Patent Act by § 271(e)(1) was also grounds for a defense in § 337 actions.²⁰⁵ Citing favorably much of the case law and statutory history relied on in the ALJ's Initial Determination, the court held that the "ruling is in consonance with congressional policy as set forth in enactment of § 271(g), and as elaborated by the Supreme Court in

¹⁹⁷ *Id.* at *27–28 (quoting S. REP. NO. 100-83 at 59 (1987)).

¹⁹⁸ *Id.* at *28.

¹⁹⁹ S. REP. NO. 100-83 at 59 (1987) (quoting 35 U.S.C. § 271(e)(1) (2006) (citation omitted)).

²⁰⁰ EPO Initial Determination, *supra* note 187, at *29.

²⁰¹ *See supra* notes 132–36 and accompanying text.

²⁰² EPO Initial Determination, *supra* note 187, at *29.

²⁰³ *Id.* at *30.

²⁰⁴ In the Matter of Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin, 71 Fed. Reg. 52,579, 52,579 (Int'l Trade Comm'n Sept. 6, 2006) [hereinafter EPO Notice of Decision Not to Review] (notice of decision not to review initial determination).

²⁰⁵ *Amgen, Inc. v. U.S. Int'l Trade Comm'n (Amgen III)*, 565 F.3d 846, 848–49 (Fed. Cir. 2009).

its application[] of [§ 271(e)(1)].”²⁰⁶ Thus, unlike its determination in *Kinik* that materially changing the product of a patented process before importing it affords no protection from § 337 violations, the court definitively established that the importation of the products of process patents is exempt from liability in § 337 actions, if reasonably related to pursuing FDA approval.²⁰⁷

A dissenting opinion, by contrast, though agreeing “with the majority’s policy judgment that § 1337 and § 271 should be brought into synchrony,” argued that the statutory language did not support the majority’s holding.²⁰⁸ “[Section] 271(e)(1) declares that certain activities ‘shall not be an act of infringement,’” the dissent argued, “while the plain language of the statute governing process claims before the Commission, 19 U.S.C. § 1337(a)(1)(B)(ii), does not require an act of infringement for the Commission to issue an exclusion order.”²⁰⁹ Rather, the dissent continued, “§ 1337(a)(1)(B)(ii) declares unlawful the importation, inter alia, of articles that ‘are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.’”²¹⁰

Furthermore, argued the dissent, Congress had foregone the opportunity to amend the Tariff Act in such a way as to incorporate the safe harbor of § 271(e)(1).²¹¹ “The thrust of the majority’s opinion,” the dissent noted, “is that Congress probably intended § 271(e)(1) to apply in section 337 proceedings the same way it applies in patent infringement litigation under Title 35. While I agree that it would make sense . . . it is not what Congress unambiguously said.”²¹² Instead, Congress chose language that “broadened the scope of section 337 proceedings beyond the scope of infringement liability under § 271.”²¹³ If § 1337(a)(1)(B)(ii) and § 271(e)(1) were to be brought into harmony, the dissent argued, it should be by an act of Congress and not the courts.²¹⁴

The majority’s opinion was not limited to incorporating § 271(e)(1)

²⁰⁶ *Id.* at 851; see *supra* notes 163–76 and accompanying text (discussing court precedent establishing that the Bolar Amendment provides its own safe harbor under 35 U.S.C. § 271(g), at least for civil actions for patent infringement).

²⁰⁷ Posting of Dennis Crouch to Patently-O, <http://www.patentlyo.com/patent/2007/12/appeals-from-th.html> (Dec. 17, 2007, 14:12 EST).

²⁰⁸ *Amgen III*, 565 F.3d at 856 (Linn, J., concurring in part and dissenting in part).

²⁰⁹ *Id.* at 855 (quoting 35 U.S.C. § 271(e)(1) (2006)).

²¹⁰ *Amgen III*, 565 F.3d at 855 (quoting 19 U.S.C. § 1337(a)(1)(B)(ii) (2006)).

²¹¹ *Amgen III*, 565 F.3d at 856.

²¹² *Id.* at 855.

²¹³ *Id.* at 856.

²¹⁴ *Id.*

into § 337 proceedings, however; the court also held that the ITC had not sufficiently determined whether all of the importation complained of by Amgen had been done for purposes reasonably related to seeking FDA approval.²¹⁵ The Supreme Court had held that “[e]ach of the accused activities must be evaluated separately to determine whether the exemption [of § 271(e)(1)] applies.”²¹⁶ Importantly, though regulatory approval was still pending, Amgen alleged that by the time it filed its complaint with the ITC, Roche had already completed obtaining and analyzing data and submitted it to the FDA.²¹⁷ “The Commission appears to have assumed that all otherwise infringing activities are exempt if conducted during the period before regulatory approval is granted. That assumption is incorrect,” held the court.²¹⁸

Amgen argued that the importation it complained of was done not in pursuit of FDA approval, but for “infringement analysis experiments, market-seeding trials, and litigation-related activity.”²¹⁹ The court suggested that importation for “commercial and marketing studies” would be subject to more scrutiny than would importation for “scientific studies,” for the purposes of a § 271(e)(1) analysis.²²⁰ Thus, although the court held that § 271(e)(1) did apply to § 337 proceedings, it also held that the ITC had not adequately determined that Roche’s importation at issue was done for the requisite purpose of seeking FDA approval, meaning it could still have been in violation of § 337.²²¹

Furthermore, the court disagreed with the ITC’s conclusion that it did not have jurisdiction to remedy Roche’s importation absent importation, sale for importation, or sale after importation into the

²¹⁵ *Id.* at 853 (majority opinion).

²¹⁶ *Id.* at 852 (quoting *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 200 (2005) (alterations in original)).

²¹⁷ *Id.* Roche submitted its application to the FDA on April 19, 2006, eight days after Amgen filed its complaint with the ITC. *Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (Roche I)*, 456 F. Supp. 2d 267, 271 (D. Mass. 2006); EPO Notice of Investigation, *supra* note 183, at 27,742. The FDA did not approve Roche’s application until November, 2007, more than a year after the ITC terminated its investigation. EPO Notice of Decision Not to Review, *supra* note 204, at 52,579; Posting of Kevin E. Noonan to Patent Docs, <http://www.patentdocs.org/2008/03/roches-micera-e.html> (Mar. 2, 2008, 22:47 EST).

²¹⁸ *Amgen III*, 565 F.3d at 852.

²¹⁹ *Id.*

²²⁰ *Id.*; *cf.* *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997) (holding that the alleged ulterior motives for performing experimentation *prior* to submission to the FDA for approval did not preclude application of the safe harbor of § 271(e)(1); thus, although the court was willing to apply the protection of the Bolar Amendment broadly in *AbTox*, in *Amgen III* the court declined to extend these protections to cover conduct occurring *after* submission to the FDA); *see supra* notes 32–36 and accompanying text.

²²¹ *Amgen III*, 565 F.3d at 853.

United States of EPO.²²² The court, in its revised panel decision, held that Amgen's allegations that Roche had imported EPO were enough to confer jurisdiction on the ITC to hear the complaint.²²³ Thus, although agreeing with the ITC that a § 271(e)(1) analysis is applicable in this § 337 action, the court also held that the ITC had failed to properly exercise its jurisdiction by refraining from analyzing whether Roche's conduct qualified for the exemption, and remanded the case to the ITC.²²⁴

Even prior to filing a complaint with the ITC in April of 2006, moreover, Amgen had commenced a declaratory judgment action against Roche in the U.S. District Court for the District of Massachusetts, on November 8, 2005,²²⁵ initiating what would come to be deemed one of the top biotechnology- and pharmacology-related patent stories of 2008.²²⁶ Facing claims of infringement of the same patents Amgen cited before the ITC,²²⁷ Roche argued the

²²² *Id.*

²²³ *Amgen III*, 565 F.3d at 853–54.

²²⁴ *Id.* at 854–55. In *Amgen I*, the court had held, on different grounds, that the ITC had jurisdiction to hear Amgen's complaint. 519 F.3d 1343, 1352 (Fed. Cir. 2008). Believing Roche's importation to be subject to the safe harbor of § 271(e)(1), the ITC had held that it lacked jurisdiction to hear Amgen's complaint absent a domestic sale or contract for sale of PEG-EPO. *Id.* at 1350. The court in *Amgen I* disagreed; imminence of FDA approval of PEG-EPO, announced by Roche, signaled an impending end to the safe harbor's applicability. *Id.* In turn, the court held that the ITC's charge in § 337 proceedings to prevent unfair competition and protect domestic industry justified intervention before a product at issue entered the stream of commerce. *Id.* at 1350–51. Thus, "the projected FDA approval established the Commission's jurisdiction to review and provide remedy to take effect as appropriate after the approval is granted and § 271(e)(1) no longer shelters liability" without regard to whether any PEG-EPO had yet been sold or offered for sale. *Id.* at 1352. This element of the *Amgen I* decision, applauded by Amgen itself, was interpreted as expanding the ITC's jurisdiction to include investigations of not only sales for importation, importation, and sales after importation of an accused product, but also anticipated, imminent violations. *Amgen Claims Victory*, *supra* note 184, at 555; Jay H. Reiziss, *The Distinctive Characteristics of Section 337*, 8 J. MARSHALL REV. INTELL. PROP. L. 231, 232–34 (2009). The revised holding in *Amgen III*, however, retreated from this assertion. 565 F.3d at 853–54; Dutra, *supra* note 1, at 48. Jurisdiction was established upon Amgen's allegation that Roche had imported PEG-EPO, the court held, so it was not necessary "to resolve the parties' dispute concerning 'imminent importations' to decide this case." *Amgen III*, 565 F.3d at 853. Thus, applicability of the § 271(e)(1) safe harbor went not to jurisdiction, as the ITC had argued, but to the merits of the complaint. *Id.* at 854. Once possessed of jurisdiction, the ITC was required to investigate "Roche's uses of [PEG-]EPO unrelated to obtaining FDA approval." *Id.* at 855.

²²⁵ *Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (Roche I)*, 456 F. Supp. 2d 267, 270 (D. Mass. 2006).

²²⁶ Posting of Donald Zuhn to Patent Docs, <http://www.patentdocs.org/2009/01/top-stories-of-2008-13-to-10.html> (Jan. 1, 2009 20:25 EST); see also Wegner, *supra* note 182 (listing the currently-pending appeal of *Roche I* to the Court of Appeals for the Federal Circuit among the top ten patent cases of 2009).

²²⁷ *Compare* EPO Notice of Investigation, *supra* note 183, at 27,742, with *Roche I*, 456 F. Supp. 2d at 270 (listing the same six patents of Amgen's at issue in each proceeding).

safe harbors of § 271(e)(1)²²⁸ and (g)(1)²²⁹ on its behalf, as well as that PEG-EPO was not infringing.²³⁰ Nonetheless, a jury held Roche liable for infringement,²³¹ whereupon the court issued a permanent injunction, enjoining Roche from infringing.²³² Thus, in addition to the possibility that the ITC may yet obstruct Roche's importation of PEG-EPO, Amgen also scored an important victory in district court, considering the significance of EPO to Amgen's revenues.²³³ Roche has appealed the district court's ruling to the Federal Circuit.²³⁴

²²⁸ Roche moved to dismiss the claims on the grounds that Amgen had failed to state a claim upon which relief could be granted, in light of 35 U.S.C. § 271(e)(1) (2006). The trial court denied the motion because it could not "conclude, as matter of law, that because Roche . . . is in the process of submitting information to the FDA, that this importation of the alleged infringing drug *must* be solely for uses that reasonably relate to the submission of that information." *Roche I*, 456 F. Supp. 2d at 274. Subsequently, Roche raised an affirmative defense and a counterclaim seeking a declaratory judgment of non-infringement under § 271(e)(1). Defendants' Answer and Counterclaims to Plaintiff's Complaint at 4, 32, Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche I*), 456 F. Supp. 2d 267 (D. Mass. 2006) (No. 05-CV-12237-WGY), 2006 WL 4969118.

²²⁹ See Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche II*), 494 F. Supp. 2d 54, 69 (D. Mass. 2007).

²³⁰ Defendants' Answer and Counterclaims to Plaintiff's Complaint at 4, 32, Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche I*), 456 F. Supp. 2d 267 (D. Mass. 2006) (No. 05-CV-12237-WGY), 2006 WL 4969118.

²³¹ Jury Verdict, Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche I*), 456 F. Supp. 2d 267 (D. Mass. Oct. 23, 2007) (No. 05-CV-12237-WGY), 2007 WL 3284120.

²³² The judge explained his reasoning for issuing a permanent injunction in an opinion issued October 2, 2008. Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche III*), 581 F. Supp. 2d 160, 212–27 (D. Mass. 2008). The judge then entered judgment fifteen days later. Judgment, Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche III*), 581 F. Supp. 2d 160, (D. Mass. 2008) (No. 05-12237-WGY). In the interim, the Federal Circuit heard oral arguments on and decided an interlocutory appeal Roche had brought earlier in the trial challenging a preliminary injunction the district court had ordered. Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche IV*), 296 F. App'x 69, 69 (Fed. Cir. 2008); see Posting of Kevin E. Noonan to Patent Docs, <http://www.patentdocs.org/2008/10/complete-vict-2.html> (Oct. 9, 2008, 23:28 EST); Posting of Kevin E. Noonan to Patent Docs, <http://www.patentdocs.org/2008/10/amgen-v-hoffman.html> (Oct. 10, 2008, 23:45 EST). The procedural and jurisdictional perplexity created and resolved by this chronology of events was manifest in the statements of the judges involved. See, e.g., Audio Recording of Oral Arguments, Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche IV*), 296 F. App'x 69 (Fed. Cir. 2008) (No. 2008-1300), available at <http://oralarguments.cafc.uscourts.gov/mp3/2008-1300.mp3> ("[District Judge] Bill [Young] and I have been friends for many years and this is one of his most amazing pieces of work."); Judgment at 1, Amgen, Inc. v. F. Hoffmann-La Roche Ltd. (*Roche III*), 581 F. Supp. 2d 160, (D. Mass. 2008) (No. 05-CV-12237-WGY) ("[T]hanks to the Federal Circuit for its courtesy in so promptly restoring this Court's jurisdiction to act . . .").

²³³ See Posting of Kevin E. Noonan to Patent Docs, http://www.patentdocs.typepad.com/patent_docs/2007/10/amgen-survives-.html (Oct. 28, 2007, 23:23 EST).

²³⁴ Supplemental Notice of Appeal, Amgen, Inc. v. F. Hoffmann-La Roche, Ltd. (*Roche III*), 581 F. Supp. 2d 160 (D. Mass. 2008) (No. 05-CV-12237-WGY), appeal docketed, No. 09-1020 (Fed. Cir. Oct. 16, 2008). Oral arguments were heard on June 4, 2009. Wegner, *supra* note 182. During prepublication editing of this article, the Federal Circuit issued its holding

VII. CONCLUSION

The Federal Circuit has affirmed the availability of the safe harbor of the Bolar Amendment of the Hatch-Waxman Act in § 337 actions before the ITC.²³⁵ Thus, in addition to the federal court's expansive construction of activities that are protected by the safe harbor in infringement litigation,²³⁶ it has also been made available in administrative proceedings.²³⁷ This holding is consistent with ITC and Federal Circuit precedent,²³⁸ and although it differs from the holding in *Kinik* insofar as the availability of another safe harbor of the Patent Act, § 271(g)(1), in § 337 actions is concerned, the independent legislative histories and case law pertaining to §§ 271(e)(1) and (g)(1) support the seemingly disparate holdings.²³⁹

Such tension as may appear to exist between the holdings is relieved by reference to the statutory language of the safe harbors, their legislative histories, and existing case precedent. The legislative history surrounding passage of the Process Patent Amendments Act of 1988 and the language of § 271(g) itself, relied on in *Kinik*, explicitly reflects Congress's intention that the safe harbor of § 271(g)(1) not be applied outside the context of the Patent Act, such as in § 337 actions.²⁴⁰ In contrast, no such intention is

affirming the inapplicability of the 271(g) safe harbor to Roche's conduct. *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd. (Roche V)*, 580 F.3d 1340, 1378–79 (Fed. Cir. 2009) ("What makes a variation significant enough to be a 'material change,' . . . is a question of degree. In this case, Amgen presented evidence that the structural and functional differences [between PEG-EPO and EPO] were not material because [PEG-EPO] still contains EPO, the structure of EPO remains intact, [PEG-EPO] binds to the EPO receptor, and [PEG-EPO] retains its claimed ability to increase the production of reticulocytes and red blood cells. . . . [W]e think there was sufficient evidence for a jury to conclude that the structural and functional differences between [PEG-EPO] and EPO recited in the process claims [of Amgen's patents] were not material."). Interestingly, Roche's patent on PEG-EPO cites Amgen's patent on EPO. *Roche V*, 580 F.3d at 1348 ("[Amgen's U.S. Patent No. 5,547,933] claims recombinant EPO, a pharmaceutical composition comprising recombinant EPO . . ."); *Roche's patent, supra* note 188, at 56 (citing U.S. Patent No. 5,547,933). Recall a suggestion from an earlier case that the patentability of both a product of a patented process, and a derivative of such product, may indicate that the derivative was "materially changed" from the product of the patented process, for the purposes of a § 271(g)(1) analysis. *See supra* notes 90–91 and accompanying text. The Federal Circuit's holding in *Roche V*, in contrast, indicates at least that such a conclusion is not required as a matter of law. Also note, however, that despite affirming grounds of Roche's liability for infringement, the court reversed some of the findings of the validity of Amgen's patents, remanding the case back to the trial court. *Id.* at 1386.

²³⁵ *See supra* Part VI.

²³⁶ *See supra* Part II.

²³⁷ *See supra* Part VI.

²³⁸ *See supra* notes 155–76 and accompanying text.

²³⁹ *See supra* Parts V and VI; Sapna Kumar, *The Other Patent Agency: Congressional Regulation of the ITC*, 61 FLA. L. REV. 529, 554–55 (2009).

²⁴⁰ *See supra* Part V.

manifest in the statutory language of, nor legislative history accompanying, § 271(e)(1). Rather, the federal bar has continually followed Supreme Court precedent in extending the reach of this safe harbor of the Bolar Amendment,²⁴¹ a tradition continued in *Amgen III*.

Moreover, rendering the protections of the Bolar Amendment available to respondents in § 337 actions comports with the Supreme Court's holding in *Microsoft Corp. v. AT&T Corp.* that "[t]he presumption that United States law governs domestically but does not rule the world applies with particular force in patent law."²⁴² Absent a clear intention that Congress intended to apply U.S. law to conduct that occurs offshore, the Supreme Court is reluctant to interpret laws in ways that would have extraterritorial reach.²⁴³

The Tariff Act has extraterritorial reach, at least as far as the offshore practice of patented processes is concerned, as it explicitly renders the importation and sale of products made by the patented process a violation.²⁴⁴ Withholding safe harbor defenses from respondents alleged to have violated 19 U.S.C. § 1337(a)(1)(B)(ii), in turn, supports expanded extraterritorial reach of the Tariff Act.²⁴⁵ Thus, in accordance with the Supreme Court's reticence to empower U.S. laws with extraterritorial reach absent manifest congressional intent,²⁴⁶ safe harbor defenses should be withheld from respondents in § 337 actions only where Congress has expressed such intention.

As to the safe harbor of the Bolar Amendment, Congress has not expressed the intention that it be withheld from respondents in § 337 actions, or that practicing patented processes pursuant to seeking FDA approval be selectively subject to prohibition extraterritorially.²⁴⁷ Thus, rendering the protections of the Bolar Amendment available to respondents in § 337 actions is consistent with the Supreme Court's cabining of the extraterritorial reach of U.S. law, and patent law in particular.²⁴⁸ In contrast, the Process

²⁴¹ See *supra* Part II; see also Kelly, *supra* note 143, at 84 n.23 (presenting a critical analysis of the Federal Circuit's reliance on legislative history in *Kinik* and *Amgen III*).

²⁴² 550 U.S. 437, 454–55 (2007).

²⁴³ Timothy R. Holbrook, *Extraterritoriality in U.S. Patent Law*, 49 WM. & MARY L. REV. 2119, 2129–30 (2008); see also *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1362 (Fed. Cir. 2009) (recapitulating the Supreme Court's message from *Microsoft v. AT&T* that "the territorial limits of patents should not be lightly breached").

²⁴⁴ See *supra* note 44 and accompanying text.

²⁴⁵ *Id.*

²⁴⁶ See Holbrook, *supra* note 243, at 2129–30.

²⁴⁷ See *supra* note 199 and accompanying text.

²⁴⁸ See *supra* notes 240–41 and accompanying text.

Patent Amendments Act of 1988 explicitly limited the application of the safe harbor of 35 U.S.C. § 271(g)(1) to enforcement of the Patent Act.²⁴⁹ Thus, although the holding in *Kinik* that this safe harbor is not available to respondents in § 337 actions²⁵⁰ has the practical effect of supporting a greater extraterritorial reach of U.S. law, this result finds support in Congress's express intent.²⁵¹

²⁴⁹ See *supra* note 132 and accompanying text.

²⁵⁰ See *supra* Part V.

²⁵¹ See also Kelly, *supra* note 143 at 105 (arguing that rendering the safe harbor of § 271(e)(1) available in proceedings before the ITC is compliant with international treaty obligations).